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

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2017–0322]

Drawbridge Operation Regulation; Hillsborough River, Tampa, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the operation of the Hillsborough Bridge across the Hillsborough River, Tampa, Florida. This deviation is necessary to allow the bridge owner, Florida Department of Transportation to repair the Hillsborough Bridge. Due to the type of repairs this bridge will be required to remain closed to navigation until all components can be removed and replaced.

DATES: This deviation is effective from 7 a.m. on May 10, 2017, until 7 p.m. on June 21, 2017.

ADDRESSES: The docket for this deviation, [USCG–2017–0322] is available at *http://www.regulations.gov.* Type the docket number in the ''SEARCH'' box and click ''SEARCH''. Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Eddie Lawrence with the Seventh Coast Guard District Bridge Office; telephone 305–415–6946, email *Eddie.H.Lawrence@uscg.mil.*

SUPPLEMENTARY INFORMATION: Florida Department of Transportation, the bridge owner, has requested a temporary deviation from the operating schedule of the Hillsborough Bridge across the Hillsborough River, Tampa, Florida to conduct needed repairs. The Florida Department of Transportation advised ''the work is not an emergency but is needed now as the original counterweight cables from 1939 are at the end of their service life. It is not possible to remove the counterweight cables and keep the bridge in operation at the same time''; the Coast Guard has taken this into consideration prior to allowing this closure. This temporary deviation will impact navigation since no vessel with a height greater than 10 feet will be able to pass during this closure period. Not allowing the necessary bridge repairs will also have an impact to navigation. The current operating regulation is under 33 CFR 117.291.

Vessels able to pass through the bridge in the closed position may do so at any time The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass through the bridge in closed positions. The Coast Guard will also inform the users of the waterways through Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

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

Dated: April 24, 2017.

Barry Dragon,

Director, Bridge Branch, Seventh Coast Guard District.

[FR Doc. 2017–08579 Filed 4–27–17; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R03–OAR–2016–0053; FRL–9961–37–Region 3]

Approval and Promulgation of Air Quality Plans; State of Maryland; Control of Emissions From Existing Hospital/Medical/Infectious Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revised section 111(d)/129 plan submitted by the State of Maryland for existing hospital/medical/infectious waste incineration (HMIWI) units. The section 111(d)/129 plan contains revisions to a previously-approved State plan for existing HMIWI units that was submitted as a result of the October 6, 2009 promulgation of federal new source performance standards (NSPS) and emission guidelines for HMIWI units, which were subsequently amended on April 4, 2011. This action is being taken under sections 111(d) and 129 of the Clean Air Act (CAA).

DATES: This final rule is effective on May 30, 2017.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2016–0053. All documents in the docket are listed on the *https://www.regulations.gov* Web site. 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 through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Mike Gordon, (215) 814–2039, or by email at *gordon.mike@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 28, 2016 (81 FR 85457), EPA published a notice of proposed rulemaking (NPR) for the State of Maryland. In the NPR, EPA proposed approval of Maryland's revised CAA section 111(d)/129 State plan for existing HMIWI units. The formal State plan revision (MD Submittal #12–11) was submitted by Maryland on January 10, 2013.

II. Summary of SIP Revision

EPA has reviewed the revised Maryland section 111(d)/129 plan submittal in the context of the

requirements of 40 CFR part 60, subparts B, Ec and Ce, and part 62, subpart A. EPA has determined that the submitted revised section 111(d)/129 plan meets the above-cited requirements for State plans for existing units covered by the emission guidelines for that source category. Thus, EPA is approving Maryland's State plan in this action. A detailed explanation of the rationale behind this approval is available in the July 22, 2016 technical support document (TSD) and in the NPR and will not be restated here. No comments were received on the proposed rule.

III. Final Action

EPA is approving the revised Maryland section 111(d)/129 plan for HMIWI units submitted pursuant to 40 CFR part 60, subpart Ce because the plan is at least as stringent as requirements in 40 CFR part 60, subpart Ce for existing HMIWI units. Therefore, EPA is amending 40 CFR part 62, subpart V to reflect this approval action. The scope of the approval of the section 111(d)/129 plan is limited to the provisions of 40 CFR parts 60 and 62 for existing HMIWI units, as referenced in the emission guidelines at 40 CFR part 60, subpart Ce.

As discussed in the NPR, the EPA Administrator continues to retain authority for several tasks affecting the regulation of HMIWI units, as stipulated in 40 CFR 60.32e(k) and 60.50c(i). This retention of authority includes the granting of waivers for performance tests.

IV. Statutory and Executive Order Reviews

A. General Requirements

In reviewing section 111(d)/129 plan submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

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

In addition, this final rule for existing HMIWI units within the State of Maryland does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the section 111(d)/129 plan is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

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

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by June 27, 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 approving Maryland's CAA Section 111(d)/129 state plan for existing HMIWI units may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 62

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

Dated: March 24, 2017.

Cecil Rodrigues,

Acting Regional Administrator, Region III.

40 CFR part 62 is amended as follows:

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

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

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

Subpart V—Maryland

■ 2. Revise § 62.5160 to read as follows:

§ 62.5160 Identification of plan.

(a) Section 111(d)/129 plan for HMIWIs and the associated Code of Maryland (COMAR) 26.11.08 regulations, as submitted on April 14, 2000.

(b) Section 111(d)/129 plan for HMIWIs and the associated Code of Maryland (COMAR) regulations, as submitted on January 10, 2013.

■ 3. Revise § 62.5161 to read as follows:

§ 62.5161 Identification of sources.

(a) The plan submitted on April 14, 2000 applies to all existing HMIWIs located in Maryland for which construction was commenced on or before June 20, 1996.

(b) The January 10, 2013 submittal applies to all existing HMIWIs as defined in the approved Maryland Section 111(d)/129 plan.

■ 4. Revise § 62.5162 to read as follows:

§ 62.5162 Effective date.

(a) The effective date of the plan submitted on April 14, 2000 is October 20, 2000.

(b) The effective date of the plan submitted on January 10, 2013 is May 30, 2017.

[FR Doc. 2017–08668 Filed 4–27–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[WC Docket No. 13–39; FCC 13–135; FCC 14–175]

Rural Call Completion Recordkeeping and Reporting Requirements; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: The Federal Communications Commission (Commission) published a document in the **Federal Register** on March 4, 2015, concerning its rural call completion recordkeeping and reporting requirements. That document inadvertently omitted reference to the *Order on Reconsideration* (*Reconsideration Order*) WC Docket No. 13–39, FCC 14–175, which adopted minor amendments to those requirements. This document corrects that error.

DATES: This correction is effective April 28, 2017.

FOR FURTHER INFORMATION CONTACT: Nirali Patel, Wireline Competition Bureau, Competition Policy Division, (202) 418–7830, or send an email to *nirali.patel@fcc.gov.*

SUPPLEMENTARY INFORMATION: This document makes the following corrections to the Commission's final rule, FR Doc. No. 2015–04415, published on March 4, 2015, at 80 FR 11594:

1. On page 115494, in the heading of the rule, add ''; FCC 14–175'' after ''FCC 13–135''.

2. On page 11594, in the **SUMMARY** section, in the first sentence, add ''and the Commission's *Order on Reconsideration (Reconsideration Order)* WC Docket No. 13–39, FCC 14–175.'' to the end of the sentence.

3. On page 11594, In the **DATES** section, add ''and the amendments to 47 CFR 64.2101, 64.2103, and 64.2105, published at 79 FR 73227, December 10, 2014, and corrected at 80 FR 1007, January 8, 2015,'' after ''December 17, 2013'' and before ''are effective on March 4, 2015.''

4. On page 11594, in the **SUPPLEMENTARY INFORMATION** section:

i. In the first sentence, add ''and the Commission's *Reconsideration Order,* FCC 14–175, published at 79 FR 73227, December 10, 2014, and corrected at 80 FR 1007, January 8, 2015.'' to the end of the sentence;

ii. In the third sentence, add '', and paragraph 66 of document WC Docket No. 13–39, FCC 14–175.'' to the end of the sentence; and

iii. In the third column, under the heading ''Needs and Uses,'' add the following two sentences between the twelfth and thirteenth sentences: ''On November 13, 2014, the Commission adopted a *Reconsideration Order* in WC Docket No. 13–39, FCC 14–175, 79 FR 73227, corrected at 80 FR 1007, Rural Call Completion. The *Reconsideration Order* reduced the burden on covered providers by excluding certain traffic from the reporting and retention requirements adopted in the *Order.*''

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2017–08581 Filed 4–27–17; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 150121066–5717–02]

RIN 0648–XF346

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries

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

ACTION: Temporary rule; inseason Angling category retention limit adjustment.

SUMMARY: NMFS has determined that the Atlantic bluefin tuna (BFT) daily retention limit that applies to vessels permitted in the Highly Migratory Species (HMS) Angling category and the HMS Charter/Headboat category (when fishing recreationally for BFT) should be adjusted for the remainder of 2017, based on consideration of the regulatory determination criteria regarding inseason adjustments. NMFS is adjusting the Angling category BFT daily retention limit to two school BFT and one large school/small medium BFT per vessel per day/trip for private vessels (*i.e.,* those with HMS Angling category permits); and three school BFT and one large school/small medium BFT per vessel per day/trip for charter vessels (*i.e.,* those with HMS Charter/Headboat permits when fishing recreationally). These retention limits are effective in all areas, except for the Gulf of Mexico, where NMFS prohibits targeted fishing for BFT.

DATES: Effective May 1, 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 Highly Migratory Species Fishery Management Plan (2006 Consolidated HMS FMP) (71 FR 58058, October 2, 2006) and amendments, and in accordance with implementing regulations. NMFS is required under ATCA and the Magnuson-Stevens Act to provide U.S. fishing vessels with a reasonable opportunity to harvest the ICCAT-recommended quota.

As a method for limiting fishing mortality on juvenile BFT, ICCAT recommends a tolerance limit on the annual harvest of BFT measuring less than 115 cm (straight fork length) to no more than 10 percent by weight of a Contracting Party's total BFT quota. Any overharvest of such tolerance limit from one year must be subtracted from the tolerance limit applicable in the next year or the year after that. The United States implements this provision by limiting the harvest of school BFT (measuring 27 to less than 47 inches) as appropriate to not exceed the 10-percent limit.

The currently codified baseline U.S. quota is 1,058.9 mt (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area). See § 635.27(a). The currently codified Angling category quota is 195.2 mt (108.4 mt for school BFT, 82.3 mt for large school/small medium BFT, and 4.5 mt for large medium/giant BFT).

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 size classes of BFT are summarized in Table 1. Please note that large school and small medium BFT traditionally have been managed as one size class, as described below, *i.e.,* a limit of one large school/small medium BFT (measuring 47 to less than 73 inches). Currently, the default Angling category daily retention limit of one school, large school, or small medium BFT applies (§ 635.23(b)(2)). This retention limit applies to HMS Angling and to HMS Charter/Headboat category permitted vessels (when fishing recreationally for BFT).

TABLE 1—BFT SIZE CLASSES

Size class	Curved fork length
School	27 to less than 47 inches (68.5 to less than 119 cm).
Large school	47 to less than 59 inches (119 to less than 150 cm).
Small medium	59 to less than 73 inches (150 to less than 185 cm).
Large medium	73 to less than 81 inches (185 to less than 206 cm).
Giant	81 inches or greater (206 cm or greater).

Table 2 summarizes the recreational quota, subquotas, landings, and retention limit information for 2015 and 2016, by size class.

TABLE 2—ANGLING CATEGORY QUOTAS (mt), ESTIMATED LANDINGS (mt), AND DAILY RETENTION LIMITS, 2015–2016

Size class	2015			2016		
	Subquotas and total quota (mt)	Landings (mt)	Amount of subquotas and total quota used (percent)	Subquotas and total quota (mt)	Landings (mt)	Amount of subquotas and total quota used (percent)
School	108.4	26.2	24	108.4	40.3	37
Large School/Small Medium	82.3	80.2	97	82.3	96.8	118
Trophy: Large Medium/Giant	4.5	6.7	149	4.5	5.9	131
Total	195.2	113.1	58	195.2	143	73
Daily Retention Limits (per Vessel)	*January 1 through May 14:* 1 school, large school, or small medium (default)			*January 1 through April 22:* 1 school, large school, or small medium (default)		
	May 15 through December 31 (80 FR 27863, May 15, 2015):			*April 23 through December 31* (81 FR 23438, April 21, 2016):		
	Private boats: 1 school *and* 1 large school/small medium			*Private boats:* 2 school *and* 1 large school/small medium		
	Charter/Headboats: 2 school *and* 1 large school/small medium			*Charter/Headboats:* 3 school *and* 1 large school/small medium		

Adjustment of Angling Category Daily Retention Limit

Under § 635.23(b)(3), NMFS may increase or decrease the Angling category retention limit for any size class of BFT after considering regulatory determination criteria provided under § 635.27(a)(8). Recreational retention limits may be adjusted separately for specific vessel type, such as private vessels, headboats, or charter vessels.

NMFS has considered all of the relevant determination criteria and their applicability to the change in the Angling category retention limit. The criteria and their application are discussed below.

NMFS considered the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(8)(i)). Biological samples collected from BFT landed by recreational fishermen continue to provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT would support the collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS considered the catches of the Angling category quota to date and the likelihood of closure of that segment of the fishery if no adjustment is made (§ 635.27(a)(8)(ii)). NMFS anticipates that the full 2017 Angling category quota would not be harvested under the default retention limit. As shown in Table 2, Angling category landings were approximately 58 and 73 percent of the 184.3-mt annual Angling category quota in 2015 and 2016, respectively.

NMFS also considered the effects of the adjustment on bluefin tuna rebuilding and overfishing and the effects of the adjustment on accomplishing the objectives of the FMP (§ 635.27(a)(8)(v) and (vi)). These retention limits would be consistent with the quotas established and analyzed in the bluefin tuna quota final rule (80 FR 52198, August 28, 2015), and with objectives of the 2006 Consolidated HMS FMP and amendments, and is not expected to negatively impact stock health or to affect the stock in ways not already analyzed in those documents. It is also important that we limit landings to the subquotas both to adhere to the FMP quota allocations and to ensure that

landings are as consistent as possible with the pattern of fishing mortality (*e.g.,* fish caught at each age) that was assumed in the projections of stock rebuilding.

Another principal consideration in setting the retention limit is the objective of providing opportunities to harvest the full Angling category quota without exceeding it based on the goals of the 2006 Consolidated HMS FMP and amendments, including to achieve optimum yield on a continuing basis and to optimize the ability of all permit categories to harvest their full BFT quota allocations (related to § 635.27(a)(8)(x)).

The 2016 school bluefin tuna landings represent 3.7 percent of the total U.S. quota for 2016, well under the ICCAT recommended 10-percent limit. Landings of school bluefin tuna in 2015 represented 2.4 percent of the total U.S. quota for 2015. Given that the Angling category landings fell short of the available quota and considering the regulatory criteria above, NMFS has determined that the Angling category retention limit applicable to participants on HMS Angling and HMS Charter/Headboat category permitted vessels should be adjusted upwards from the default level. NMFS has also concluded that implementation of separate limits for private and charter/headboat vessels remains appropriate, recognizing the different nature, socio-economic needs, and recent landings results of the two components of the recreational BFT fishery. For example, charter operators historically have indicated that a multi-fish retention limit is vital to their ability to attract customers. In addition, Large Pelagics Survey estimates indicate that charter/headboat BFT landings averaged approximately 30 percent of recent recreational landings for 2015 through 2016, with the remaining 70 percent landed by private vessels.

Therefore, for private vessels (*i.e.,* those with HMS Angling category permits), this action adjusts the limit upwards to two school BFT and one large school/small medium BFT per vessel per day/trip (*i.e.,* two BFT measuring 27 to less than 47 inches, and one BFT measuring 47 to less than 73 inches). For charter vessels (*i.e.,* those with HMS Charter/Headboat permits), this action adjusts the limit upwards to three school BFT and one large school/small medium BFT per vessel per day/trip when fishing recreationally for BFT (*i.e.,* three BFT measuring 27 to less than 47 inches, and one BFT measuring 47 to less than 73 inches). These retention limits are effective in all areas, except for the Gulf of Mexico, where NMFS prohibits targeted fishing for BFT. Regardless of the duration of a fishing trip, the daily retention limit applies upon landing. For example, whether a private vessel (fishing under the Angling category retention limit) takes a two-day trip or makes two trips in one day, the day/trip limit of two school BFT and one large school/small medium BFT applies and may not be exceeded upon landing.

NMFS anticipates that the BFT daily retention limits in this action will result in landings during 2017 that would not exceed the available subquotas. Lower retention limits could result in substantial underharvest of the codified Angling category subquota, and increasing the daily limits further may risk exceeding the available quota, contrary to the objectives of the 2006 Consolidated HMS FMP and amendments. NMFS is not setting higher school BFT limit for private and charter vessels due to the potential risk of exceeding the ICCAT tolerance limit on school BFT and other considerations, such as potential effort shifts to BFT fishing as a result of current, reduced recreational retention limits for New England groundfish and striped bass. NMFS will monitor 2017 landings closely and will make further adjustments, including closure if necessary, with an inseason action if warranted.

Monitoring and Reporting

NMFS will continue to monitor the BFT fisheries closely through the mandatory landings and catch reports. 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 Android or iPhone app. Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional retention limit adjustments or closures are necessary to ensure available quota is not exceeded or to enhance scientific data collection from, and fishing opportunities in, all geographic areas. Subsequent actions, if any, will be published in the **Federal Register**. In addition, fishermen may call the Atlantic Tunas Information Line at (978) 281–9260, or access *hmspermits.noaa.gov,* for updates on quota monitoring and inseason adjustments.

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/.*

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 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. Affording prior notice and opportunity for public comment to implement the daily retention limit for the remainder of 2017 at this time is impracticable. Based on available BFT quotas, fishery performance in recent years, and the availability of BFT on the fishing grounds, immediate adjustment to the Angling category BFT daily retention limit from the default levels is warranted to allow fishermen to take advantage of the availability of fish and of quota. NMFS could not have proposed these actions earlier, as it needed to consider and respond to updated data and information from the 2016 Angling category fishery. If NMFS was to offer a public comment period now, after having appropriately considered that data, it would preclude fishermen from harvesting BFT that are legally available consistent with all of the regulatory criteria, and/or could result in selection of a retention limit inappropriately high or low for the amount of quota available for the period.

Fisheries under the Angling category daily retention limit are currently underway and thus prior notice would be contrary to the public interest. Delays in increasing daily recreational BFT retention limit would adversely affect those HMS Angling and Charter/Headboat category vessels that would otherwise have an opportunity to harvest more than the default retention limit of one school, large school, or small medium BFT per day/trip and may exacerbate the problem of low catch rates and quota rollovers. Analysis of available data shows that adjustment to the BFT daily retention limit from the default level would result in minimal

risks of exceeding the ICCAT-allocated quota. NMFS provides notification of retention limit adjustments 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.* 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 these reasons, there also is good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness.

This action is being taken under § 635.23(b)(3), and is exempt from review under Executive Order 12866.

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

Dated: April 26, 2017.

Karen H. Abrams,

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

[FR Doc. 2017–08777 Filed 4–27–17; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 170104016–7016–01]

RIN 0648–XF138

Magnuson-Stevens Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; 2017 and 2018 Sector Operations Plans and 2017 Allocation of Northeast Multispecies Annual Catch Entitlements

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

ACTION: Interim final rule.

SUMMARY: We have approved sector operations plans for fishing years 2017 and 2018, granting regulatory exemptions for fishing years 2017 and 2018, and providing Northeast multispecies annual catch entitlements to approved sectors for fishing year 2017. Approval of sector operations plans is necessary to allocate annual catch entitlements to the sectors and for the sectors to operate. The Northeast Multispecies Fishery Management Plan allows limited access permit holders to form sectors, and requires sectors to submit their operations plans and contracts to us, NMFS, for approval or disapproval. This interim final rule approves sector operations plans, grants regulatory exemptions for sectors, and provides preliminary allocations of annual catch entitlements to sectors for the start of the 2017 fishing year. Changes to exemptions and updates to sector annual catch entitlements may be considered in subsequent rulemakings.

DATES: Sector operations plans and regulatory exemptions are effective May 1, 2017, through April 30, 2019. Northeast multispecies annual catch entitlements for sectors are effective May 1, 2017, through April 30, 2018. The default catch limit for Eastern Georges Bank cod is effective May 1, 2017, through July 31, 2017, or until the final rule for Framework 56 is implemented if prior to July 31, 2017. Written comments must be received on or before May 30, 2017.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2017–0016, by either of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0016,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Kyle Molton, 55 Great Republic Drive, Gloucester, MA 01930.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of each sector's final operations plan and contract are available from the NMFS Greater Atlantic Regional Fisheries Office: John K. Bullard, Regional Administrator, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930. These documents are also accessible via the Federal eRulemaking Portal: *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kyle Molton, Fishery Management Specialist, (978) 281–9236. To review **Federal Register** documents referenced in this rule, you can visit: *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies.*

SUPPLEMENTARY INFORMATION:

Background

Amendment 13 to the Northeast (NE) Multispecies Fishery Management Plan (FMP) (69 FR 22906; April 27, 2004) established a process for forming sectors within the NE multispecies (groundfish) fishery, and Amendment 16 to the FMP (74 FR 18262; April 9, 2010), followed by Framework Adjustment 45 to the FMP (76 FR 23042; April 25, 2011) and Framework 48 to the FMP (78 FR 26118; May 3, 2013), expanded and revised sector management.

The FMP defines a sector as ''[a] group of persons (three or more persons, none of whom have an ownership interest in the other two persons in the sector) holding limited access vessel permits who have voluntarily entered into a contract and agree to certain fishing restrictions for a specified period of time, and which has been granted a TAC(s) [*sic*] in order to achieve objectives consistent with applicable FMP goals and objectives.'' Sectors are self-selecting, meaning each sector can choose its members.

The NE multispecies sector management system allocates a portion of the NE multispecies stocks to each sector. These annual sector allocations are known as annual catch entitlements (ACEs) and are based on the collective fishing history of a sector's members. Sectors may receive allocations of large-mesh NE multispecies stocks with the exception of Atlantic halibut, windowpane flounder, Atlantic wolffish, and ocean pout, which are non-allocated species. The ACEs are a portion of a stock's annual catch limit (ACL) available to commercial NE multispecies vessels within a sector. A sector determines how to harvest its ACEs and may decide to limit operations to fewer vessels.

Because sectors elect to receive an allocation under a quota-based system, the FMP grants sector vessels several ''universal'' exemptions from the FMP's effort controls. These universal exemptions apply to: Trip limits on allocated stocks; the Georges Bank (GB) Seasonal Closure Area; NE multispecies days-at-sea (DAS) restrictions; the requirement to use a 6.5-inch (16.5-cm) mesh codend when fishing with selective gear on GB; portions of the Gulf of Maine (GOM) Cod Protection Closures; and the at-sea monitoring (ASM) coverage level for sector vessels fishing exclusively in the Southern New England (SNE) and Inshore GB Broad Stock Areas (BSA) with extra-large mesh

gillnets (10-inch [25.4-cm] or greater). The FMP prohibits sectors from requesting exemptions from permitting restrictions, gear restrictions designed to minimize habitat impacts, and most reporting requirements.

We received operations plans and preliminary contracts for fishing years 2017 and 2018 from 19 sectors. The operations plans are similar to previously approved versions and cover two fishing years. Continuing to approve two-year sector operations plans will help streamline the process for sector managers and reduce administrative burdens for both sectors and NMFS. In addition to the approved sectors, there are several state-operated permit banks, which receive allocation based on the history of the permits owned by the states. The final rule implementing Amendment 17 to the FMP allowed a state-operated permit bank to receive an allocation without needing to comply with the administrative and procedural requirements for sectors (77 FR 16942; March 23, 2012). Instead, permit banks are required to submit a list of participating permits to us, as specified in the permit bank's Memorandum of Agreement, to determine the ACE allocated to the permit bank. These allocations may be leased to fishermen enrolled in sectors. Although state-operated permit banks are no longer approved through the sector approval process, they are included in this discussion of allocations because they contribute to the total allocation under the sector system.

We have determined that the 19 sector operations plans and contracts that we have approved, and 21 of the 26 regulatory exemptions requested, are consistent with the FMP's goals and objectives, and meet sector requirements outlined in the regulations at § 648.87. These 19 operations plans are similar to previously approved plans. Copies of the operations plans and contracts, and the environmental assessment (EA), are available at: *http://www.regulations.gov* and from NMFS (see **ADDRESSES**).

Default Catch Limits for Fishing Year 2017

Last year, Framework 55 (81 FR 26412; May 2, 2016) set fishing year 2017 catch limits for all groundfish stocks. The 2017 catch limits for most stocks remain the same as, or similar, to 2016 limits, with minor adjustments for projected stock growth or revised estimates of Canadian catch. Framework 55 did not, however, specify a 2017 catch limit for Eastern GB cod, which is a management unit of the GB cod stock that is jointly managed with Canada. In addition, the Northeast Fisheries Science Center conducted a new benchmark assessment for witch flounder in December 2016.

This year, in Framework 56, the Council adopted a new 2017 catch limit for witch flounder based on the 2016 benchmark assessment, as well as 2017 catch limits for the three U.S./Canada stocks (Eastern GB cod, Eastern GB haddock, and GB yellowtail flounder). We are working to publish a proposed rule to request comments on the Framework 56 measures. Given the timing of the 2016 witch flounder stock assessment, the development and submission of Framework 56 was delayed, and it will not be possible to implement Framework 56 measures in time for May 1, 2017.

As a result, this rule sets a default catch limit for Eastern GB cod to prevent disruption to the groundfish fishery. The default catch limit for Eastern GB cod is set at 35 percent of the previous year's (2016) catch limit. This rule also announces the 2017 catch limits that will be effective on May 1, 2017, including the sector and common pool allocations based on the preliminary fishing year 2017 sector rosters (Table 1). The default catch limit for Eastern GB cod would be effective from May 1, 2017, through July 31, 2017, or the date on which the final rule for Framework 56 is implemented if prior to July 31. The catch limits for GB cod, GB haddock, GB yellowtail flounder, and witch flounder would be replaced once Framework 56 is implemented.

In Framework 56, the Council recommended a 23-percent decrease for GB yellowtail flounder for fishing year 2017 compared to 2016, and compared to the fishing year 2017 catch limit previously set in Framework 55. The recommended decrease is based on the Transboundary Management Guidance Committee's recommendation, which is the joint U.S./Canada management body that meets annually to recommend shared quotas for the three transboundary stocks. This recommendation will be further discussed in the Framework 56 proposed rule. We are highlighting this proposed decrease to sectors in this rule because the GB yellowtail flounder sector allocation issued in this rule is based on the higher 2017 catch limit previously approved in Framework 55.

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Table 1. NE Multispecies Catch Limits for 2017

Stock	Total ACL	Groundfish sub-ACL	Preliminary Sector sub-ACL	Preliminary Common Pool sub-ACL	Recreational sub-ACL	Midwater Trawl Fishery	Scallop Fishery	Small-Mesh Fisheries	State Waters sub-component	Other sub-component
	A to H	A+B+C	A	B	C	D	E	F	G	H
GB Cod*	730	608	596	12					23	99
GOM Cod	473	437	270	10	157				27	10
GB Haddock*	46,017	44,599	44,287	312		450			484	484
GOM Haddock	4,285	4,177	2,980	37	1,160	42			33	33
GB Yellowtail Flounder*	261	211	208	3			42	5	0	3
SNE/MA Yellowtail Flounder	256	187	153	34			34		5	29
CC/GOM Yellowtail Flounder	409	341	325	16					43	26
American Plaice	1,272	1,218	1,197	22					27	27
Witch Flounder*	441	370	361	9					12	59
GB Winter Flounder	650	590	585	5					0	60
GOM Winter Flounder	776	639	605	34					122	16
SNE/MA Winter Flounder	749	585	519	67					70	94
Redfish	10,514	10,183	10,126	57					111	221
White Hake	3,448	3,340	3,314	26					36	72
Pollock	20,374	17,817	17,701	116					1,279	1,279
N. Windowpane Flounder	177	66		66					2	109
S. Windowpane Flounder	599	104		104			209		37	249
Ocean Pout	155	137		137					2	17
Atlantic Halibut	119	91		91					25	4
Atlantic Wolffish	77	72		72					1	3

*Catch limit will be replaced when the final rule for Framework 56 becomes effective.

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Sector Allocations

Based on preliminary sector rosters submitted on March 20, 2017, we have projected fishing year 2017 allocations in this final rule. All permits enrolled in a sector, and the vessels associated with those permits, have until April 30, 2017, to withdraw from a sector and fish in the common pool for fishing year 2017. For fishing year 2018, we will set similar roster deadlines, notify permit holders of the fishing year 2018 deadlines, and allow permit holders to change sectors separate from the annual sector operations plans approval process.

We calculate the sector's allocation for each stock by summing its members' potential sector contributions (PSC) for a stock and then multiplying that total percentage by the available commercial sub-ACL for that stock. Table 2 shows the projected total PSC for each sector by stock for fishing year 2017. Tables 3 and 4 show the initial allocations that each sector will be allocated, in pounds and metric tons, respectively, for fishing year 2017, based on their preliminary fishing year 2017 rosters. At the start of the fishing year, we provide the final allocations, to the nearest pound, to the individual sectors, and we use those final allocations to monitor sector catch. The common pool sub-ACLs are also included in each of these tables for comparison.

We do not assign a permit separate PSCs for the Eastern GB cod or Eastern GB haddock; instead, we assign each permit a PSC for the GB cod stock and GB haddock stock. Each sector's GB cod and GB haddock allocations are then divided into an Eastern ACE and a Western ACE, based on each sector's percentage of the GB cod and GB haddock ACLs. For example, if a sector is allocated 4 percent of the GB cod ACL and 6 percent of the GB haddock ACL, the sector is allocated 4 percent of the commercial Eastern U.S./Canada Area GB cod total allowable catch (TAC) and 6 percent of the commercial Eastern U.S./Canada Area GB haddock TAC as its Eastern GB cod and haddock ACEs. These amounts are then subtracted from the sector's overall GB cod and haddock allocations to determine its Western GB cod and haddock ACEs. A sector may only harvest its Eastern GB cod and haddock ACEs in the Eastern U.S./Canada Area, but may ''convert,'' or transfer, its Eastern GB cod or haddock allocation into Western GB allocation and fish that converted ACE outside the Eastern GB area.

We expect to finalize 2016 catch information in summer 2017. We will allow sectors to transfer fishing year 2016 ACE for 2 weeks upon our completion of year-end catch accounting to reduce or eliminate any fishing year 2016 overages. If necessary, we will reduce any sector's fishing year 2017 allocation to account for a remaining overage in fishing year 2016. We will follow the same process for fishing year 2018. Each year of the operations plans, we will notify the Council and sector managers of this deadline in writing and will announce this decision on our Web site at: *http://www.greateratlantic.fisheries.noaa.gov/.*

BILLING CODE 3510–22–P

Table 2. Cumulative PSC (percentage) each sector would receive by stock for fishing year 2017.*

Sector Name	MRI Count	GB Cod	GOM Cod	GB Haddock	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector/FGS	114	28.55088469	2.98184781	6.34066056	2.05986188	0.01410317	0.37015063	3.06163632	1.00120862	2.15174107	0.02840963	13.60089150	2.33905249	2.78896863	5.84241146	8.01301842
Maine Coast Community Sector	64	0.96681005	9.52130659	0.96065073	6.34858867	1.58666588	1.27352349	3.25375532	9.90276015	7.47002898	0.66990195	3.11274949	1.48754318	5.95496715	10.49289957	10.68115015
Maine Permit Bank	11	0.13359371	1.15229526	0.04432773	1.12267471	0.01377700	0.03180706	0.31762428	1.16396845	0.72685826	0.00021716	0.42608652	0.01789057	0.82179392	1.65260336	1.69358132
NCCS	31	0.39767691	2.09639037	0.35133778	1.53239089	0.83924990	0.70058623	1.89733263	0.61211670	1.25009064	0.05429194	2.14164276	0.70544113	0.99917766	1.95739966	1.76182806
NEFS 1	3	0.00000000	0.03068546	0.00000000	0.00248698	0.00000000	0.00000000	0.03756612	0.00855916	0.01274888	0.00000096	0.05214631	0.00000323	0.00000000	0.00000000	0.00000000
NEFS 2	86	5.85541718	18.55271390	10.66649307	17.12546537	1.86551235	1.73025022	19.85266791	9.45690548	13.25717042	3.20670608	18.97105983	3.50565010	14.84594282	6.44691098	11.38834524
NEFS 3	56	0.73328653	9.91701816	0.05053684	6.81641846	0.04401911	0.06601225	6.08162313	2.07048057	1.68826788	0.01361530	6.98897919	0.40775084	0.75394968	3.23935331	3.96316950
NEFS 4	51	4.15307137	9.97051530	5.34806481	8.39956066	2.16156175	2.35080531	5.47382222	9.29315100	8.49568840	0.69179797	6.31786267	1.28099662	6.71055733	8.07912629	6.31919085
NEFS 5	26	0.48697009	0.00070532	0.81553839	0.00357186	1.27642416	21.85972631	0.20637978	0.43352335	0.56559236	0.43634226	0.02248155	12.62851159	0.01572242	0.10890777	0.04252833
NEFS 6	22	2.86957812	2.96017293	2.92681853	3.84084576	2.70263541	5.27021762	3.73595895	3.89175649	5.20520629	1.50474419	4.56247441	1.93853382	5.31060100	3.91460371	3.30548119
NEFS 7	20	1.25480636	0.80376681	1.35247704	0.59037186	3.41209604	2.47183060	2.26724135	0.73975638	0.93610137	1.28133136	2.38588460	0.80357683	0.35693646	0.55809083	0.45451036
NEFS 8	16	6.51790722	0.15594187	5.94719762	0.06821334	10.63224074	5.21885960	2.59779718	2.08752528	2.44109420	21.16004781	0.68022107	8.97265613	0.50683898	0.46632724	0.61322607
NEFS 9	60	13.16828902	3.01666261	11.24352608	7.39149111	25.19220000	8.72232143	10.61700121	9.70689545	9.41350439	32.56133094	2.94647951	17.95005455	9.05149193	6.37855417	6.36126311
NEFS 10	27	0.33828109	2.34583468	0.16461659	1.24660884	0.00114042	0.54741703	4.00864630	0.93107515	1.69016836	0.01083151	8.95328087	0.48768027	0.32509525	0.61408657	0.69606092
NEFS 11	52	0.40629927	12.45006609	0.03722788	3.08313551	0.00149970	0.01949288	2.52128782	2.08085291	1.98241521	0.00330849	2.13135985	0.02152270	1.96478551	4.72755390	9.01991409
NEFS 12	19	0.63151303	2.98152458	0.09401144	1.04520246	0.00042969	0.01049524	7.95034035	0.50391090	0.56855101	0.00043898	7.66448782	0.21889325	0.22950555	0.29535685	0.82496955
NEFS 13	62	12.18285679	0.90896251	20.11363366	1.05046789	34.49943811	21.02740300	8.83804125	8.48405225	9.29843980	17.82189215	3.04937928	16.60357909	4.28302829	2.14904573	2.61919403
New Hampshire Permit Bank	4	0.00082205	1.14256555	0.00003406	0.03229444	0.00002026	0.00001788	0.02178570	0.02847521	0.00615947	0.00000324	0.06062793	0.00003630	0.01939980	0.08127664	0.11125510
Sustainable Harvest Sector 1	30	2.67295101	5.96556815	2.52270202	4.76510605	0.96587585	0.31532637	3.22108149	6.40294382	4.35110313	5.73641170	4.67381419	0.82222986	6.07538462	8.41351804	7.28519039
Sustainable Harvest Sector 2	14	0.28812111	0.29347573	0.40165710	0.07151001	2.20948828	2.24516980	0.84146135	0.71550373	0.61479620	0.45961600	0.93029859	1.10566785	0.26110454	0.33427366	0.26502607
Sustainable Harvest Sector 3	70	16.45431014	9.19155572	29.91874848	32.18195071	11.05985642	7.43666217	8.55607607	28.70228915	25.53629888	13.53562739	4.99272245	17.32857563	38.16429030	33.47229065	23.92968571
Common Pool	500	1.93655425	3.56042462	0.69973960	1.22178256	1.52176575	18.33192486	4.64087327	1.78228978	2.33797478	0.82313297	5.33506961	11.37415396	0.56045817	0.77540961	0.65141150

* The data in this table are based on preliminary fishing year 2017 sector rosters.

Table 3. ACE (in 1,000 lbs), by stock, for each sector for fishing year 2017.*#^

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
FGS	30	352	18	2,866	3,369	137	0	2	23	27	18	0	192	30	626	430	3,147
MCCS	1	12	59	434	510	422	7	5	24	266	61	9	44	19	1,337	773	4,196
MPB	0	2	7	20	24	75	0	0	2	31	6	0	6	0	184	122	665
NCCS	0	5	13	159	187	102	4	3	14	16	10	1	30	9	224	144	692
NEFS 1	-	-	0	-	-	0	-	-	0	0	0	0	1	0	-	-	-
NEFS 2	6	72	115	4,821	5,667	1,139	9	7	149	254	108	42	267	45	3,333	475	4,473
NEFS 3	1	9	61	23	27	453	0	0	46	56	14	0	98	5	169	239	1,557
NEFS 4	4	51	62	2,417	2,841	559	10	10	41	250	69	9	89	17	1,506	595	2,482
NEFS 5	1	6	0	369	433	0	6	90	2	12	5	6	0	163	4	8	17
NEFS 6	3	35	18	1,323	1,555	255	13	22	28	105	42	20	64	25	1,192	288	1,298
NEFS 7	1	15	5	611	719	39	16	10	17	20	8	17	34	10	80	41	179
NEFS 8	7	80	1	2,688	3,160	5	49	22	20	56	20	275	10	116	114	34	241
NEFS 9	14	162	19	5,081	5,974	492	117	36	80	261	77	424	42	232	2,032	470	2,499
NEFS 10	0	4	14	74	87	83	0	2	30	25	14	0	126	6	73	45	273
NEFS 11	0	5	77	17	20	205	0	0	19	56	16	0	30	0	441	348	3,543
NEFS 12	1	8	18	42	50	70	0	0	60	14	5	0	108	3	52	22	324
NEFS 13	13	150	6	9,090	10,686	70	160	87	66	228	76	232	43	214	962	158	1,029
NHPB	0	0	7	0	0	2	0	0	0	1	0	0	1	0	4	6	44
SHS 1	3	33	37	1,140	1,340	317	4	1	24	172	35	75	66	11	1,364	620	2,862
SHS 2	0	4	2	182	213	5	10	9	6	19	5	6	13	14	59	25	104
SHS 3	18	203	57	13,522	15,896	2,141	51	31	64	771	208	176	70	223	8,568	2,465	9,400
Common Pool	**2**	**24**	**22**	**316**	**372**	**81**	**7**	**76**	**35**	**48**	**19**	**11**	**75**	**147**	**126**	**57**	**256**
Sector Total	**104**	**1,210**	**595**	**44,879**	**52,757**	**6,570**	**458**	**337**	**717**	**2,637**	**797**	**1,290**	**1,334**	**1,143**	**22,324**	**7,306**	**39,024**

*The data in this table are based on preliminary fishing year 2017 sector rosters.

#Numbers are rounded to the nearest thousand pounds. In some cases, this table shows an allocation of 0, but that sector may be allocated a small amount of that stock in tens or hundreds pounds.

^ The data in the table represent the total allocations to each sector.

Table 4. ACE (in metric tons), by stock, for each sector for fishing year 2017.*#^

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
FGS	14	160	8	1,300	1,528	62	0	1	10	12	8	0	87	14	284	195	1,428
MCCS	0	5	27	197	232	192	3	2	11	121	28	4	20	9	606	350	1,903
MPB	0	1	3	9	11	34	0	0	1	14	3	0	3	0	84	55	302
NCCS	0	2	6	72	85	46	2	1	6	7	5	0	14	4	102	65	314
NEFS 1	-	-	0	-	-	0	-	-	0	0	0	0	0	0	-	-	-
NEFS 2	3	33	52	2,187	2,571	517	4	3	68	115	49	19	121	21	1,512	215	2,029
NEFS 3	0	4	28	10	12	206	0	0	21	25	6	0	45	2	77	108	706
NEFS 4	2	23	28	1,096	1,289	253	5	4	19	113	31	4	40	7	683	270	1,126
NEFS 5	0	3	0	167	197	0	3	41	1	5	2	3	0	74	2	4	8
NEFS 6	1	16	8	600	705	116	6	10	13	47	19	9	29	11	541	131	589
NEFS 7	1	7	2	277	326	18	7	5	8	9	3	8	15	5	36	19	81
NEFS 8	3	36	0	1,219	1,433	2	22	10	9	25	9	125	4	52	52	16	109
NEFS 9	6	74	8	2,305	2,710	223	53	16	36	118	35	192	19	105	922	213	1,133
NEFS 10	0	2	7	34	40	38	0	1	14	11	6	0	57	3	33	21	124
NEFS 11	0	2	35	8	9	93	0	0	9	25	7	0	14	0	200	158	1,607
NEFS 12	0	4	8	19	23	32	0	0	27	6	2	0	49	1	23	10	147
NEFS 13	6	68	3	4,123	4,847	32	73	39	30	103	34	105	19	97	436	72	467
NHPB	0	0	3	0	0	1	0	0	0	0	0	0	0	0	2	3	20
SHS 1	1	15	17	517	608	144	2	1	11	78	16	34	30	5	619	281	1,298
SHS 2	0	2	1	82	97	2	5	4	3	9	2	3	6	6	27	11	47
SHS 3	8	92	26	6,133	7,210	971	23	14	29	350	94	80	32	101	3,886	1,118	4,264
Common Pool	**1**	**11**	**10**	**143**	**169**	**37**	**3**	**34**	**16**	**22**	**9**	**5**	**34**	**67**	**57**	**26**	**116**
Sector Total	**47**	**549**	**270**	**20,357**	**23,930**	**2,980**	**208**	**153**	**325**	**1,196**	**361**	**585**	**605**	**518**	**10,126**	**3,314**	**17,701**

*The data in this table are based on preliminary fishing year 2017 sector rosters.

#Numbers are rounded to the nearest metric ton, but allocations are made in pounds. In some cases, this table shows a sector allocation of 0 metric tons, but that sector may be allocated a small amount of that stock in pounds.

^ The data in the table represent the total allocations to each sector.

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Sector Operations Plans and Contracts

Approved Sectors

As previously stated, we received and are approving 19 sector operations plans and contracts for fishing years 2017 and 2018. In order to approve a sector's operations plan for fishing years 2017 and 2018, we consider whether a sector has been compliant with reporting requirements from previous years, including the year-end reporting requirements found at § 648.87(b)(1)(vi)(C). Approved operations plans, provided on our Web site as a single document for each sector, not only contain the rules under which each sector would fish, but also provide the legal contract that binds each member to the sector for the length of the sector's operations plan. Each sector's operations plan, and each sector's members, must comply with the regulations governing sectors, found at § 648.87. In addition, each sector must conduct fishing activities as detailed in its approved operations plan.

Participating vessels are required to comply with all pertinent Federal fishing regulations, except as specifically exempted in the letter of authorization (LOA) issued by the Regional Administrator, which details any approved sector exemptions from the regulations. If, during a fishing year, or between fishing years 2017 and 2018, a sector requests an exemption that we have already granted, or proposes a change to administrative provisions, we may amend the sector operations plans. Should any such amendments require modifications to LOAs, we would include these changes in updated LOAs and provide them to the appropriate sectors.

As in previous years, we retain the right to revoke exemptions in-season if: We determine that the exemption jeopardizes management measures, objectives, or rebuilding efforts; the exemption results in unforeseen negative impacts on other managed fish stocks, habitat, or protected resources; the exemption causes enforcement concerns; catch from trips utilizing the exemption cannot adequately be monitored; or a sector is not meeting certain administrative or operational requirements. If it becomes necessary to revoke an exemption, we will do so through a process consistent with the Administrative Procedure Act.

Each sector is required to ensure that it does not exceed its ACE during the fishing year. Sector vessels are required to retain all legal-sized allocated NE multispecies stocks, unless a sector is granted an exemption allowing its member vessels to discard legal-sized unmarketable fish at sea. Catch (defined as landings and dead discards) of all allocated NE multispecies stocks by a sector's vessels count against the sector's allocation. Catch from a sector trip targeting dogfish, monkfish, skate, and lobster (with non-trap gear) would be deducted from the sector's ACE because these are groundfish trips using gear capable of catching groundfish. This includes trips that have declared into the small-mesh exemption described below, because vessels fishing under this sector exemption, (*i.e.,* vessels fishing with both small mesh and large mesh during the same trip) are considered to be on a sector trip for purposes of monitoring ACE. Catch from a non-sector trip in an exempted fishery does not count against a sector's allocation and is assigned to a separate ACL sub-component to account for any groundfish bycatch that occurs in non-groundfish fisheries.

In fishing years 2010 and 2011, we funded an ASM program with a target ASM coverage level of 30 percent of all trips. In addition, we provided 8-percent observer coverage through the Northeast Fishery Observer Program (NEFOP), which helps to support the Standardized Bycatch Reporting Methodology (SBRM) and stock assessments. This resulted in an overall target coverage level of 38 percent for fishing years 2010 and 2011, between ASM and NEFOP. Beginning in fishing year 2012, we have conducted an annual analysis to determine the total target coverage level. Industry has been required to pay for their costs of ASM coverage since 2012, while we continued to fund NEFOP coverage. However, we were able to fund the industry's portion of ASM costs and NEFOP coverage in fishing years 2012 through most of 2015. Industry began paying for their portion of the ASM program in March 2016. In June 2016, after determining that the SBRM monitoring program could be fully funded, NOAA Fisheries announced that we had remaining funds to offset some of industry's costs of the groundfish ASM program in 2016. We provided a grant to the Atlantic States Marine Fisheries Commission (ASMFC) to reimburse sectors for 85 percent of their costs for at-sea monitoring. We expect that there will be funds remaining in the grant to the ASMFC at the end of the 2016 fishing year that will be available to reimburse sectors for a portion of their ASM costs in fishing year 2017. We have not yet determined the reimbursement rate for 2017. However, it may be lower than 85 percent. Table 5 shows the target coverage level in previous fishing years.

TABLE 5—HISTORIC TARGET COVERAGE LEVEL FOR MONITORING

Fishing year	Total target coverage level (%)	ASM target coverage level (%)	NEFOP target coverage level (%)
2010	38	30	8
2011	38	30	8
2012	25	17	8
2013	22	14	8
2014	26	18	8
2015	16	12	4
2016	14	10	4

Sectors are responsible for paying the at-sea portion of costs associated with the sector ASM program and for designing, implementing, and funding an ASM program that will provide the level of ASM coverage specified annually. We are required to specify a level of ASM coverage using a process described in Framework 55 that attempts to balance minimizing the cost burden to sectors and NMFS to the extent practicable, while still providing a reliable estimate of overall catch by sectors needed for monitoring ACEs and ACLs. Using this method, NMFS has determined that the total appropriate target coverage level for fishing year 2017 is 16 percent of all eligible sector

trips. Federally-funded observer coverage provided by NEFOP to meet SBRM will partially satisfy the 16-percent coverage requirement, so sectors will pay for ASM coverage on less than 16 percent of their groundfish trips. We will use discards derived from these observed and monitored trips to calculate and apply discards to unobserved sector trips. We have published a more detailed summary of the supporting information, explanation and justification for this decision at: *http://www.greateratlantic.fisheries.noaa.gov/ro/fso/reports/Sectors/ASM/FY2017_Multispecies_Sector_ASM_Requirements_Summary.pdf.*

The draft operations plans submitted in September 2016 included industry-funded ASM plans to be used for fishing year 2017. As in previous years, we gave sectors the option to design their own programs in compliance with regulations, or elect to adopt the NMFS-designed ASM program that we have used in previous fishing years. As in past years, several sectors chose to adopt the NMFS-designed program while others proposed programs of their own design. Sector-designed ASM programs for fishing years 2017 and 2018 were similar to those approved in past years. We reviewed all sector-proposed ASM programs for consistency with ASM requirements and have approved them. ASM programs proposed by the sectors are described in detail later in this final rule.

Each sector contract details the method for initial ACE sub-allocation to sector members. For fishing years 2017 and 2018, each sector has proposed that each sector member could harvest an amount of fish equal to the amount each individual member's permit contributed to the sector, as modified by the sector for reserves or other management measures. Each sector operations plan submitted for fishing years 2017 and 2018 states that the sector would withhold an initial reserve from the sector's ACE sub-allocation to each individual member to prevent the sector from exceeding its ACE. A sector and sector members can be held jointly and severally liable for ACE overages, discarding legal-sized fish, and/or misreporting catch (landings or discards). Each sector contract provides procedures for enforcement of the sector's rules, explains sector monitoring and reporting requirements, provides sector managers with the authority to issue stop fishing orders to sector members who violate provisions of the operations plan and contract, and presents a schedule of penalties that managers may levy for sector plan violations.

Sectors are required to monitor their allocations and catch. To help ensure that a sector does not exceed its ACE, each sector operations plan explains sector monitoring and reporting requirements, including a requirement to submit weekly catch reports to us. If a sector reaches an ACE threshold (specified in the operations plan), the sector must provide us with sector allocation usage reports on a daily basis. Once a sector's allocation for a particular stock is caught, that sector is required to cease all sector fishing operations in that stock area until it acquires more ACE, likely by an ACE transfer between sectors. Within 60 days of when we complete year-end catch accounting, each sector is required to submit an annual report detailing the sector's catch (landings and discards), enforcement actions, and pertinent information necessary to evaluate the biological, economic, and social impacts of each sector.

Future Consideration of 2017 Sector Operations

An ongoing case, *United States* v. *Carlos Rafael,* may affect sector operations for the 2017 fishing year. On March 30, 2017, Carlos Rafael pleaded guilty to federal criminal charges involving falsely reporting catch information on dealer reports and vessel trip reports. All of the vessels involved were enrolled in NEFS 9 during the period of misreporting, are currently enrolled in the sector for fishing year 2016, and are on the preliminary sector roster for fishing year 2017. Sentencing for these violations is currently scheduled for June 27, 2017, and may provide additional information that could affect sector operations. Because the case is ongoing, we are approving the NEFS 9 operations plan at this time. However, we intend to take into account additional information regarding NEFS 9 operations as it becomes available and take further action, as necessary, including consideration of further management or monitoring requirements and continued approval of the sector.

Granted Exemptions for Fishing Years 2017 and 2018

Previously Granted Exemptions Granted for Fishing Years 2017 and 2018 (1–20)

We are granting exemptions from the following requirements for fishing years 2017 and 2018, all of which have been requested and granted in previous years: (1) 120-day block out of the fishery required for Day gillnet vessels; (2) 20-day spawning block out of the fishery required for all vessels; (3) prohibition on a vessel hauling another vessel's gillnet gear; (4) limits on the number of gillnets that may be hauled on GB when fishing under a NE multispecies/monkfish DAS; (5) limits on the number of hooks that may be fished; (6) DAS Leasing Program length and horsepower restrictions; (7) prohibition on discarding; (8) daily catch reporting by sector managers for sector vessels participating in the Closed Area (CA) I Hook Gear Haddock Special Access Program (SAP); (9) prohibition on fishing inside and outside of the CA I Hook Gear Haddock SAP while on the same trip; (10) prohibition on a vessel hauling another vessel's hook gear; (11) the requirement to declare an intent to fish in the Eastern U.S./Canada SAP and the CA II Yellowtail Flounder/Haddock SAP prior to leaving the dock; (12) gear requirements in the Eastern U.S./Canada Management Area; (13) seasonal restrictions for the Eastern U.S./Canada Haddock SAP; (14) seasonal restrictions for the CA II Yellowtail Flounder/Haddock SAP; (15) sampling exemption; (16) prohibition on groundfish trips in the Nantucket Lightship Closed Area; (17) prohibition on combining small-mesh exempted fishery and sector trips in Southern New England; (18) limits on the number of gillnets for day gillnet vessels fishing outside the GOM; (19) 6.5-inch minimum mesh size requirement for trawl nets to allow a 5.5 inch codend on directed redfish trips; and (20) extra-large mesh requirement to target dogfish on trips excluded from ASM in SNE and Inshore GB. A detailed description of the previously granted exemptions and supporting rationale can be found in the applicable final rules identified in Table 6 below.

TABLE 6—EXEMPTIONS FROM PREVIOUS FISHING YEARS THAT ARE GRANTED IN FISHING YEARS 2017 AND 2018

Exemptions	Rulemaking	Date of publication	Citation
1–8, 12	Fishing Year 2011 Sector Operations Final Rule	April 25, 2011	76 FR 23076.
9–11	Fishing Year 2012 Sector Operations Final Rule	May 2, 2012	77 FR 26129.
13–15	Fishing Year 2013 Sector Operations Interim Final Rule	May 2, 2013	78 FR 25591.
16	Fishing Year 2014 Sector Operations Final Rule	April 28, 2014	79 FR 23278.
17–19	Fishing Years 2015–2016 Sector Operations Final Rule	May 1, 2015	80 FR 25143.
20	Framework 55 Final Rule	May 2, 2016	81 FR 26412.

NE Multispecies **Federal Register** documents can be found at *http://www.greateratlantic.fisheries.noaa.gov/sustainable/species/multispecies/.*

New Exemption Granted for Fishing Years 2017 and 2018

(21) Requirement To Carry a VMS for Handgear A Vessels Fishing in a Single Broad Stock Area

Sectors are prohibited from requesting exemptions from reporting requirements. However, Amendment 18 included a measure that allows a sector to request a VMS exemption for Handgear A vessels, and we are granting this exemption for the 2017 and 2018 fishing years. Because the cost of VMS units is often a significant barrier to sector participation for handgear vessels, this exemption is intended to increase Handgear A vessel participation in sectors. Handgear A vessels using the VMS exemption (enrolled in a sector that has the exemption and fishing in a single broad stock area) must declare the start of trips to NMFS using the interactive voice response (IVR) system. Vessels must also declare their trip end through IVR, similar to a VMS trip end hail.

To ensure that catch and discards are reported to the correct broad stock area, Handgear A vessels may only use the VMS exemption when fishing in a single broad stock area. Handgear vessels intending to fish in multiple broad stock areas (for example, Gulf of Maine and Inshore Georges Bank) must declare their trip through a VMS system and submit daily VMS catch reports when fishing inside and outside of the Gulf of Maine on the same trip. A VMS unit is also required when fishing in the Eastern and Western U.S./Canada Areas, and may be required for some sector exemptions or special access areas, and this exemption does not waive those requirements.

Handgear A vessels using the VMS exemption are still required to call into the pre-trip notification system (PTNS) at least 48 hours prior to the start of a trip to facilitate ASM selection procedures. Additionally, all other reporting and monitoring requirements still apply, including the requirement to complete a vessel trip report (VTR) and declare their trip end before beginning to offload. We expect the requirement to complete a VTR and declare a trip end before offloading to assist with coordinating dockside enforcement and sampling.

As with other exemptions, sectors that have requested the exemption must include it in their operations plan, and have their plan approved, in order for their sector members to use the exemption. We will monitor the use of this exemption and update requirements, as necessary.

Denied Fishing Years 2017 and 2018 Exemption Requests

We are denying five exemption requests. Three of these requests sought to allow the use of nets with mesh smaller than the minimum mesh size to target healthy stocks. We are denying these exemptions because of concerns about bycatch of undersized groundfish, concerns about impacts on stocks in poor condition, like cod, and a lack of available data to support approval. Increasing fishing opportunities to catch healthy stocks is important, but we must ensure that these opportunities do not negatively affect stocks in poor condition. As such, testing these concepts and collecting data necessary to support future exemption requests are needed. These ideas should be pursued through experimental fishing permits and other research to collect data useful in evaluating their effectiveness. We are also denying an exemption request that would allow certain gillnet vessels to leave nets in the water between trips because this could undermine effort controls in the Monkfish FMP due to interactions between that plan and the groundfish FMP. Because of the complicated interplay between this exemption request and multiple FMP's we have forwarded this request to the New England Council for their consideration in future groundfish or monkfish actions, should they choose. We are denying the VMS powerdown exemption because of a lack of compliance with the requirements of the exemptions when it was granted in previous years. In years when this exemption was granted, we worked with sectors to improve use of this exemption; however, compliance did not improve. As a result, we did not approve this exemption for fishing years 2015 and 2016. Requests for this exemption for fishing years 2017 and 2018 did not include any additional requirements or information that would suggest use of this exemption would improve from previous years. For these reasons, we do not have confidence that compliance with this exemption would be adequate, which would undermine our ability to adequately monitor the fishery. For these reasons, we are again denying this exemption.

Exemption We Propose To Modify

Modifications to the Sectors Small-Mesh Fishery Exemption Area

We received a request to modify the area for an approved exemption (17) that allows the use of small-mesh and large mesh trawl gear on a sector trip in portions of Southern New England. As approved in fishing years 2015 and 2016, and in this rule for fishing years 2017 and 2018, the exemption allows vessels to combine sector and small-mesh fishery trips by first targeting groundfish with large mesh and then switching to small-mesh mid-trip to target exempted fishery species. There are additional requirements for gear modifications on the small-mesh portion of the trip to reduce bycatch of groundfish, and all legal groundfish caught on the small-mesh portion of the trip must be kept and counted against the sector's allocation. A vessel using this exemption is still required to meet the same NEFOP and ASM coverage as groundfish trips, and is also required to submit a VMS catch report when switching gears.

The current small-mesh sector exemption area as described in the Final 2015 and 2016 Sector Rule (80 FR 25143, May 1 2015) includes two discrete areas, one that parallels the southern shore of Long Island to the waters just off Narragansett Bay, and a second area south of Martha's Vineyard (see Figure 1). The request was to modify the area to include all of statistical areas 537, 539 and 613, which would expand the geographic footprint

of the exemption area, to better reflect fishing practices in the area and increase efficiency and opportunities for sector vessels (see Figure 2). We are proposing to grant the modification to the exemption area, as requested, but the exemption would not be applicable to any areas that overlap groundfish closed areas or southern windowpane flounder accountability measure (AM) areas, regardless of whether the AM areas are triggered. We are excluding the overlapping southern windowpane flounder AM areas because of concerns about interactions with windowpane flounder and other regulated groundfish species within the AM area. As with all sector exemptions, we will continue to monitor the use of the updated exemption, as well as any changes to AM areas by the New England Council, in future consideration of this exemption.

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Figure 1. Current Sectors Small-Mesh Fishery Exemption Areas, and Overlapping Southern Windowpane Accountability Measure and Groundfish Closed Areas.

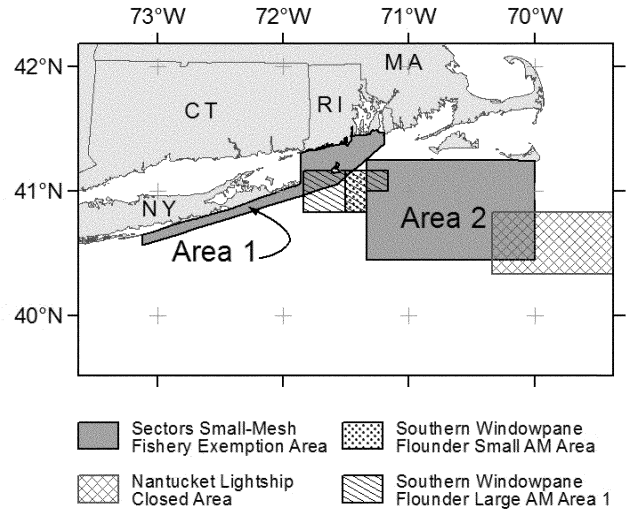
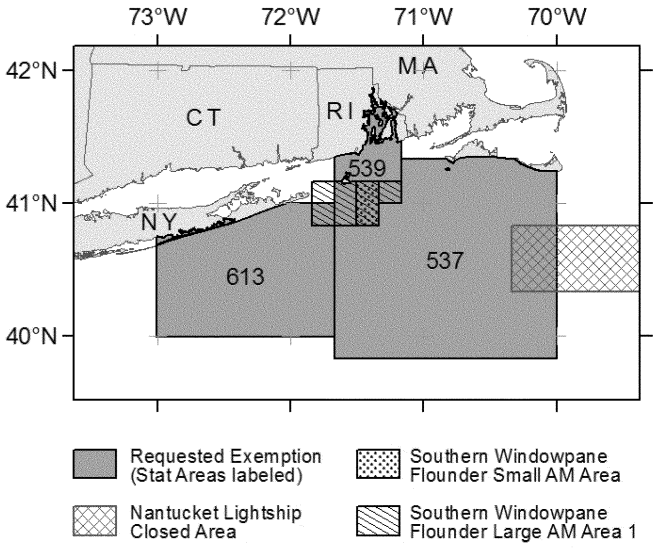


Figure 2. Proposed Sectors Small-Mesh Fishery Exemption Area, and Overlapping Southern Windowpane Accountability Measure and Groundfish Closed Areas.



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Modified Exemption Reporting Requirements

Changes to the Reporting Requirements for the Exemption From the Extra-Large Mesh Requirement To Target Dogfish on Trips Excluded From ASM

Last year, Framework 55 removed the ASM coverage requirement for sector trips using gillnets with extra-large mesh (10 inches (25.4 cm) or greater) in the SNE and Inshore GB Broad Stock Areas. We also approved a sector exemption that allows vessels on these ASM-excluded sector trips to target dogfish using 6.5-inch (16.5-cm) mesh gillnet gear within the footprint and season of either the Nantucket Shoals Dogfish Exemption Area (June 1 to October 15), the Eastern Area of the Cape Cod Spiny Dogfish Exemption Area (June 1 to December 31), or the Southern New England Dogfish Gillnet Exemption Area (May 1 to October 31). At the time, we announced that we would closely monitor the exemption during the 2016 fishing year to evaluate whether additional reporting measures are necessary. In order to improve the monitoring of this exemption, and to be consistent with reporting requirements of similar exemptions, we are updating the reporting requirements for this exemption beginning in the 2017 fishing year.

In addition to the PTNS requirement, a vessel is now required to declare its intent to use gillnets with extra-large mesh (10 inches (25.4 cm) or greater) in the SNE/MA and Inshore GB Broad Stock Areas by submitting a trip start hail through its VMS unit prior to departure. This trip start hail will be used for monitoring and enforcement purposes. Trips declaring this exemption must stow their regulated mesh gear and use their extra large mesh (10 inches (25.4 cm) or greater) first. Also starting fishing year 2017, the vessel, once finished with the extra-large mesh portion of the trip, must submit a Multispecies Catch Report via VMS with a good faith estimate of all catch on board, and an indication of the switch to regulated mesh. The vessel could then fish with regulated mesh within the allowable dogfish exemption areas, and comply with the remaining requirements of a sector trip, including the submission of VTRs, a trip end hail, and a final Multispecies Catch Report.

We will continue to closely monitor this exemption to evaluate whether additional reporting measures are necessary. While sector trips using this exemption are exempt from ASM coverage, any legal-sized allocated groundfish stocks caught during these trips must be landed and the associated landed weight (dealer or VTR) will be deducted from the sector's ACE.

Additional Sector Operations Plan Provisions

Inshore GOM Restrictions

Several sectors have proposed an operations plan provision to limit and more accurately document a vessel's behavior when fishing in an area they define as the inshore portion of the GOM BSA, or the area to the west of 70°15′ W. long. As in fishing years 2015 and 2016, we are approving this provision, but note that a sector may elect to remove this provision in the final version of its operations plan, and it is not a requirement under NMFS regulations.

Under this provision, a vessel that is carrying an observer or at-sea monitor would remain free to fish in all areas, including the inshore GOM area, without restriction. If a vessel is not carrying an observer or at-sea monitor and fishes any part of its trip in the GOM west of 70°15′ W. long., the vessel would be prohibited from fishing outside of the GOM BSA. Also, if a vessel is not carrying an observer or at-sea monitor and fishes any part of its trip outside the GOM BSA, this provision would prohibit a vessel from fishing west of 70°15′ W. long. within the GOM BSA. The approved provision includes a requirement that a vessel declare whether it intends to fish in the inshore GOM area through the trip start hail using its VMS unit prior to departure. We provide sector managers with the ability to monitor this provision through the Sector Information Management Module, a Web site where we also provide roster, trip, discard, and observer information to sector managers. A sector vessel may use a federally funded NEFOP observer or at-sea monitor on these trips because we believe it will not create bias in coverage or discard estimates, as fishing behavior is not expected to change as a result of this provision.

Prohibition on a Vessel Hauling Another Vessel's Trap Gear To Target Groundfish

Several sectors have requested a provision to allow a vessel to haul another vessel's fish trap gear, similar to the current exemptions that allow a vessel to haul another vessel's gillnet gear or hook gear. These exemptions have generally been referred to as ''community'' gear exemptions. Regulations at § 648.84(a) require a vessel to mark all bottom-tending fixed gear, which would include fish trap gear used to target groundfish. To facilitate enforcement of this regulation, we are requiring that any community fish trap gear be tagged by each vessel that plans to haul the gear, similar to how this sector operations plan provision was implemented in fishing years 2014 through 2016. This allows one vessel to deploy the trap gear and another vessel to haul the trap gear, provided both vessels tag the gear prior to deployment. This requirement is included in the sector's operations plan to provide the opportunity for the sector to monitor the use of this provision and ensure that the Office of Law Enforcement (OLE) and the U.S. Coast Guard can enforce the marking requirement.

At-Sea Monitoring Proposals

For fishing years 2017 and 2018, each sector is required to develop and fund an approved ASM program. In the event we cannot approve a proposed ASM program we asked all sectors to include an option to use the current NMFS-designed ASM program as a back-up. Sustainable Harvest Sectors 1, 2, and 3, GB Cod Fixed Gear Sector, Northeast Coastal Communities Sector, and Maine Coast Community Sector have proposed to use the ASM program that was developed by NMFS. We approve this program for these sectors because it is consistent with goals and objectives of monitoring, and with regulatory requirements. Sectors that operate only as permit banks, and explicitly prohibit fishing in their operations plans, are not required to include provisions for an ASM program.

We approve the ASM programs proposed by the remaining 12 sectors, which state that they will: Contract with a NMFS-approved ASM provider; meet the specified coverage level; and utilize the PTNS for random selection of monitored trips and notification to providers. These ASM programs also include additional protocols for ASM coverage waivers, incident reporting, and safety requirements for their sector mangers and members. We have determined that the programs are consistent with the goals and objectives of at-sea monitoring, and within the regulatory requirements.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), the NMFS Assistant Administrator has determined that this interim final rule is consistent with the NE Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

The AA finds that prior notice and the opportunity for public comment would be contrary to the public interest, consistent with 5 U.S.C. 553(b)(B). The purpose of this action is to allocate quotas to sectors and to authorize vessels to fish under the sector operations plans during the 2017 fishing year. The sector operations plans must be approved before sector vessels can fish in the sector fishery. In 2015, Framework Adjustment 55 to the NE Multispecies FMP set 2017 annual catch limits for groundfish stocks. However, in January 2017 the New England Fishery Management Council approved Framework Adjustment 56 to the FMP which would change the annual catch limits for 2017 for some stocks (some stocks would increase and others would decrease). To avoid public confusion and a mid-year change in allocations, we initially developed this rule to complement the Framework 56 rulemaking process. Typically, the framework rulemaking and related sector operations rule are completed in time for the start of the fishing year on May 1. However, the Council did not formally submit Framework 56 to us until April 13, 2017, which prohibited us from coordinating the publication of the two actions. Due to the late submission of Framework 56, this rule instead makes allocations based on the quota previously set by Framework 55. This rule could not be revised, as necessary, in time to provide prior notice and comment and still be effective for the start of the 2017 fishing year on May 1, 2017.

Delaying the effective date of this action past the beginning of the fishing year on May 1 would cause a major disruption in sector member fishing plans and impose substantial opportunity costs through lost fishing opportunities. Sectors include 838 permits and 99 percent of fishing activity. Thus, any delay past the beginning of the fishing year would effectively shut down nearly the entire groundfish fishery during that delay. This delay may also require sector members to reconsider their decision and plans to fish in the sector rather than the common pool. Shutting down the fishery and disrupting business plans is contrary to this rule's intended purpose of providing operational flexibility and maximum opportunity for catching up to the fishery's allocated amounts. Further, these allocated amounts are gauged to achieve Optimum Yield and producing the greatest benefit to the nation as required by the Magnuson-Stevens Fishery Conservation and Management Act. A delay in the beginning of the fishery would be contrary to this statutory requirement and FMP goal. The economic loss from this lost opportunity and disruption would further exacerbate the severe economic impacts experienced by the groundfish fishery that have resulted from the substantial catch limit reductions for many key groundfish stocks over the past 5 years. For these reasons, delaying the effective date of this action to provide prior opportunity for public comment is contrary to the public interest. The AA finds that there is adequate justification under 5. U.S.C. 553(d)(1) to waive the 30-day delay in effective date because this rule relieves several restrictions. This action allocates quotas and approves sector operations plans for fishing year 2017. A delay in effectiveness would not be in the public interest because this rule does not impose any new requirements or costs on industry for which industry needs time to prepare to comply. Further, if the effectiveness of this action is delayed beyond the May 1, 2017, start of the fishing year, the 838 permits enrolled to fish in a sector in 2017 would either need to cease fishing on May 1, until this rule became effective, or forego fishing as part of a sector, including the associated regulatory exemptions, for the entirety of the fishing year and instead fish under the effort control regulations of the common pool. For example, vessels fishing in the common pool would be subject to effort controls that do not apply to vessels fishing under an approved sector operations plan. Common pool vessels will have their catch limited each trip, will be further limited in the number of days they could fish, and will be subject to several seasonal closures that sector vessels will be exempted from.

Additionally, there is good cause under 5 U.S.C. 553(d)(3), to waive the 30-day delay in effectiveness so that the purpose of this rule is not undermined. As stated above, the purpose of this action is to allocate quotas to sectors and to authorize vessels to fish under the sector operations plans during the 2017 fishing year. If the effectiveness of this action is delayed beyond the May 1, 2017, start of the fishing year, the 838 permits enrolled to fish in a sector in 2017 would either need to cease fishing on May 1 until this rule became effective, or forego fishing as part of a sector, including the associated regulatory exemptions, for the entirety of the fishing year and instead fish under the effort control regulations of the common pool. Preventing vessels from fishing under the provisions of an approved operations plan either for the whole year, or a portion of the year, would severely disrupt the sector fishery and have direct negative economic effects on the affected vessels.

This interim final rule does not contain policies with Federalism or ''takings'' implications as those terms are defined in E.O. 13132 and E.O. 12630, respectively.

This interim final rule is exempt from the procedures of the Regulatory Flexibility Act because the rule is issued without opportunity for prior notice and opportunity for public comment.

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

Dated: April 25, 2017.

Alan D. Risenhoover,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–08617 Filed 4–27–17; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 150630567–7360–02]

RIN 0648–BF26

Magnuson-Stevens Fishery Conservation and Management Act Provisions; Fisheries of the Northeastern United States; Northeast Groundfish Fishery; Amendment 18

Correction

In rule document 2017–8035 beginning on page 18706 in the issue of Friday, April 21, 2017, make the following correction:

On page 18713, in the first column, in the second paragraph, the first sentence should read ''This final rule contains a collection-of-information requirement subject to the Paperwork Reduction Act (PRA) and which has been approved by OMB under control number 0648–0752.''.

[FR Doc. C1–2017–08035 Filed 4–27–17; 8:45 am]

BILLING CODE 1301–00–D

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 161222999–7413–01]

RIN 0648–BG59

Fisheries Off West Coast States; West Coast Salmon Fisheries; 2017 Management Measures and a Temporary Rule

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

ACTION: Final rule; and a temporary rule for emergency action.

SUMMARY: Through this final rule, NMFS establishes fishery management measures for the 2017 ocean salmon fisheries off Washington, Oregon, and California and the 2018 salmon seasons opening earlier than May 1, 2018. The temporary rule for emergency action (emergency rule), under the Magnuson-Stevens Fishery Conservation and Management Act (MSA), implements the 2017 annual management measures for the West Coast ocean salmon fisheries for the area from the U.S./Canada border to Cape Falcon, OR, from May 1, 2017, through October 28, 2018. The emergency rule is required because allocation of coho harvest between recreational and commercial fisheries will not be consistent with the allocation schedule specified in the Pacific Coast Salmon Fishery Management Plan (FMP) in order to limit fishery impacts on Queets coho and meet conservation and management objectives. The fishery management measures for the area from Cape Falcon, OR, to the U.S./Mexico border are consistent with the FMP and are implemented through a final rule. Specific fishery management measures vary by fishery and by area. The measures establish fishing areas, seasons, quotas, legal gear, recreational fishing days and catch limits, possession and landing restrictions, and minimum lengths for salmon taken in the U.S. exclusive economic zone (EEZ) (3–200 NM) off Washington, Oregon, and California. The management measures are intended to prevent overfishing and to apportion the ocean harvest equitably among treaty Indian, non-treaty commercial, and recreational fisheries. The measures are also intended to allow a portion of the salmon runs to escape the ocean fisheries in order to provide for spawning escapement and inside fisheries (fisheries occurring in state internal waters).

DATES: The final rule covering fisheries south of Cape Falcon, Oregon, is effective from 0001 hours Pacific Daylight Time, May 1, 2017, until the effective date of the 2018 management measures, which will be published in the **Federal Register**. The temporary rule covering fisheries north of Cape Falcon, Oregon, is effective from 0001 hours Pacific Daylight Time, May 1, 2017, through 2400 hours Pacific Daylight Time, October 28, 2017, or the attainment of the specific quotas listed below in section two of this rule.

ADDRESSES: The documents cited in this document are available on the Pacific Fishery Management Council's (Council's) Web site (*www.pcouncil.org*).

FOR FURTHER INFORMATION CONTACT: Peggy Mundy at 206–526–4323.

SUPPLEMENTARY INFORMATION:

Background

The ocean salmon fisheries in the EEZ off Washington, Oregon, and California are managed under a ''framework'' FMP. Regulations at 50 CFR part 660, subpart H, provide the mechanism for making preseason and inseason adjustments to the management measures, within limits set by the FMP, by notification in the **Federal Register**. Establishing annual management measures is authorized at 50 CFR 660.408.

The management measures for the 2017 and pre-May 2018 ocean salmon fisheries that are implemented in this final rule were recommended by the Council at its April 6 to 11, 2017, meeting.

Process Used To Establish 2017 Management Measures

The Council announced its annual preseason management process for the 2017 ocean salmon fisheries in the **Federal Register** on December 28, 2016 (81 FR 95568), and on the Council's Web site at (*www.pcouncil.org*). NMFS published an additional notice of opportunities to submit public comments on the 2017 ocean salmon fisheries in the **Federal Register** on January 17, 2017 (82 FR 4859). These notices announced the availability of Council documents, the dates and locations of Council meetings and public hearings comprising the Council's complete schedule of events for determining the annual proposed and final modifications to ocean salmon fishery management measures, and instructions on how to comment on the development of the 2017 ocean salmon fisheries. The agendas for the March and April Council meetings were published in the **Federal Register** (82 FR 10881, February 16, 2017, and 82 FR 14353, March 20, 2017, respectively) and posted on the Council's Web site prior to the actual meetings.

In accordance with the FMP, the Council's Salmon Technical Team (STT) and staff economist prepared four reports for the Council, its advisors, and the public. All four reports were made available on the Council's Web site upon their completion. The first of the reports, ''Review of 2016 Ocean Salmon Fisheries,'' was prepared in February when the scientific information necessary for crafting management measures for the 2017 and pre-May 2018 ocean salmon fisheries first became available. The first report summarizes biological and socio-economic data for the 2016 ocean salmon fisheries and assesses how well the Council's 2016 management objectives were met. The second report, ''Preseason Report I Stock Abundance Analysis and Environmental Assessment Part 1 for 2017 Ocean Salmon Fishery Regulations'' (PRE I), provides the 2017 salmon stock abundance projections and analyzes the impacts on the stocks and Council management goals if the 2016 regulations and regulatory procedures were applied to the projected 2017 stock abundances. The completion of PRE I is the initial step in developing and evaluating the full suite of preseason alternatives.

Following completion of the first two reports, the Council met in Vancouver, WA, from March 7 to 13, 2017, to develop 2017 management alternatives for proposal to the public. The Council proposed three alternatives for commercial and recreational fisheries management for analysis and public comment. These alternatives consisted of various combinations of management measures designed to protect weak stocks of coho and Chinook salmon, and to provide for ocean harvests of more abundant stocks. After the March Council meeting, the Council's STT and staff economist prepared a third report, ''Preseason Report II Proposed Alternatives and Environmental Assessment Part 2 for 2017 Ocean Salmon Fishery Regulations'' (PRE II), which analyzes the effects of the proposed 2017 management alternatives.

Public hearings, sponsored by the Council, to receive testimony on the proposed alternatives were held on March 27, 2017, in Westport, WA, and Coos Bay, OR; and on March 28, 2017, in Fort Bragg, CA. The States of Washington, Oregon, and California

sponsored meetings in various fora that also collected public testimony, which was then presented to the Council by each state's Council representative. The Council also received public testimony at both the March and April meetings and received written comments at the Council office.

The Council met from April 6 to 11, 2017, in Vancouver, WA, to adopt its final 2017 salmon management recommendations. Following the April Council meeting, the Council's STT and staff economist prepared a fourth report, ''Preseason Report III Analysis of Council-Adopted Management Measures for 2017 Ocean Salmon Fisheries'' (PRE III), which analyzes the environmental and socio-economic effects of the Council's final recommendations. After the Council took final action on the annual ocean salmon specifications in April, it transmitted the recommended management measures to NMFS, published them in its newsletter, and also posted them on the Council Web site (*www.pcouncil.org*).

National Environmental Policy Act (NEPA)

The environmental assessment (EA) for this action comprises the Council's documents described above (PRE I, PRE II, and PRE III), providing analysis of environmental and socioeconomic effects under NEPA. The EA and its related Finding of No Significant Impact (FONSI) are posted on the NMFS West Coast Region Web site (*www.westcoast.fisheries.noaa.gov*).

Resource Status

Stocks of Concern

The FMP requires that the fisheries be shaped to meet escapement-based Annual Catch Limits (ACLs), Endangered Species Act (ESA) consultation requirements, obligations of the Pacific Salmon Treaty (PST) between the U.S. and Canada, and other conservation objectives detailed in the FMP. Because the ocean salmon fisheries are mixed-stock fisheries, this requires ''weak stock'' management to avoid exceeding limits for the stocks with the most constraining limits. Abundance forecasts for individual salmon stocks can vary significantly from one year to the next; therefore, the stocks that constrain the fishery in one year may differ from those that constrain the fishery in the next. For 2017, limits for three stocks are the most constraining on the fisheries; these are described below.

Fisheries south of Cape Falcon, OR, are limited in 2017 primarily by the low abundance forecast of Klamath River fall Chinook salmon (KRFC) and concern for the status of ESA-listed Sacramento River winter Chinook salmon (SRWC). Fisheries north of Cape Falcon are limited primarily by the low abundance forecast for Queets coho. The limitations imposed in order to protect these stocks are described below. The alternatives and the Council's recommended management measures for 2017 were designed to avoid exceeding these limitations.

Sacramento River winter Chinook salmon (SRWC): In 2010, NMFS consulted under ESA section 7 and provided guidance to the Council regarding the effects of Council area fisheries on SRWC, ESA-listed as endangered. NMFS completed a biological opinion that includes a reasonable and prudent alternative (RPA) to avoid jeopardizing the continued existence of this evolutionarily significant unit (ESU). The RPA included management-area-specific fishing season openings and closures, and minimum size limits for both commercial and recreational fisheries. It also directed NMFS to develop a second component to the RPA—an abundance-based management (ABM) framework. In 2012, NMFS implemented this ABM framework, which supplements the above management restrictions with maximum allowable impact rates that apply when abundance is low, based on the three-year geometric mean spawning escapement of SRWC. Using the methodology specified in the ABM framework, the age-3 impact rate on SRWC in 2017 fisheries south of Point Arena recommended by NMFS would be limited to a maximum of 15.8 percent. At the start of the preseason planning process for the 2017 management season, NMFS provided a letter to the Council, dated March 3, 2017, summarizing limits to impacts on ESA-listed species for 2017, based on existing biological opinions and 2017 abundance information, as required by the Salmon FMP. The letter stated the 15.8 percent maximum impact rate on SRWC.

However, as in 2016, the Council expressed concern that the methodology used to recommend that impact rate is retrospective in nature and may not be responsive to the effects of recent environmental events on salmon survival and productivity, including the perilously high mortality rates of out-migrating SRWC smolts in recent years due to warm water conditions caused by drought in California. Estimates of juvenile SRWC passage at Red Bluff Diversion Dam on the Sacramento River indicate that, while 2016 brood year outmigration was slightly higher than the previous two brood years, juvenile abundance remains about one-third the 2007–2015 average. The Council has formed a workgroup to develop new scientific methodology to incorporate information about future SRWC abundance into fishery management; however, that new methodology is not yet available. For 2017, the Council recommended precautionary management measures including time and area restrictions based on data presented by the California Department of Fish and Wildlife (CDFW) regarding SRWC encounters in the fishery resulting in an impact rate for SRWC of 12.2 percent. Conservation measures for SRWC will constrain 2017 salmon fisheries south of Point Arena, California.

Klamath River fall Chinook salmon (KRFC): KRFC is not an ESA-listed stock; however, forecast abundance for this stock in 2017 is historically low, only 30 percent of the 2016 forecast. KRFC currently meets the FMP's status determination criteria (SDC) for approaching an overfished condition based on escapements in 2015 and 2016, coupled with the projected escapement in 2017. The FMP defines ''overfished'' status in terms of a three-year geometric mean escapement level and whether it is above the minimum stock sized threshold (MSST). Based on preliminary information, it is possible that KRFC will be determined to have a three-year geometric mean escapement level below MSST once post-season escapement estimates are available, and meet the definition of ''overfished'' in 2018, but, given the minimal impacts of Council-area fisheries on KRFC, this is the case whether or not there are any fishery impacts.

The FMP's harvest control rule for this stock allows for minimal levels of impact at very low abundance levels. Given the forecast abundance of KRFC for 2017, the control rule limits impacts on the stock to 8.1 percent. Fisheries south of Cape Falcon and north of Point Sur will be constrained by this limit. The FMP specifies a set of circumstances that the Council should consider in applying the control rule at very low abundance levels: Critically low spawner abundance that may affect crucial genetic thresholds of substocks, spawner abundance in recent years, status of co-mingled stocks, marine and freshwater environmental conditions, needs for tribal fisheries, whether the stock is currently in an approaching overfished condition, and whether the stock is currently overfished. The Council and its advisors discussed these

circumstances. The risk for substocks to fall below crucial genetic thresholds in 2017 was expected to be substantial (greater than 80 percent) under either a no-fishing scenario or fishing at levels specified by the control rule level. In 2016, KRFC spawner escapement was well below both the level for maximum sustained yield (S_{MSY}) and minimum stock size threshold (MSST) specified in the FMP. Regarding the status of co-mingled stocks, the STT reported that the primary stocks that comingle with KRFC have relatively low forecast abundance for 2017. The Yurok and Hoopa Valley Tribes have reserved fishing rights and are dependent on salmon for their subsistence and culture. NMFS' Northwest and Southwest Fisheries Science Centers presented information indicating that the broods that will contribute to 2017 harvest and escapement encountered poor ocean conditions in the California Current Ecosystem. As stated above, KRFC currently meet the FMP SDC criteria for approaching an overfished condition; although NMFS has not yet made a determination. Finally, KRFC are not currently overfished. After consideration of these circumstances, the Council adopted the 8.1 percent impact rate, consistent with the KRFC control rule. The Council developed management measures that utilize time and area closures to minimize fishery impacts on KRFC: The Klamath Management Zone (KMZ), Humbug Mountain, OR south to Humboldt South Jetty, CA, will be closed for the entire year to both commercial and recreational fishing and the area from Florence South Jetty, OR south to Humbug Mountain will be closed to commercial fishing to provide an additional buffer; in California, there will be very little fishing opportunity in the Fort Bragg management area, specifically avoiding times when KRFC impacts are known to be high in that area; and, finally, CDFW will recommend to the California Fish and Game Commission that fall Chinook fishing in the Klamath River be closed in 2017. The combination of the KRFC and SRWC control rules will constrain fisheries severely in California in 2017.

Queets coho: Queets coho are not ESA-listed. However, the 2017 abundance forecast for this stock is very low; 6,548 fish compared to a 2009–2016 average of 18,700 fish. The FMP's conservation objective for Queets coho is a spawning escapement of 5,800 fish. Although the Council's recommended management measures would allow for an ocean escapement of 5,800 Queets coho, the conservation objective in the FMP is for a spawning escapement that accounts for in-river fishery impacts. The FMP provides flexibility in setting the annual spawning escapement for several Washington coho stocks, including Queets coho, provided there is agreement between the Washington Department of Fish and Wildlife (WDFW) and the treaty tribes, consistent with court orders in *U.S.* v *Washington.* Therefore, based on agreement between those parties and discussion on the Council floor that the reduced spawning escapement is unlikely to jeopardize the capacity of the fishery to produce maximum sustainable yield on a continuing basis, the Council adopted a 2017 spawning escapement target of 5,130 Queets coho to allow for limited harvest opportunity in ocean and in-river fisheries directed at other higher-abundance stocks. Additionally, under the criteria of the PST's Southern Coho Management Plan, Queets coho abundance is in the ''low'' category in 2017 and subject to a total exploitation rate of 20 percent. The state and treaty tribal co-managers relied on a provision in the PST to request that the Southern Panel of the Pacific Salmon Commission agree to permit a 22 percent exploitation rate on Queets coho in 2017 to allow the U.S. to meet fishery management objectives [(Pacific Salmon Treaty, Article XV, Annex IV, Chapter 5, paragraph 11(c)]. The Southern Panel did agree to this request. Managing for impacts to Queets coho will constrain salmon fisheries north of Cape Falcon, Oregon.

Annual Catch Limits and Status Determination Criteria

Annual Catch Limits (ACLs) are set for two Chinook salmon stocks, Sacramento River fall Chinook (SRFC) and KRFC, and one coho stock, Willapa Bay natural coho. The Chinook salmon stocks are indicator stocks for the Central Valley Fall Chinook complex and the Southern Oregon/Northern California Chinook complex, respectively. The Far North Migrating Coastal Chinook complex includes a group of Chinook salmon stocks that are caught primarily in fisheries north of Cape Falcon, Oregon, and other fisheries that occur north of the U.S./Canada border. No ACL is set for these stocks because they are managed according to the PST with Canada. Other Chinook salmon stocks caught in fisheries north of Cape Falcon are ESA-listed or hatchery produced, and are managed consistent with ESA consultations or hatchery goals. Willapa Bay natural coho is the only coho stock for which an ACL is set, as the other coho stocks in the FMP are either ESA-listed, hatchery produced, or managed under the PST.

ACLs for salmon stocks are escapement-based, which means they establish a number of adults that must escape the fisheries to return to the spawning grounds. ACLs are set based on the annual abundance projection and a fishing rate reduced to account for scientific uncertainty. For SRFC in 2017, the overfishing limit (OFL) is S_{OFL} = 230,700 (projected abundance) multiplied by $1 - F_{MSY}$ (1 − 0.78) or 50,754 returning spawners (F_{MSY} is the fishing mortality rate that would result in maximum sustainable yield − MSY). S_{ABC} is 230,700 multiplied by $1 - F_{ABC}$ (1 − 0.70) (F_{MSY} reduced for scientific uncertainty = 0.70) or 69,210. The S_{ACL} is set equal to $S_{ABC,}$ i.e, 69,210 spawners. The adopted management measures provide for an expected SRFC spawning escapement of 133,200. For KRFC in 2017, S_{OFL} is 12,383 (abundance projection) multiplied by $1 - F_{MSY}$ (1 − 0.71), or 3,591 returning spawners. S_{ABC} is 12,383 multiplied by $1 - F_{ABC}$ (1 − 0.68) (F_{MSY} reduced for scientific uncertainty = 0.68) or 3,963 returning spawners. S_{ACL} is set equal to S_{ABC}, *i.e.,* 3,963 spawners. The adopted management measures provide for an expected KRFC spawning escapement of 11,379. For Willapa Bay natural coho in 2017, the overfishing limit (OFL) is S_{OFL} = 36,720 (projected abundance) multiplied by $1 - F_{MSY}$ (1 − 0.74) or 9,547 returning spawners. S_{ABC} is 36,720 multiplied by $1 - F_{ABC}$ (1 − 0.70) (F_{MSY} reduced for scientific uncertainty = 0.70) or 11,016. S_{ACL} is set equal to S_{ABC}, *i.e.,* 11,016 spawners. The adopted management measures provide for an expected Willapa Bay natural coho ocean escapement of 34,400.

As explained in more detail above under ''Stocks of Concern,'' fisheries north and south of Cape Falcon, are constrained by impact limits necessary to protect ESA-listed salmon stocks including SRWC and KRFC and Queets coho which are not ESA-listed. For 2017, projected abundance of the three stocks with ACLs (SRFC, KRFC, and Willapa Bay natural coho), in combination with the constraints for ESA-listed and non-ESA-listed stocks, are expected to result in escapements greater than required to meet the ACLs for all three stocks with defined ACLs.

Emergency Rule

The Council's final recommendation for the ocean salmon fishing seasons that commence May 1, 2017, deviates from the FMP specifically with regard to the FMP's allocation schedule for coho harvest in the area north of Cape Falcon, between commercial and recreational

fisheries. The total allowable catch (TAC) of coho in non-treaty commercial and recreational fisheries north of Cape Falcon is 47,600 marked coho in 2017. At that TAC level, the FMP allocates 25 percent (16 percent marked coho equivalent) of coho to the commercial fishery and 75 percent (84 percent marked coho equivalent) of coho to the recreational fishery. To limit fishery impacts on coho consistent with the adopted spawning escapement and exploitation rates described above, the Council recommended the following allocations of marked coho TAC: 12 percent commercial and 88 percent recreational. Recreational fisheries are more dependent on coho, while commercial fisheries are more dependent on Chinook salmon. Additionally, in mark-selective fisheries, recreational fisheries have a lower impact rate due to lower hooking mortality. This deviation from the FMP allocation schedule should provide fishing opportunity on abundant stocks while limiting fishery impacts on Queets coho.

The Council considered three alternative fishery management schemes for the fisheries north of Cape Falcon; two of the three alternatives were inconsistent with the FMP coho allocation schedule. Alternative I would have limited the commercial fishery to nine percent of the north of Falcon coho TAC, inconsistent with the FMP allocation schedule between commercial and recreational fisheries; Alternative II would have been consistent with the FMP coho allocation schedule; and Alternative III would have prohibited coho retention in the non-treaty commercial fishery north of Cape Falcon and would have restricted coho retention in the recreational fishery to the area south of Leadbetter Point, WA, this would be inconsistent with the FMP allocation schedule between commercial and recreational fisheries and among recreational fishery subareas. The Council's state and tribal representatives, and industry advisory committee, supported consideration of these three alternatives. The Council's final recommended management measures fall between the second and third alternatives in terms of impacts to coho. These management measures reflect agreement between the State of Washington and coastal treaty tribes on spawning escapement and exploitation rate goals on Queets coho for combined ocean fisheries and fisheries landward of the EEZ; the projected impacts of the combined fisheries are managed such that Queets coho meets these escapement and exploitation rate goals. The Council voted unanimously to adopt these measures, and members spoke about the need to conserve Queets coho while providing harvest opportunity on abundant stocks to provide economic benefit to fishery dependent communities.

The proposed fisheries have minimal impacts on Queets coho and are not expected to jeopardize the capacity of the fishery to produce maximum sustainable yield on a continuing basis. The FMP defines overfishing and overfished status for this stock. Queets would not be subject to overfishing under the proposed management measures, in fact the overfishing limits in the FMP are much higher than the expected impact rates (65 percent MFMT compared to a 22 percent projected impact rate). Queets coho currently meet the FMP's SDC for approaching an overfished condition based on escapements in 2014 and 2015, coupled with the projected escapement in 2017. Escapements in 2016 are not available but are reported to have been much higher than anticipated during the 2016 preseason process. Based on preliminary information, it is possible that Queets coho will have a three-year geometric mean escapement level below MSST, and meet the definition of ''overfished'' in 2018, but, given the minimal impacts of Council-area fisheries on Queets coho, this is the case whether or not there are any fishery impacts. The marginal decreases in the abundance of Queets coho expected from the proposed fisheries (approximately 267 fish out of the forecasted abundance of 6,548 fish may be taken by the proposed fisheries) are not expected to affect the ability of the fisheries to produce MSY on a continuing basis.

The temporary rule for emergency action implements the 2017 annual management measures for the West Coast ocean salmon fisheries for the area from the U.S./Canada border to Cape Falcon, OR, for 180 days, from May 1, 2017, through October 28, 2017 (16 U.S.C. 1855(c)).

Public Comments

The Council invited written comments on developing 2017 salmon management measures in their notice announcing public meetings and hearings (81 FR 95568, December 28, 2016). At its March meeting, the Council adopted three alternatives for 2017 salmon management measures having a range of quotas, season structure, and impacts, from the least restrictive in Alternative I to the most restrictive in Alternative III. These alternatives are described in detail in PRE II. Subsequently, comments were taken at three public hearings held in March, staffed by representatives of the Council and NMFS. The Council received several written comments directly. The three public hearings were attended by a total of 154 people; 34 people provided oral comments. Comments came from individual fishers, fishing associations, fish buyers, and processors. Written and oral comments addressed the 2017 management alternatives described in PRE II, and generally expressed preferences for a specific alternative or for particular season structures. All comments were included in the Council's briefing book for their April 2017 meeting and were considered by the Council, which includes a representative from NMFS, in developing the recommended management measures transmitted to NMFS on April 20, 2017. In addition to comments collected at the public hearings and those submitted directly to the Council, a few people provided oral comments at the April 2017 Council meeting. NMFS also invited comments to be submitted directly to the Council or to NMFS, via the Federal Rulemaking Portal (*www.regulations.gov*) in a notice (82 FR 4859, January 17, 2017). No comments were submitted via *www.regulations.gov.*

Comments on alternatives for fisheries north of Cape Falcon. For fisheries north of Cape Falcon, Alternative I was favored by most commercial and recreational fishery commenters at the public hearing in Westport, WA. A variety of modifications to the alternatives were presented, most designed to maximize fishing opportunity in both commercial and recreational fisheries.

Comments on alternatives for fisheries south of Cape Falcon. Comments supporting a particular alternative south of Cape Falcon varied with geographic location of the meeting or commenter. Those attending the meeting in Coos Bay, OR, largely favored Alternative I for both commercial and recreational fisheries, while those attending the meeting in Fort Bragg, CA, expressed overwhelming support for Alternative III. The Council received a large number of emailed comments from members of a recreational fishing club in California who favored Alternative I. Comments included concern for Klamath and Sacramento River salmon and various environmental and management concerns that affect them.

Comments on incidental halibut retention in the commercial salmon fisheries. At its March meeting, the Council identified three alternatives for landing limits for incidentally caught

halibut that are retained in the salmon troll fishery. There were a few comments received on halibut and these focused on the ability to access the full halibut allocation (severely constrained salmon fisheries in 2016 resulted in the commercial fleet being unable to access all of the incidental halibut allocation available).

Comments from treaty tribe representatives. At its March and April meetings, the Council heard testimony from members of several treaty tribes; additional comments were submitted in writing. There was strong concern about environmental conditions in the Klamath River that are deleterious to salmon survival, including promoting increased rates of infection by the parasite *Ceratonova shasta.* Comments were made on the need for sufficient spawning escapement in the Columbia River Basin and in support of successful artificial propagation and reintroduction efforts implemented there by the tribes. Comments were made on the reserved treaty rights of tribes to fish and frustration with insufficient salmon for tribal needs. Finally, there were written comments expressing concern over the low abundance of coho salmon in Puget Sound rivers and stressing the need to limit fisheries to provide spawning escapement.

The Council, including the NMFS representative, took all of these comments into consideration. The Council's final recommendation generally includes aspects of all three alternatives, while taking into account the best available scientific information and ensuring that fisheries are consistent with ESA consultation standards, ACLs, PST obligations, and tribal fishing rights. These management tools assist the Council in meeting impact limits on weak stocks. The Council adopted alternative III for incidental halibut retention, this alternative provides for more liberal landing limits for halibut than were adopted for 2016 salmon fisheries and April 2017 salmon fisheries (81 FR 26157, May 2, 2016).

Management Measures for 2017 Fisheries

The Council's recommended ocean harvest levels and management measures for the 2017 fisheries are designed to apportion the burden of protecting the weak stocks identified and discussed in PRE I equitably among ocean fisheries and to allow maximum harvest of natural and hatchery runs surplus to inside fishery and spawning needs. NMFS finds the Council's recommendations to be responsive to the goals of the FMP, the requirements of the resource, and the socioeconomic factors affecting resource users. The recommendations are consistent with the requirements of the MSA, U.S. obligations to Indian tribes with federally recognized fishing rights, and U.S. international obligations regarding Pacific salmon. The Council's recommended management measures also comply with NMFS ESA consultation standards and guidance, for those ESA-listed salmon species that may be affected by Council fisheries. Accordingly, NMFS, through this final rule and temporary rule, approves and implements the Council's recommendations.

North of Cape Falcon, 2017 management measures for non-Indian commercial troll and recreational fisheries have increased quotas for Chinook and coho salmon compared to 2016, when historically low abundance for several coho stocks severely constrained fisheries. North of Cape Falcon in 2017, commercial and recreational fisheries will have access to coho salmon in all management areas. Chinook harvest north of Cape Falcon will be moderately improved over the 2016 level for both commercial and recreational fisheries.

Quotas for the 2017 treaty-Indian commercial troll fishery North of Cape Falcon 2017 are 40,000 Chinook salmon and 12,500 coho in ocean management areas and Washington State Statistical Area 4B combined. These quotas are unchanged for Chinook from 2016 and allow coho retention which was not available in 2016. The treaty-Indian fishery commercial fisheries include a May and June fishery and a July and August fishery, with a quota of 20,000 Chinook in each fishery and 12,500 coho in the July and August fishery. Although the fishing opportunity North of Cape Falcon is better than in 2016, fisheries are reduced significantly compared to those implemented over the last ten years.

Recreational fisheries south of Cape Falcon will be directed primarily at Chinook salmon and are shaped to minimize impacts to KRFC, with opportunity for coho salmon limited to the area between Cape Falcon and Humbug Mountain, OR. Commercial fisheries south of Cape Falcon will be directed at Chinook in the areas north of the Florence South Jetty in Oregon and south of Horse Mountain in California and have no coho retention.

Management Measures for 2018 Fisheries

The timing of the March and April Council meetings makes it impracticable for the Council to recommend fishing seasons that begin before May 1 of the same year. Therefore, this action also establishes the 2018 fishing seasons that open earlier than May 1. The Council recommended, and NMFS concurs, that the commercial season off Oregon from Cape Falcon to the Oregon/California border, the commercial season off California from Horse Mountain to Point Arena, the recreational season off Oregon from Cape Falcon to Humbug Mountain, and the recreational season off California from Horse Mountain to the U.S./Mexico border will open in 2018 as indicated in the ''Season Description'' section of this document. At the March 2018 meeting, the Council may consider inseason recommendations to adjust the commercial and recreational seasons prior to May 1 in the areas off Oregon and California.

The following sections set out the management regime for the ocean salmon fishery. Open seasons and days are described in Sections 1, 2, and 3 of the 2017 management measures. Inseason closures in the commercial and recreational fisheries are announced on the NMFS hotline and through the U.S. Coast Guard (USCG) Notice to Mariners as described in Section 6. Other inseason adjustments to management measures are also announced on the hotline and through the Notice to Mariners. Inseason actions will also be published in the **Federal Register** as soon as practicable.

The following are the management measures recommended by the Council and approved and implemented here for 2017 and, as specified, for 2018.

Section 1. Commercial Management Measures for 2017 Ocean Salmon Fisheries

Parts A, B, and C of this section contain restrictions that must be followed for lawful participation in the fishery. Part A identifies each fishing area and provides the geographic boundaries from north to south, the open seasons for the area, the salmon species allowed to be caught during the seasons, and any other special restrictions effective in the area. Part B specifies minimum size limits. Part C specifies special requirements, definitions, restrictions, and exceptions.

A. Season Description

North of Cape Falcon, OR

—U.S./Canada border to Cape Falcon

May 1 through the earlier of June 30 or 27,000 Chinook, no more than 8,900 of which may be caught in the area between the U.S./Canada border and the Queets River and no more than 9,000 of

which may be caught in the area between Leadbetter Point and Cape Falcon (C.8). In the area between the U.S./Canada border and the Queets River, a landing and possession limit of 60 Chinook per vessel per calendar week (Monday through Sunday) will be in place. Seven days per week (C.1). All salmon except coho (C.4, C.7). Chinook minimum size limit of 28 inches total length (B). Vessels in possession of salmon north of the Queets River may not cross the Queets River line (see Section 5. Geographical Landmarks) without first notifying WDFW at 360–249–1215 with area fished, total Chinook and halibut catch aboard, and destination. Vessels in possession of salmon south of the Queets River may not cross the Queets River line (see Section 5. Geographical Landmarks) without first notifying WDFW at 360–249–1215 with area fished, total Chinook and halibut catch aboard, and destination. When it is projected that approximately 75 percent of the overall Chinook guideline has been landed, or approximately 75 percent of the Chinook subarea guideline has been landed in the area between the U.S./Canada border and the Queets River, or approximately 75 percent of the Chinook subarea guideline has been landed in the area between Leadbetter Point and Cape Falcon, inseason action will be considered to ensure the guideline is not exceeded. See compliance requirements (C.1) and gear restrictions and definitions (C.2, C.3).

July 1–4, July 7–September 19 or 18,000 Chinook or 5,600 coho, whichever comes first; no more than 7,200 Chinook may be caught in the area between the U.S./Canada border and the Queets River (C.8). Open five days per week, Friday through Tuesday. In the area between the U.S./Canada border and the Queets River, a landing and possession limit of 60 Chinook and 10 coho per vessel per open period will be in place (C.1, C.6). In the area from the Queets River to Cape Falcon, a landing and possession limit of 75 Chinook and 10 coho per vessel per open period will be in place (C.1, C.6). Chinook minimum size limit of 28 inches total length. Coho minimum size limit of 16 inches total length (B, C.1). All coho must be marked with a healed adipose fin clip (C.8.c). No chum retention north of Cape Alava, WA in August and September (C.4, C.7). See compliance requirements (C.1) and gear restrictions and definitions (C.2, C.3). Vessels in possession of salmon north of the Queets River may not cross the Queets River line (see Section 5. Geographical Landmarks) without first notifying WDFW at 360–249–1215 with area fished, total Chinook and halibut catch aboard, and destination. Vessels in possession of salmon south of the Queets River may not cross the Queets River line (see Section 5. Geographical Landmarks) without first notifying WDFW at 360–249–1215 with area fished, total Chinook and halibut catch aboard, and destination. When it is projected that approximately 75 percent of the overall Chinook guideline has been landed, or approximately 75 percent of the Chinook subarea guideline has been landed in the area between the U.S./Canada border to the Queets River, inseason action will be considered to ensure the guideline is not exceeded.

For all commercial troll fisheries north of Cape Falcon, mandatory closed areas include: Salmon Troll Yelloweye Rockfish Conservation Area, Cape Flattery and Columbia Control Zones, and, beginning August 14, Grays Harbor Control Zone closed (C.5). Vessels must land and deliver their fish within 24 hours of any closure of this fishery. Vessels fishing or in possession of salmon while fishing north of Leadbetter Point must land and deliver their fish within the area and north of Leadbetter Point. Vessels fishing or in possession of salmon while fishing south of Leadbetter Point must land and deliver their fish within the area and south of Leadbetter Point, except that Oregon permitted vessels may also land their fish in Garibaldi, OR. Under state law, vessels must report their catch on a state fish receiving ticket. Oregon State regulations require all fishers landing salmon into Oregon from any fishery between Leadbetter Point, WA, and Cape Falcon, OR, must notify Oregon Department of Fish and Wildlife (ODFW) within one hour of delivery or prior to transport away from the port of landing by either calling 541–867–0300 ext. 271 or sending notification via email to *nfalcon.trollreport@state.or.us.* Notification shall include vessel name and number, number of salmon by species, port of landing and location of delivery, and estimated time of delivery. Inseason actions may modify harvest guidelines in later fisheries to achieve or prevent exceeding the overall allowable troll harvest impacts (C.8).

South of Cape Falcon, OR

—Cape Falcon to Florence South Jetty

April 15–May 31;
June 7–12, June 15–30, July 8–31;
September 1–30, October 1–31 (C.9.a).

Seven days per week. All salmon except coho (C.4, C.7). Chinook minimum size limit of 28 inches total length (B, C.1). All vessels fishing in the area must land their fish in the state of Oregon. See gear restrictions and definitions (C.2, C.3) and Oregon State regulations for a description of special regulations at the mouth of Tillamook Bay. Beginning September 1, no more than 45 Chinook per vessel per landing week (Thursday through Wednesday), and only open shoreward of the 40 fathom regulatory line (C.5.f).

In 2018, the season will open March 15 for all salmon except coho. Chinook minimum size limit of 28 inches total length (B, C.1). Gear restrictions same as in 2017 (C.2, C.3, C.4, C.6, C.7, C.8). This opening could be modified following Council review at its March 2018 meeting.

—Florence South Jetty to Humbug Mountain

Closed (C.9.a).

In 2018, the season will open March 15 for all salmon except coho. Chinook minimum size limit of 28 inches total length (B, C.1). Gear restrictions same as in 2017 (C.2, C.3, C.4, C.6, C.7, C.8). This opening could be modified following Council review at its March 2018 meeting.

—Humbug Mountain to Oregon/California border (Oregon Klamath Management Zone (KMZ))

Closed (C.9.a).

In 2018, the season will open March 15 for all salmon except coho. Chinook minimum size limit of 28 inches total length (B, C.1). Gear restrictions same as in 2017 (C.2, C.3, C.4, C.6, C.7, C.8). This opening could be modified following Council review at its March 2018 meeting.

—Oregon/California border to Humboldt South Jetty (California KMZ)

Closed (C.9.a).

—Humboldt South Jetty to Horse Mt.

Closed.

When the fishery is closed between the Oregon/California border and Humbug Mountain and open to the south, vessels with fish on board caught in the open area off California may seek temporary mooring in Brookings, OR prior to landing in California only if such vessels first notify the Chetco River Coast Guard Station via VHF channel 22A between the hours of 0500 and 2200 and provide the vessel name, number of fish on board, and estimated time of arrival (C.6).

—Horse Mt. to Point Arena (Fort Bragg)

September 1 through the earlier of September 30, or a 3,000 Chinook quota (C.9.b).

Five days per week, Friday through Tuesday. All salmon except coho (C.4, C.7). Chinook minimum size limit of 27

inches total length (B, C.1). Landing and possession limit of 60 Chinook per vessel per open period (C.8.e). All fish caught in this area must be landed between the Oregon/California border and Point Arena (C.6). All fish must be offloaded within 24 hours of any closure of the fishery and prior to fishing outside the area (C.1). See compliance requirements (C.1) and gear restrictions and definitions (C.2, C.3).

In 2018, the season will open April 16–30 for all salmon except coho, with a 27-inch Chinook minimum size limit and the same gear restrictions as in 2017. All fish caught in the area must be landed in the area. This opening could be modified following Council review at its March 2018 meeting.

—Point Arena to Pigeon Point (San Francisco)

August 1–29;

September 1–30 (C.9.b).

Seven days per week. All salmon except coho (C.4, C.7). Chinook minimum size limit of 27 inches total length prior to September 1, 26 inches thereafter (B, C.1). All fish must be landed in California. All salmon caught in California prior to September 1 must be landed and offloaded no later than 11:59 p.m., August 30 (C.6). In September, all fish must be landed south of Point Arena until the quota in the Fort Bragg fishery is met and the fishery has closed for 24 hours (C.6). See compliance requirements (C.1) and gear restrictions and definitions (C.2, C.3).

• Point Reyes to Point San Pedro (Fall Area Target Zone)

October 2–6 and 9–13.

Five days per week, Monday through Friday. All salmon except coho (C.4, C.7). Chinook minimum size limit of 26 inches total length (B, C.1). All fish caught in this area must be landed between Point Arena and Pigeon Point (C.6). See compliance requirements (C.1) and gear restrictions and definitions (C.2, C.3).

—Pigeon Point to U.S./Mexico border (Monterey)

May 1–31;

June 1–30 (C.9.b).

Seven days per week. All salmon except coho (C.4, C.7). Chinook minimum size limit of 27 inches total length (B, C.1). All fish must be landed in California. All salmon caught in California prior to September 1 must be landed and offloaded no later than 11:59 p.m., August 30 (C.6). See compliance requirements (C.1) and gear restrictions and definitions (C.2, C.3).

California State regulations require all salmon be made available to a CDFW representative for sampling immediately at port of landing. Any person in possession of a salmon with a missing adipose fin, upon request by an authorized agent or employee of the CDFW, shall immediately relinquish the head of the salmon to the state (California Fish and Game Code § 8226).

B. Minimum Size (Inches) (See C.1)

Area (when open)	Chinook		Coho		Pink
	Total length	Head-off	Total length	Head-off	
North of Cape Falcon, OR	28.0	21.5	16	12	None.
Cape Falcon to Humbug Mountain	28.0	21.5			None.
Humbug Mountain to OR/CA border					
OR/CA border to Humboldt South Jetty					
Horse Mountain to Point Arena	27.0	20.5			None.
Point Arena to Pigeon Point:					
Prior to September 1	27.0	20.5			None.
September 1 and thereafter	26.0	19.5			None.
Pigeon Point to U.S./Mexico border	27.0	20.5			None.

Metric equivalents: 28.0 in = 71.1 cm, 27.0 in = 68.6 cm, 26.0 in = 66.0 cm, 21.5 in = 54.6 cm, 20.5 in = 52.1 cm, 19.5 in = 49.5 cm, 16.0 in = 40.6 cm, and 12.0 in = 30.5 cm.

C. Requirements, Definitions, Restrictions, or Exceptions

C.1. Compliance With Minimum Size or Other Special Restrictions

All salmon on board a vessel must meet the minimum size, landing/possession limit, or other special requirements for the area being fished and the area in which they are landed if the area is open or has been closed less than 48 hours for that species of salmon. Salmon may be landed in an area that has been closed for a species of salmon more than 48 hours only if they meet the minimum size, landing/possession limit, or other special requirements for the area in which they were caught. Salmon may not be filleted prior to landing.

Any person who is required to report a salmon landing by applicable state law must include on the state landing receipt for that landing both the number and weight of salmon landed by species. States may require fish landing/receiving tickets be kept on board the vessel for 90 days or more after landing to account for all previous salmon landings.

C.2. Gear Restrictions

a. Salmon may be taken only by hook and line using single point, single shank, barbless hooks.

b. Cape Falcon, Oregon, to the Oregon/California border: No more than 4 spreads are allowed per line.

c. Oregon/California border to U.S./Mexico border: No more than 6 lines are allowed per vessel, and barbless circle hooks are required when fishing with bait by any means other than trolling.

C.3. Gear Definitions

Trolling defined: Fishing from a boat or floating device that is making way by means of a source of power, other than drifting by means of the prevailing water current or weather conditions.

Troll fishing gear defined: One or more lines that drag hooks behind a moving fishing vessel. In that portion of the fishery management area off Oregon and Washington, the line or lines must be affixed to the vessel and must not be intentionally disengaged from the vessel at any time during the fishing operation.

Spread defined: A single leader connected to an individual lure and/or bait.

Circle hook defined: A hook with a generally circular shape and a point which turns inward, pointing directly to the shank at a 90° angle.

C.4. Vessel Operation in Closed Areas With Salmon on Board

a. Except as provided under C.4.b below, it is unlawful for a vessel to have troll or recreational gear in the water while in any area closed to fishing for a certain species of salmon, while possessing that species of salmon; however, fishing for species other than salmon is not prohibited if the area is open for such species, and no salmon are in possession.

b. *When Genetic Stock Identification (GSI) samples will be collected in an area closed to commercial salmon fishing, the scientific research permit holder shall notify NOAA Office of Law Enforcement, USCG, CDFW, WDFW, and Oregon State Police at least 24 hours prior to sampling and provide the following information:* The vessel name, date, location and time collection activities will be done. Any vessel collecting GSI samples in a closed area shall not possess any salmon other than those from which GSI samples are being collected. Salmon caught for collection of GSI samples must be immediately released in good condition after collection of samples.

C.5. Control Zone Definitions

a. *Cape Flattery Control Zone*—The area from Cape Flattery (48°23′00″ N. lat.) to the northern boundary of the U.S. EEZ; and the area from Cape Flattery south to Cape Alava (48°10′00″ N. lat.) and east of 125°05′00″ W. long.

b. *Salmon Troll Yelloweye Rockfish Conservation Area (50 CFR 660.70(c))*—The area in Washington Marine Catch Area 3 from 48°00.00′ N. lat.; 125°14.00′ W. long. to 48°02.00′ N. lat.; 125°14.00′ W. long. to 48°02.00′ N. lat.; 125°16.50′ W. long. to 48°00.00′ N. lat.; 125°16.50′ W. long. and connecting back to 48°00.00′ N. lat.; 125°14.00′ W. long.

c. *Grays Harbor Control Zone*—The area defined by a line drawn from the Westport Lighthouse (46° 53′18″ N. lat., 124°07′01″ W. long.) to Buoy #2 (46°52′42″ N. lat., 124°12′42″ W. long.) to Buoy #3 (46°55′00″ N. lat., 124°14′48″ W. long.) to the Grays Harbor north jetty (46°55′36″ N. lat., 124°10′51″ W. long.).

d. *Columbia Control Zone*—An area at the Columbia River mouth, bounded on the west by a line running northeast/southwest between the red lighted Buoy #4 (46°13′35″ N. lat., 124°06′50″ W. long.) and the green lighted Buoy #7 (46°15′09″ N. lat., 124°06′16″ W. long.); on the east, by the Buoy #10 line which bears north/south at 357° true from the south jetty at 46°14′00″ N. lat., 124°03′07″ W. long. to its intersection with the north jetty; on the north, by a line running northeast/southwest between the green lighted Buoy #7 to the tip of the north jetty (46°15′48″ N. lat., 124°05′20″ W. long.), and then along the north jetty to the point of intersection with the Buoy #10 line; and, on the south, by a line running northeast/southwest between the red lighted Buoy #4 and tip of the south jetty (46°14′03″ N. lat., 124°04′05″ W. long.), and then along the south jetty to the point of intersection with the Buoy #10 line.

e. *Klamath Control Zone*—The ocean area at the Klamath River mouth bounded on the north by 41°38′48″ N. lat. (approximately 6 nautical miles north of the Klamath River mouth); on the west by 124°23′00″ W. long. (approximately 12 nautical miles off shore); and on the south by 41°26′48″ N. lat. (approximately 6 nautical miles south of the Klamath River mouth).

f. Waypoints for the 40 fathom regulatory line from Cape Falcon to Humbug Mountain (50 CFR 660.71(k)).

(12) 45°46.00′ N. lat., 124°04.49′ W. long.;
(13) 45°44.34′ N. lat., 124°05.09′ W. long.;
(14) 45°40.64′ N. lat., 124°04.90′ W. long.;
(15) 45°33.00′ N. lat., 124°04.46′ W. long.;
(16) 45°32.27′ N. lat., 124°04.74′ W. long.;
(17) 45°29.26′ N. lat., 124°04.22′ W. long.;
(18) 45°20.25′ N. lat., 124°04.67′ W. long.;
(19) 45°19.99′ N. lat., 124°04.62′ W. long.;
(20) 45°17.50′ N. lat., 124°04.91′ W. long.;
(21) 45°11.29′ N. lat., 124°05.20′ W. long.;
(22) 45°05.80′ N. lat., 124°05.40′ W. long.;
(23) 45°05.08′ N. lat., 124°05.93′ W. long.;
(24) 45°03.83′ N. lat., 124°06.47′ W. long.;
(25) 45°01.70′ N. lat., 124°06.53′ W. long.;
(26) 44°58.75′ N. lat., 124°07.14′ W. long.;
(27) 44°51.28′ N. lat., 124°10.21′ W. long.;
(28) 44°49.49′ N. lat., 124°10.90′ W. long.;
(29) 44°44.96′ N. lat., 124°14.39′ W. long.;
(30) 44°43.44′ N. lat., 124°14.78′ W. long.;
(31) 44°42.26′ N. lat., 124°13.81′ W. long.;
(32) 44°41.68′ N. lat., 124°15.38′ W. long.;
(33) 44°34.87′ N. lat., 124°15.80′ W. long.;
(34) 44°33.74′ N. lat., 124°14.44′ W. long.;
(35) 44°27.66′ N. lat., 124°16.99′ W. long.;
(36) 44°19.13′ N. lat., 124°19.22′ W. long.;
(37) 44°15.35′ N. lat., 124°17.38′ W. long.;
(38) 44°14.38′ N. lat., 124°17.78′ W. long.;
(39) 44°12.80′ N. lat., 124°17.18′ W. long.;
(40) 44°09.23′ N. lat., 124°15.96′ W. long.;
(41) 44°08.38′ N. lat., 124°16.79′ W. long.;
(42) 44°08.30′ N. lat., 124°16.75′ W. long.;
(43) 44°01.18′ N. lat., 124°15.42′ W. long.;
(44) 43°51.61′ N. lat., 124°14.68′ W. long.;
(45) 43°42.66′ N. lat., 124°15.46′ W. long.;
(46) 43°40.49′ N. lat., 124°15.74′ W. long.;
(47) 43°38.77′ N. lat., 124°15.64′ W. long.;
(48) 43°34.52′ N. lat., 124°16.73′ W. long.;
(49) 43°28.82′ N. lat., 124°19.52′ W. long.;
(50) 43°23.91′ N. lat., 124°24.28′ W. long.;
(51) 43°20.83′ N. lat., 124°26.63′ W. long.;
(52) 43°17.96′ N. lat., 124°28.81′ W. long.;
(53) 43°16.75′ N. lat., 124°28.42′ W. long.;
(54) 43°13.97′ N. lat., 124°31.99′ W. long.;
(55) 43°13.72′ N. lat., 124°33.25′ W. long.;
(56) 43°12.26′ N. lat., 124°34.16′ W. long.;
(57) 43°10.96′ N. lat., 124°32.33′ W. long.;
(58) 43°05.65′ N. lat., 124°31.52′ W. long.;
(59) 42°59.66′ N. lat., 124°32.58′ W. long.;
(60) 42°54.97′ N. lat., 124°36.99′ W. long.;
(61) 42°53.81′ N. lat., 124°38.57′ W. long.;
(62) 42°50.00′ N. lat., 124°39.68′ W. long.;
(63) 42°49.13′ N. lat., 124°39.70′ W. long.;
(64) 42°46.47′ N. lat., 124°38.89′ W. long.;
(65) 42°45.74′ N. lat., 124°38.86′ W. long.;
(66) 42°44.79′ N. lat., 124°37.96′ W. long.;
(67) 42°45.01′ N. lat., 124°36.39′ W. long.;
(68) 42°44.14′ N. lat., 124°35.17′ W. long.;
(69) 42°42.14′ N. lat., 124°32.82′ W. long.;
(70) 42°40.50′ N. lat., 124°31.98′ W. long.

C.6. Notification When Unsafe Conditions Prevent Compliance With Regulations

If prevented by unsafe weather conditions or mechanical problems from meeting special management area

landing restrictions, vessels must notify the U.S. Coast Guard and receive acknowledgment of such notification prior to leaving the area. This notification shall include the name of the vessel, port where delivery will be made, approximate amount of salmon (by species) on board, the estimated time of arrival, and the specific reason the vessel is not able to meet special management area landing restrictions.

In addition to contacting the U.S. Coast Guard, vessels fishing south of the Oregon/California border must notify CDFW within one hour of leaving the management area by calling 800–889–8346 and providing the same information as reported to the U.S. Coast Guard. All salmon must be offloaded within 24 hours of reaching port.

C.7. Incidental Halibut Harvest

During authorized periods, the operator of a vessel that has been issued an incidental halibut harvest license by the International Pacific Halibut Commission (IPHC) may retain Pacific halibut caught incidentally in Area 2A while trolling for salmon. Halibut retained must be no less than 32 inches in total length, measured from the tip of the lower jaw with the mouth closed to the extreme end of the middle of the tail, and must be landed with the head on. When halibut are caught and landed incidental to commercial salmon fishing by an IPHC license holder, any person who is required to report the salmon landing by applicable state law must include on the state landing receipt for that landing both the number of halibut landed, and the total dressed, head-on weight of halibut landed, in pounds, as well as the number and species of salmon landed.

License applications for incidental harvest must be obtained from the IPHC (phone: 206–634–1838). Applicants must apply prior to mid-March 2018 for 2018 permits (exact date to be set by the IPHC in early 2018). Incidental harvest is authorized only during April, May, and June of the 2017 troll seasons and after June 30 in 2017 if quota remains and if announced on the NMFS hotline (phone: 800–662–9825 or 206–526–6667). WDFW, ODFW, and CDFW will monitor landings. If the landings are projected to exceed the IPHC's 39,810 pound preseason allocation or the total Area 2A non-Indian commercial halibut allocation, NMFS will take inseason action to prohibit retention of halibut in the non-Indian salmon troll fishery.

May 1, 2017, through December 31, 2017, and April 1–30, 2018, license holders may land or possess no more than one Pacific halibut per each two Chinook, except one Pacific halibut may be possessed or landed without meeting the ratio requirement, and no more than 35 halibut may be possessed or landed per trip. Pacific halibut retained must be no less than 32 inches in total length (with head on). IPHC license holders must comply with all applicable IPHC regulations.

Incidental Pacific halibut catch regulations in the commercial salmon troll fishery adopted for 2017, prior to any 2017 inseason action, will be in effect when incidental Pacific halibut retention opens on April 1, 2018 unless otherwise modified by inseason action at the March 2018 Council meeting.

a. ''C-shaped'' yelloweye rockfish conservation area is an area to be voluntarily avoided for salmon trolling. NMFS and the Council request salmon trollers voluntarily avoid this area in order to protect yelloweye rockfish. The area is defined in the Pacific Council Halibut Catch Sharing Plan in the North Coast subarea (Washington marine area 3), with the following coordinates in the order listed:

48°18′ N. lat.; 125°18′ W. long.;
48°18′ N. lat.; 124°59′ W. long.;
48°11′ N. lat.; 124°59′ W. long.;
48°11′ N. lat.; 125°11′ W. long.;
48°04′ N. lat.; 125°11′ W. long.;
48°04′ N. lat.; 124°59′ W. long.;
48°00′ N. lat.; 124°59′ W. long.;
48°00′ N. lat.; 125°18′ W. long.;
and connecting back to 48°18′ N. lat.;
125°18′ W. long.

C.8. Inseason Management

In addition to standard inseason actions or modifications already noted under the season description, the following inseason guidance applies:

a. Chinook remaining from the May through June non-Indian commercial troll harvest guideline north of Cape Falcon may be transferred to the July through September harvest guideline if the transfer would not result in exceeding preseason impact expectations on any stocks.

b. NMFS may transfer fish between the recreational and commercial fisheries north of Cape Falcon if there is agreement among the areas' representatives on the Salmon Advisory Subpanel (SAS), and if the transfer would not result in exceeding preseason impact expectations on any stocks.

c. At the March 2018 meeting, the Council will consider inseason recommendations for special regulations for any experimental fisheries (proposals must meet Council protocol and be received in November 2017).

d. If retention of unmarked coho is permitted by inseason action, the allowable coho quota will be adjusted to ensure preseason projected impacts on all stocks is not exceeded.

e. Landing limits may be modified inseason to sustain season length and keep harvest within overall quotas.

C.9. State Waters Fisheries

Consistent with Council management objectives:

a. The State of Oregon may establish additional late-season fisheries in state waters.

b. The State of California may establish limited fisheries in selected state waters.

Check state regulations for details.

C.10. For the Purposes of California Fish and Game Code, Section 8232.5, the Definition of the KMZ for the Ocean Salmon Season Shall be That Area From Humbug Mountain, Oregon, to Horse Mountain, California

Section 2. Recreational Management Measures for 2017 Ocean Salmon Fisheries

Parts A, B, and C of this section contain restrictions that must be followed for lawful participation in the fishery. Part A identifies each fishing area and provides the geographic boundaries from north to south, the open seasons for the area, the salmon species allowed to be caught during the seasons, and any other special restrictions effective in the area. Part B specifies minimum size limits. Part C specifies special requirements, definitions, restrictions and exceptions.

A. Season Description

North of Cape Falcon, OR

—U.S./Canada border to Cape Alava (Neah Bay Subarea)

June 24 through earlier of September 4 or 4,370 marked coho subarea quota with a subarea guideline of 7,900 Chinook (C.5).

Seven days per week. All salmon, except no chum beginning August 1; two fish per day. All coho must be marked with a healed adipose fin clip (C.1). Beginning August 1, Chinook non-retention east of the Bonilla-Tatoosh line (C.4.a) during Council managed ocean fishery. See gear restrictions and definitions (C.2, C.3). Inseason management may be used to sustain season length and keep harvest within the overall Chinook and coho recreational TACs for north of Cape Falcon (C.5).

—Cape Alava to Queets River (La Push Subarea)

June 24 through earlier of September 4 or 1,090 marked coho subarea quota with a subarea guideline of 2,500 Chinook (C.5).

Seven days per week. All salmon, two fish per day. All coho must be marked with a healed adipose fin clip. See gear restrictions and definitions (C.2, C.3). Inseason management may be used to sustain season length and keep harvest within the overall Chinook and coho recreational TACs for north of Cape Falcon (C.5).

—Queets River to Leadbetter Point (Westport Subarea)

July 1 through earlier of September 4 or 15,540 marked coho subarea quota with a subarea guideline of 21,400 Chinook (C.5).

Seven days per week. All salmon; two fish per day, no more than one of which can be a Chinook. All coho must be marked with a healed adipose fin clip (C.1). See gear restrictions and definitions (C.2, C.3). Grays Harbor Control Zone closed beginning August 14 (C.4.b). Inseason management may be used to sustain season length and keep harvest within the overall Chinook and coho recreational TACs for north of Cape Falcon (C.5).

—Leadbetter Point to Cape Falcon (Columbia River Subarea)

June 24 through earlier of September 4 or 21,000 marked coho subarea quota with a subarea guideline of 13,200 Chinook (C.5).

Seven days per week. All salmon; two fish per day, no more than one of which can be a Chinook. All coho must be marked with a healed adipose fin clip (C.1). See gear restrictions and definitions (C.2, C.3). Columbia Control Zone closed (C.4.c). Inseason management may be used to sustain season length and keep harvest within the overall Chinook and coho recreational TACs for north of Cape Falcon (C.5).

South of Cape Falcon, OR

—Cape Falcon to Humbug Mountain.

March 15 through October 31 (C.6), except as provided below during the all-salmon mark-selective and September non-mark-selective coho fisheries.

Seven days per week. All salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length (B). See gear restrictions and definitions (C.2, C.3).

• Non-mark-selective coho fishery: September 2 through the earlier of September 30 or a landed catch of 6,000 coho (C.5).

Seven days per week. All salmon, two fish per day (C.1). Chinook minimum size limit of 24 inches total length. Coho minimum size limit of 16 inches total length (B). See gear restrictions and definitions (C.2, C.3).

The all salmon except coho season reopens the earlier of October 1 or attainment of the coho quota (C.5). During October, the fishery is only open shoreward of the 40 fathom regulatory line (C.4.f).

In 2018, the season between Cape Falcon and Humbug Mountain will open March 15 for all salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length (B); and the same gear restrictions as in 2017 (C.2, C.3). This opening could be modified following Council review at the March 2018 Council meeting.

Fishing in the Stonewall Bank yelloweye rockfish conservation area restricted to trolling only on days the all depth recreational halibut fishery is open (call the halibut fishing hotline 1–800–662–9825 for specific dates) (C.3.b, C.4.d).

—Cape Falcon to Humbug Mountain

All-salmon mark-selective coho fishery: June 24 through the earlier of July 31 or a landed catch of 18,000 marked coho (C.5).

Seven days per week. All salmon, two fish per day. All retained coho must be marked with a healed adipose fin clip (C.1). Chinook minimum size limit of 24 inches total length. Coho minimum size limit of 16 inches total length (b). See gear restrictions and definitions (C.2, C.3). Any remainder of the mark-selective quota may be transferred on an impact neutral basis to the September non-mark-selective quota from Cape Falcon to Humbug Mountain. The all salmon except coho season reopens the earlier of August 1 or attainment of the coho quota (C.5.e).

Fishing in the Stonewall Bank Yelloweye Rockfish Conservation Area restricted to trolling only on days the all depth recreational halibut fishery is open (call the halibut fishing hotline 1–800–662–9825 for specific dates) (C.3b, C.4.d).

—Humbug Mountain to Oregon/California border (Oregon KMZ)

Closed (C.6).

—Oregon/California border to Horse Mountain (California KMZ)

Closed (C.6).

—Horse Mountain to Point Arena (Fort Bragg)

April 1–May 31;
August 15–November 12 (C.6).

Seven days per week. All salmon except coho; two fish per day (C.1). Chinook minimum size limit of 20 inches total length (B). See gear restrictions and definitions (C.2, C.3).

In 2018, season opens April 7 for all salmon except coho; two fish per day (C.1). Chinook minimum size limit of 20 inches total length (B); and the same gear restrictions as in 2017 (C.2, C.3). This opening could be modified following Council review at the March 2018 Council meeting.

—Point Arena to Pigeon Point (San Francisco)

April 1–30;
May 15–October 31 (C.6).

Seven days per week. All salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length through April 30, 20 inches thereafter (B). See gear restrictions and definitions (C.2, C.3).

In 2018, season opens April 7 for all salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length (B); and the same gear restrictions as in 2017 (C.2, C.3). This opening could be modified following Council review at the March 2018 Council meeting.

—Pigeon Point to Point Sur (Monterey North)

April 1–July 15 (C.6).

Seven days per week. All salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length (B). See gear restrictions and definitions (C.2, C.3).

In 2018, season opens April 7 for all salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length (B); and the same gear restrictions as in 2017 (C.2, C.3). This opening could be modified following Council review at the March 2018 Council meeting.

—Point Sur to U.S./Mexico border (Monterey South)

April 1–May 31 (C.6).

Seven days per week. All salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length (B). See gear restrictions and definitions (C.2, C.3).

In 2018, season opens April 7 for all salmon except coho; two fish per day (C.1). Chinook minimum size limit of 24 inches total length (B); and the same gear restrictions as in 2017 (C.2, C.3). This opening could be modified following Council review at the March 2018 Council meeting.

California State regulations require all salmon be made available to a CDFW representative for sampling immediately at port of landing. Any person in possession of a salmon with a missing adipose fin, upon request by an authorized agent or employee of the CDFW, shall immediately relinquish the head of the salmon to the state (California Code of Regulations Title 14 Section 1.73).

B. Minimum Size (Total Length in Inches) (See C.1)

Area (when open)	Chinook	Coho	Pink
North of Cape Falcon	24.0	16.0	None.
Cape Falcon to Humbug Mountain	24.0	16.0	None.
Humbug Mt. to OR/CA border.			
OR/CA border to Horse Mountain.			
Horse Mountain to Point Arena	20.0	.....	20.0.
Point Arena to Pigeon Point:			
Through April 30	24.0	.....	24.0.
After April 30	20.0	.....	20.0.
Pigeon Point to Point Sur	24.0	.....	24.0.
Point Sur to U.S./Mexico border	24.0	.....	24.0.

Metric equivalents: 24.0 in = 61.0 cm, 20.0 in = 50.8 cm, and 16.0in = 40.6 cm.

C. Requirements, Definitions, Restrictions, or Exceptions

C.1. Compliance With Minimum Size and Other Special Restrictions

All salmon on board a vessel must meet the minimum size or other special requirements for the area being fished and the area in which they are landed if that area is open. Salmon may be landed in an area that is closed only if they meet the minimum size or other special requirements for the area in which they were caught. Salmon may not be filleted prior to landing.

Ocean Boat Limits: Off the coast of Washington, Oregon, and California, each fisher aboard a vessel may continue to use angling gear until the combined daily limits of Chinook and coho salmon for all licensed and juvenile anglers aboard have been attained (additional state restrictions may apply).

C.2. Gear Restrictions

Salmon may be taken only by hook and line using barbless hooks. All persons fishing for salmon, and all persons fishing from a boat with salmon on board, must meet the gear restrictions listed below for specific areas or seasons.

a. *U.S./Canada border to Point Conception, California:* No more than one rod may be used per angler; and no more than two single point, single shank barbless hooks are required for all fishing gear. [Note: ODFW regulations in the state-water fishery off Tillamook Bay may allow the use of barbed hooks to be consistent with inside regulations.]

b. *Horse Mountain, California, to Point Conception, California:* Single point, single shank, barbless circle hooks (see gear definitions below) are required when fishing with bait by any means other than trolling, and no more than two such hooks shall be used. When angling with two hooks, the distance between the hooks must not exceed five inches when measured from the top of the eye of the top hook to the inner base of the curve of the lower hook, and both hooks must be permanently tied in place (hard tied). Circle hooks are not required when artificial lures are used without bait.

C.3. Gear Definitions

a. *Recreational fishing gear defined:* Off Oregon and Washington, angling tackle consists of a single line that must be attached to a rod and reel held by hand or closely attended; the rod and reel must be held by hand while playing a hooked fish. No person may use more than one rod and line while fishing off Oregon or Washington. Off California, the line must be attached to a rod and reel held by hand or closely attended; weights directly attached to a line may not exceed four pounds (1.8 kg). While fishing off California north of Point Conception, no person fishing for salmon, and no person fishing from a boat with salmon on board, may use more than one rod and line. Fishing includes any activity which can reasonably be expected to result in the catching, taking, or harvesting of fish.

b. *Trolling defined:* Angling from a boat or floating device that is making way by means of a source of power, other than drifting by means of the prevailing water current or weather conditions.

c. *Circle hook defined:* A hook with a generally circular shape and a point which turns inward, pointing directly to the shank at a 90° angle.

C.4. Control Zone Definitions

a. *The Bonilla-Tatoosh Line:* A line running from the western end of Cape Flattery to Tatoosh Island Lighthouse (48°23′30″ N. lat., 124°44′12″ W. long.) to the buoy adjacent to Duntze Rock (48°24′37″ N. lat., 124°44′37″ W. long.), then in a straight line to Bonilla Point (48°35′39″ N. lat., 124°42′58″ W. long.) on Vancouver Island, British Columbia.

b. Grays Harbor Control Zone—The area defined by a line drawn from the Westport Lighthouse (46°53′18″ N. lat., 124° 07′01″ W. long.) to Buoy #2 (46°52′42″ N. lat., 124°12′42″ W. long.) to Buoy #3 (46°55′00″ N. lat., 124°14′48″ W. long.) to the Grays Harbor north jetty (46°55′36″ N. lat., 124°10′51″ W. long.).

c. *Columbia Control Zone:* An area at the Columbia River mouth, bounded on the west by a line running northeast/southwest between the red lighted Buoy #4 (46°13′35″ N. lat., 124°06′50″ W. long.) and the green lighted Buoy #7 (46°15′09′ N. lat., 124°06′16″ W. long.); on the east, by the Buoy #10 line which bears north/south at 357° true from the south jetty at 46°14′00″ N. lat., 124°03′07″ W. long. to its intersection with the north jetty; on the north, by a line running northeast/southwest between the green lighted Buoy #7 to the tip of the north jetty (46°15′48″ N. lat., 124°05′20″ W. long. and then along the north jetty to the point of intersection with the Buoy #10 line; and on the south, by a line running northeast/southwest between the red lighted Buoy #4 and tip of the south jetty (46°14′03″ N. lat., 124°04′05″ W. long.), and then along the south jetty to the point of intersection with the Buoy #10 line.

d. Stonewall Bank Yelloweye Rockfish Conservation Area: The area defined by the following coordinates in the order listed:

44°37.46′ N. lat.; 124°24.92′ W. long.
44°37.46′ N. lat.; 124°23.63′ W. long.
44°28.71′ N. lat.; 124°21.80′ W. long.
44°28.71′ N. lat.; 124°24.10′ W. long.
44°31.42′ N. lat.; 124°25.47′ W. long.
and connecting back to 44°37.46′ N. lat.; 124°24.92′ W. long.

e. *Klamath Control Zone:* The ocean area at the Klamath River mouth bounded on the north by 41°38′48″ N. lat. (approximately 6 nautical miles north of the Klamath River mouth); on the west by 124°23′00″ W. long. (approximately 12 nautical miles off

shore); and, on the south by 41°26′48″ N. lat. (approximately 6 nautical miles south of the Klamath River mouth).

f. Waypoints for the 40 fathom regulatory line from Cape Falcon to Humbug Mountain (50 CFR 660.71(k)).

(12) 45°46.00′ N. lat., 124°04.49′ W. long.;
(13) 45°44.34′ N. lat., 124°05.09′ W. long.;
(14) 45°40.64′ N. lat., 124°04.90′ W. long.;
(15) 45°33.00′ N. lat., 124°04.46′ W. long.;
(16) 45°32.27′ N. lat., 124°04.74′ W. long.;
(17) 45°29.26′ N. lat., 124°04.22′ W. long.;
(18) 45°20.25′ N. lat., 124°04.67′ W. long.;
(19) 45°19.99′ N. lat., 124°04.62′ W. long.;
(20) 45°17.50′ N. lat., 124°04.91′ W. long.;
(21) 45°11.29′ N. lat., 124°05.20′ W. long.;
(22) 45°05.80′ N. lat., 124°05.40′ W. long.;
(23) 45°05.08′ N. lat., 124°05.93′ W. long.;
(24) 45°03.83′ N. lat., 124°06.47′ W. long.;
(25) 45°01.70′ N. lat., 124°06.53′ W. long.;
(26) 44°58.75′ N. lat., 124°07.14′ W. long.;
(27) 44°51.28′ N. lat., 124°10.21′ W. long.;
(28) 44°49.49′ N. lat., 124°10.90′ W. long.;
(29) 44°44.96′ N. lat., 124°14.39′ W. long.;
(30) 44°43.44′ N. lat., 124°14.78′ W. long.;
(31) 44°42.26′ N. lat., 124°13.81′ W. long.;
(32) 44°41.68′ N. lat., 124°15.38′ W. long.;
(33) 44°34.87′ N. lat., 124°15.80′ W. long.;
(34) 44°33.74′ N. lat., 124°14.44′ W. long.;
(35) 44°27.66′ N. lat., 124°16.99′ W. long.;
(36) 44°19.13′ N. lat., 124°19.22′ W. long.;
(37) 44°15.35′ N. lat., 124°17.38′ W. long.;
(38) 44°14.38′ N. lat., 124°17.78′ W. long.;
(39) 44°12.80′ N. lat., 124°17.18′ W. long.;
(40) 44°09.23′ N. lat., 124°15.96′ W. long.;
(41) 44°08.38′ N. lat., 124°16.79′ W. long.;
(42) 44°08.30′ N. lat., 124°16.75′ W. long.;
(43) 44°01.18′ N. lat., 124°15.42′ W. long.;
(44) 43°51.61′ N. lat., 124°14.68′ W. long.;
(45) 43°42.66′ N. lat., 124°15.46′ W. long.;
(46) 43°40.49′ N. lat., 124°15.74′ W. long.;
(47) 43°38.77′ N. lat., 124°15.64′ W. long.;
(48) 43°34.52′ N. lat., 124°16.73′ W. long.;
(49) 43°28.82′ N. lat., 124°19.52′ W. long.;
(50) 43°23.91′ N. lat., 124°24.28′ W. long.;
(51) 43°20.83′ N. lat., 124°26.63′ W. long.;
(52) 43°17.96′ N. lat., 124°28.81′ W. long.;
(53) 43°16.75′ N. lat., 124°28.42′ W. long.;
(54) 43°13.97′ N. lat., 124°31.99′ W. long.;
(55) 43°13.72′ N. lat., 124°33.25′ W. long.;
(56) 43°12.26′ N. lat., 124°34.16′ W. long.;
(57) 43°10.96′ N. lat., 124°32.33′ W. long.;
(58) 43°05.65′ N. lat., 124°31.52′ W. long.;
(59) 42°59.66′ N. lat., 124°32.58′ W. long.;
(60) 42°54.97′ N. lat., 124°36.99′ W. long.;
(61) 42°53.81′ N. lat., 124°38.57′ W. long.;
(62) 42°50.00′ N. lat., 124°39.68′ W. long.;
(63) 42°49.13′ N. lat., 124°39.70′ W. long.;
(64) 42°46.47′ N. lat., 124°38.89′ W. long.;
(65) 42°45.74′ N. lat., 124°38.86′ W. long.;
(66) 42°44.79′ N. lat., 124°37.96′ W. long.;
(67) 42°45.01′ N. lat., 124°36.39′ W. long.;
(68) 42°44.14′ N. lat., 124°35.17′ W. long.;
(69) 42°42.14′ N. lat., 124°32.82′ W. long.;
(70) 42°40.50′ N. lat., 124°31.98′ W. long.;

C.5. Inseason Management

Regulatory modifications may become necessary inseason to meet preseason management objectives such as quotas, harvest guidelines, and season duration. In addition to standard inseason actions or modifications already noted under the season description, the following inseason guidance applies:

a. Actions could include modifications to bag limits, or days open to fishing, or extensions or reductions in areas open to fishing.

b. Coho may be transferred inseason among recreational subareas north of Cape Falcon to help meet the recreational season duration objectives (for each subarea) after conferring with representatives of the affected ports and the Council's SAS recreational representatives north of Cape Falcon, and if the transfer would not result in exceeding preseason impact expectations on any stocks.

c. Chinook and coho may be transferred between the recreational and commercial fisheries north of Cape Falcon if there is agreement among the representatives of the SAS, and if the transfer would not result in exceeding preseason impact expectations on any stocks.

d. Fishery managers may consider inseason action modifying regulations restricting retention of unmarked coho. To remain consistent with preseason expectations, any inseason action shall consider, if significant, the difference between observed and preseason forecasted mark rates. Such a consideration may also include a change in bag limit of two salmon, no more than one of which may be a coho.

e. Marked coho remaining from the Cape Falcon to Humbug Mountain recreational mark-selective coho quota may be transferred inseason to the Cape Falcon to Humbug Mountain non-mark-selective recreational fishery if the transfer would not result in exceeding preseason impact expectations on any stocks.

C.6. Additional Seasons in State Territorial Waters

Consistent with Council management objectives, the States of Washington, Oregon, and California may establish limited seasons in state waters. Check state regulations for details.

Section 3. Treaty Indian Management Measures for 2017 Ocean Salmon Fisheries

Parts A, B, and C of this section contain requirements that must be followed for lawful participation in the fishery.

A. Season Descriptions

May 1 through the earlier of June 30 or 20,000 Chinook quota.

All salmon except coho. If the Chinook quota for the May–June fishery is not fully utilized, the excess fish may be transferred into the later all-salmon season (C.5.a). If the Chinook quota is exceeded, the excess will be deducted from the later all-salmon season (C.5). See size limit (B) and other restrictions (C).

July 1 through the earlier of September 15, or 20,000 Chinook quota (C.5), or 12,500 coho quota.

All salmon. See size limit (B) and other restrictions (C).

B. Minimum Size (Inches)

Area (when open)	Chinook		Coho		Pink
	Total	Head-off	Total	Head-off	
North of Cape Falcon	24.0	18.0	16.0	12.0	None.

Metric equivalents: 24.0 in = 61.0 cm, 18.0 in = 45.7 cm, 12.0 in = 30.5 cm.

C. Requirements, Restrictions, and Exceptions

C.1. Tribe and Area Boundaries.

All boundaries may be changed to include such other areas as may hereafter be authorized by a Federal court for that tribe's treaty fishery.

S'KLALLAM—Washington State Statistical Area 4B (All).

MAKAH—Washington State Statistical Area 4B and that portion of the FMA north of 48°02′15″ N. lat. (Norwegian Memorial) and east of 125°44′00″ W. long.

QUILEUTE—That portion of the FMA between 48°10′00″ N. lat. (Cape Alava.) and 47°31′42″ N. lat. (Queets River) and east of 125°44′00″ W. long.

HOH—That portion of the FMA between 47°54′18″ N. lat. (Quillayute River) and 47°21′00″ N. lat. (Quinault River) and east of 125°44′00″ W. long.

QUINAULT—That portion of the FMA between 47°40′06″ N. lat. (Destruction Island) and 46°53′18″N. lat. (Point Chehalis) and east of 125°08′30″ W. long.

C.2. Gear Restrictions

a. Single point, single shank, barbless hooks are required in all fisheries.

b. No more than eight fixed lines per boat.

c. No more than four hand held lines per person in the Makah area fishery (Washington State Statistical Area 4B and that portion of the FMA north of 48°02′15″ N. lat. (Norwegian Memorial) and east of 125°44′00″ W. long.).

C.3. Quotas

a. The quotas include troll catches by the S'Klallam and Makah tribes in Washington State Statistical Area 4B from May 1 through September 15.

b. The Quileute Tribe will continue a ceremonial and subsistence fishery during the time frame of September 15 through October 15 in the same manner as in 2004–2015. Fish taken during this fishery are to be counted against treaty troll quotas established for the 2017 season (estimated harvest during the September-October ceremonial and subsistence fishery: 20 Chinook; 40 coho).

C.4. Area Closures

a. The area within a six nautical mile radius of the mouths of the Queets River (47°31′42″ N. lat.) and the Hoh River (47°45′12″ N. lat.) will be closed to commercial fishing.

b. A closure within two nautical miles of the mouth of the Quinault River (47°21′00″ N. lat.) may be enacted by the Quinault Nation and/or the State of Washington and will not adversely affect the Secretary of Commerce's management regime.

C.5. Inseason Management: In Addition to Standard Inseason Actions or Modifications Already Noted Under the Season Description, the Following Inseason Guidance Applies

a. Chinook remaining from the May through June treaty-Indian ocean troll harvest guideline north of Cape Falcon may be transferred to the July through September harvest guideline on a fishery impact equivalent basis.

Section 4. Halibut Retention

Under the authority of the Northern Pacific Halibut Act, NMFS promulgated regulations governing the Pacific halibut fishery, which appear at 50 CFR part 300, subpart E. On March 7, 2017, NMFS published a rule announcing the IPHC's regulations, and fishery regulations for U.S. waters off Alaska (82 FR 12730). On April 20, 2017, NMFS published a final rule (82 FR 18581) approving and implementing the Area 2A (U.S. West Coast) Pacific halibut Catch Sharing Plan and the Area 2A management measures for 2017. The Catch Sharing Plan, in combination with the IPHC regulations, provides that vessels participating in the salmon troll fishery in Area 2A, which have obtained the appropriate IPHC license, may retain halibut caught incidentally during authorized periods in conformance with provisions published with the annual salmon management measures. A salmon troller may participate in the halibut incidental catch fishery during the salmon troll season or in the directed commercial fishery targeting halibut, but not both.

The following measures have been approved by the IPHC, and implemented by NMFS. During authorized periods, the operator of a vessel that has been issued an incidental halibut harvest license may retain Pacific halibut caught incidentally in Area 2A while trolling for salmon. Halibut retained must be no less than 32 inches (81.28 cm) in total length, measured from the tip of the lower jaw with the mouth closed to the extreme end of the middle of the tail, and must be landed with the head on.

License applications for incidental harvest must be obtained from the IPHC (phone: 206–634–1838). Applicants must apply prior to mid-March 2018 for 2018 permits (exact date to be set by the IPHC in early 2018). Incidental harvest is authorized only during April, May, and June of the 2017 troll seasons and after June 30 in 2017 if quota remains and if announced on the NMFS hotline (phone: 1–800–662–9825 or 206–526–6667). WDFW, ODFW, and CDFW will monitor landings. If the landings are projected to exceed the 39,810 pound preseason allocation or the total Area 2A non-Indian commercial halibut allocation, NMFS will take inseason action to prohibit retention of halibut in the non-Indian salmon troll fishery.

May 1, 2017, through December 31, 2017, and April 1–30, 2018, license holders may land or possess no more than one Pacific halibut per each two Chinook, except one Pacific halibut may be possessed or landed without meeting the ratio requirement, and no more than 35 halibut may be possessed or landed per trip. Pacific halibut retained must be no less than 32 inches in total length (with head on). IPHC license holders must comply with all applicable IPHC regulations.

Incidental Pacific halibut catch regulations in the commercial salmon troll fishery adopted for 2017, prior to any 2017 inseason action, will be in effect when incidental Pacific halibut retention opens on April 1, 2018, unless otherwise modified by inseason action at the March 2018 Council meeting.

NMFS and the Council request that salmon trollers voluntarily avoid a ''C-shaped'' YRCA (also known as the

Salmon Troll YRCA) in order to protect yelloweye rockfish. Coordinates for the Salmon Troll YRCA are defined at 50 CFR 660.70(a) in the North Coast subarea (Washington marine area 3). See Section 1.C.7. in this document for the coordinates.

Section 5. Geographical Landmarks

Wherever the words ''nautical miles off shore'' are used in this document, the distance is measured from the baseline from which the territorial sea is measured.

Geographical landmarks referenced in this document are at the following locations:

Cape Flattery, WA	48°23′00″ N. lat.
Cape Alava, WA	48°10′00″ N. lat.
Queets River, WA	47°31′42″ N. lat.
Leadbetter Point, WA	46°38′10″ N. lat.
Cape Falcon, OR	45°46′00″ N. lat.
Florence South Jetty, OR	44°00′54″ N. lat.
Humbug Mountain, OR	42°40′30″ N. lat.
Oregon-California border	42°00′00″ N. lat.
Humboldt South Jetty, CA	40°45′53″ N. lat.
Horse Mountain, CA	40°05′00″ N. lat.
Point Arena, CA	38°57′30″ N. lat.
Point Reyes, CA	37°59′44″ N. lat.
Point San Pedro, CA	37°35′40″ N. lat.
Pigeon Point, CA	37°11′00″ N. lat.
Point Sur, CA	36°18′00″ N. lat.
Point Conception, CA	34°27′00″ N. lat.

Section 6. Inseason Notice Procedures

Notice of inseason management actions will be provided by a telephone hotline administered by the West Coast Region, NMFS, 1–800–662–9825 or 206–526–6667, and by USCG Notice to Mariners broadcasts. These broadcasts are announced on Channel 16 VHF–FM and 2182 KHz at frequent intervals. The announcements designate the channel or frequency over which the Notice to Mariners will be immediately broadcast. Inseason actions will also be published in the **Federal Register** as soon as practicable. Since provisions of these management measures may be altered by inseason actions, fishermen should monitor either the telephone hotline or Coast Guard broadcasts for current information for the area in which they are fishing.

Classification

This final rule is necessary for conservation and management of Pacific coast salmon stocks and is consistent with the Magnuson-Stevens Act and other applicable law. These regulations are being promulgated under the authority of 16 U.S.C. 1855(d) and 16 U.S.C. 773(c).

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Assistant Administrator for Fisheries finds good cause under 5 U.S.C. 553(b)(B), to waive the requirement for prior notice and opportunity for public comment, as such procedures would be impracticable and contrary to the public interest.

The annual salmon management cycle begins May 1 and continues through April 30 of the following year. May 1 was chosen because the pre-May harvests constitute a relatively small portion of the annual catch. The time frame of the preseason process for determining the annual modifications to ocean salmon fishery management measures depends on when the pertinent biological data are available. Salmon stocks are managed to meet annual spawning escapement goals or specific exploitation rates. Achieving either of these objectives requires designing management measures that are appropriate for the ocean abundance predicted for that year. These pre-season abundance forecasts, which are derived from previous years' observed spawning escapement, vary substantially from year to year, and are not available until January or February because spawning escapement continues through the fall.

The preseason planning and public review process associated with developing Council recommendations is initiated in February as soon as the forecast information becomes available. The public planning process requires coordination of management actions of four states, numerous Indian tribes, and the Federal Government, all of which have management authority over the stocks. This complex process includes the affected user groups, as well as the general public. The process is compressed into a two-month period culminating with the April Council meeting at which the Council adopts a recommendation that is forwarded to NMFS for review, approval, and implementation of fishing regulations effective on May 1.

Providing opportunity for prior notice and public comments on the Council's recommended measures through a proposed and final rulemaking process would require 30 to 60 days in addition to the two-month period required for development of the regulations. Delaying implementation of annual fishing regulations, which are based on the current stock abundance projections, for an additional 60 days would require that fishing regulations for May and June be set in the previous year, without the benefit of information regarding current stock status. For the 2017 fishing regulations, the current stock status was not available to the Council until February. Because a substantial amount of fishing occurs during May and June, managing the fishery with measures developed using the prior year's data could have significant adverse effects on the managed stocks, including ESA-listed stocks. Although salmon fisheries that open prior to May are managed under the prior year's measures, as modified by the Council at its March meeting, relatively little harvest occurs during that period (*e.g.,* on average, less than 5 percent of commercial and recreational harvest occurred prior to May 1 during the years 2001 through 2015). Allowing the much more substantial harvest levels normally associated with the May and June salmon seasons to be promulgated under the prior year's regulations would impair NMFS' ability to protect weak and ESA-listed salmon stocks, and to provide harvest opportunity where appropriate. The choice of May 1 as the beginning of the regulatory season balances the need to gather and analyze the data needed to meet the management objectives of the Salmon FMP and the need to manage the fishery using the best available scientific information.

If these measures are not in place on May 1, salmon fisheries will not open as scheduled, or would open based on 2016 management measures which do not account for 2017 abundance projections without inseason action by NMFS. This would result in lost fishing opportunity, negative economic impacts, and confusion for the public as the state fisheries adopt concurrent regulations that conform to the Federal management measures.

Overall, the annual population dynamics of the various salmon stocks require managers to adjust the season structure of the West Coast salmon fisheries to both protect weaker stocks and give fishers access to stronger salmon stocks, particularly hatchery produced fish. Failure to implement these measures immediately could compromise the status of certain stocks, or result in foregone opportunity to harvest stocks whose abundance has

increased relative to the previous year thereby undermining the purpose of this agency action.

In addition, public comment was received and considered by the Council and NMFS throughout the process of developing these management measures. As described above, the Council took comment at its March and April meetings, and heard summaries of comments received at public meetings held between the March and April meetings in each of the coastal states. NMFS also invited comments in a notice published prior to the March Council meeting, and considered comments received by the Council through its representative on the Council. Thus, these measures were developed with significant public input.

Based upon the above-described need to have these measures effective on May 1 and the fact that there is limited time available to implement these new measures after the final Council meeting in April and before the commencement of the ocean salmon fishing year on May 1, NMFS has concluded it is impracticable and contrary to the public interest to provide an opportunity for prior notice and public comment under 5 U.S.C. 553(b)(B).

The Assistant Administrator for Fisheries also finds that good cause exists under 5 U.S.C. 553(d)(3), to waive the 30-day delay in effectiveness of this final rule. As previously discussed, data were not available until February and management measures were not finalized until mid-April. These measures are essential to conserve threatened and endangered ocean salmon stocks, and to provide for harvest of more abundant stocks. Delaying the effectiveness of these measures by 30 days could compromise the ability of some stocks to attain their conservation objectives, preclude harvest opportunity, and negatively impact anticipated international, state, and tribal salmon fisheries, thereby undermining the purposes of this agency action and the requirements of the Magnuson-Stevens Act.

To enhance the fishing industry's notification of these new measures, and to minimize the burden on the regulated community required to comply with the new regulations, NMFS is announcing the new measures over the telephone hotline used for inseason management actions and is posting the regulations on its West Coast Region Web site (*http://www.westcoast.fisheries.noaa.gov*). NMFS is also advising the states of Washington, Oregon, and California on the new management measures. These states announce the seasons for applicable state and Federal fisheries through their own public notification systems.

Because prior notice and an opportunity for public comment are not required to be provided for these portions of this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable. Accordingly, no Regulatory Flexibility Analysis is required for this portion of the rule and none has been prepared.

This action contains collection-of-information requirements subject to the Paperwork Reduction Act (PRA), and which have been approved by the Office of Management and Budget (OMB) under control number 0648–0433. The current information collection approval expires on July 31, 2017; renewal of this approval has been submitted to OMB and approval is pending. The public reporting burden for providing notifications if landing area restrictions cannot be met is estimated to average 15 minutes per response. This estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

NMFS has current ESA biological opinions that cover fishing under these regulations on all listed salmon species. NMFS reiterated their consultation standards for all ESA listed salmon and steelhead species in their annual Guidance letter to the Council dated March 3, 2017. Some of NMFS past biological opinions have found no jeopardy, and others have found jeopardy, but provided reasonable and prudent alternatives to avoid jeopardy. The management measures for 2017 are consistent with the biological opinions that found no jeopardy, and with the reasonable and prudent alternatives in the jeopardy biological opinions. The Council's recommended management measures therefore comply with NMFS' consultation standards and guidance for all listed salmon species which may be affected by Council fisheries. In some cases, the recommended measures are more restrictive than NMFS' ESA requirements.

In 2009, NMFS consulted on the effects of fishing under the Salmon FMP on the endangered Southern Resident Killer Whale Distinct Population Segment (SRKW) and concluded the salmon fisheries were not likely to jeopardize SRKW. The 2017 salmon management measures are consistent with the terms of that biological opinion.

This final rule was developed after meaningful and collaboration with the affected tribes. The tribal representative on the Council made the motion for the regulations that apply to the tribal fisheries.

Authority: 16 U.S.C. 773–773k; 1801 *et seq.*

Dated: April 25, 2017.

Alan D. Risenhoover,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2017–08638 Filed 4–27–17; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 82, No. 81
Friday, April 28, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–0395; Directorate Identifier 2017–CE–011–AD]

RIN 2120–AA64

Airworthiness Directives; British Aerospace Regional Aircraft Airplanes

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

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for British Aerospace Regional Aircraft Model HP.137 Jetstream Mk.1, Jetstream Series 200 and 3101, and Jetstream Model 3201 airplanes that would supersede AD 97–10–05. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracks in the main landing gear (MLG) fitting at the pintle to cylinder interface, which could cause failure of the MLG during takeoff and landing. We are issuing this proposed AD to require actions to address the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by June 12, 2017.

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

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

For the British Aerospace Jetstream Series 3100 and 3200 service information identified in this proposed AD, contact BAE Systems (Operations) Ltd, Business Support Team-Technical Publications, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; phone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *https://www.regional-services.com/spares_and_support/support/aircraft-technical-publications/.* For the Heroux Devtek service information identified in this proposed AD, contact Heroux Devtek Product Support, Unit 1, Pembroke Court, Chancellor Road, Manor Park, Runcorn, Cheshire, WA7 1TG, England; phone: +44 01928 530530; fax: +44 01928 579454; email: *technical_support@herouxdevtek.com;* Internet: *http://www.herouxdevtek.com/aog-product-support.* You may review copies of the referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0395; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2017–0395; Directorate Identifier 2017–CE–011–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

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

Discussion

On December 9, 1996, we issued AD 97–10–05, Amendment 39–10017 (62 FR 28318; May 23, 1997) (''AD 97–10–05''). That AD required actions intended to address an unsafe condition on British Aerospace Regional Aircraft Model HP.137 Jetstream Mk.1, Jetstream Series 200 and 3101, and Jetstream Model 3201 airplanes and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country.

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2017–0053, dated March 24, 2017 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Cracks were found during early fatigue testing and in service on the main landing gear (MLG) main fitting at the pintle to cylinder interface.
>
> This condition, if not detected and corrected, could lead to structural failure of the MLG, possibly resulting in loss of control of the aeroplane during take-off or landing runs.
>
> To address this unsafe condition, BAE Systems (Operations) Ltd published several Service Bulletins (SB) which, in 1996, were consolidated into a single SB 32–JA960142 to provide instructions for inspection. CAA UK issued AD 005–03–96 accordingly to require repetitive inspections of the MLG.
>
> Recently, a crack was found which was below the critical crack length, but unusually large compared to other similar cracks

previously found in service. Further investigation into the subject determined that the existing inspection interval remains valid, but also showed that the assumed detectable defect size of 1.27 mm (0.05 in) crack cannot be guaranteed using the current accomplishment instructions for high frequency eddy current (HFEC) or fluorescent dye penetrant (FDP) inspection.

Consequently, BAE Systems (Operations) Ltd issued SB 32–JA960142 Revision 04, which provides improved procedures for HFEC and FDP inspection to ensure the detection of cracks of 1.27 mm (0.05 in).

For the reason described above, the [EASA] AD retains the requirements of CAA UK AD 005–03–96, which is superseded, and requires accomplishment of repetitive inspections in accordance with the improved procedures.

You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0395.

Related Service Information Under 1 CFR Part 51

We reviewed British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016, which describes procedures for doing non-destructive testing for cracks in the MLG and corrective actions if cracks found exceed a certain crack length. (The appendix to the service bulletin specifically describes fluorescent liquid penetrant testing.) We reviewed Heroux Devtek Service Bulletin 32–56, Revision 4, dated August 16, 2016, which describes procedures for doing a non-destructive testing eddy current inspection for cracks in the MLG. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

We estimate that this proposed AD will affect 26 products of U.S. registry. We also estimate that it would take about 6 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $85 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $13,260, or $510 per product.

In addition, we estimate that any necessary follow-on actions would take about 1 work-hour and require parts costing $5,000, for a cost of $5,085 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Amendment 39–10017 (62 FR 28318; May 23, 1997), and adding the following new AD:

British Aerospace Regional Aircraft: Docket No. FAA–2017–0395; Directorate Identifier 2017–CE–011–AD.

(a) Comments Due Date

We must receive comments by June 12, 2017.

(b) Affected ADs

This AD replaces AD 97–10–05; Amendment 39–10017 (62 FR 28318; May 23, 1997) (''AD 97–10–05'').

(c) Applicability

This AD applies to British Aerospace Regional Aircraft Model HP.137 Jetstream Mk.1, Jetstream Series 200 and 3101, and Jetstream Model 3201 airplanes, all serial numbers, certificated in any category.

(d) Subject

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

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as cracks in the main landing gear (MLG) fitting at the pintle to cylinder interface, which could cause failure of the MLG during takeoff and landing. We are issuing this proposed AD to detect and correct cracks in the main landing gear (MLG), which could lead to structural failure of the MLG and could result in loss of control during takeoffs and landings.

(f) Actions and Compliance

Unless already done, do the following actions listed in paragraphs (f)(1) through (3) of this AD:

(1) Within the compliance times listed in paragraph (f)(1)(i) or (ii) of this AD, as applicable, inspect the MLG for cracks following Appendix 1 of British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016; or Heroux Devtek Service

Bulletin 32–56, Revision 4, dated August 16, 2016, as specified in British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016.

(i) For airplanes that have been inspected following AD 97–10–05: Do the initial inspection within 1,200 flight cycles (FC) after the last inspection required by AD 97–10–05 and repetitively thereafter at intervals not to exceed 1,200 FC.

(ii) For airplanes that have not been inspected following AD 97–10–05: Do the initial inspection within 8,000 FC after installation of the MLG or within the next 100 FC after the effective date of this AD, whichever occurs later, and repetitively thereafter at intervals not to exceed 1,200 FC.

(2) If any cracks are found during any of the inspections required in paragraph (f)(1) of this AD, before further flight, replace the MLG with an airworthy part following British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA960142, Revision No. 4, October 21, 2016.

(3) The compliance times in paragraphs (f)(1)(i) and (ii) of this AD are presented in flight cycles (landings). If the total flight cycles have not been kept, multiply the total number of airplane hours time-in-service (TIS) by 0.75 to calculate the cycles. For the purposes of this AD:

(i) 100 hours TIS × .75 = 75 cycles; and

(ii) 1,000 hours TIS × .75 = 750 cycles.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.* Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

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

(h) Related Information

(1) Refer to MCAI European Aviation Safety Agency (EASA) AD 2017–0053, dated March 24, 2017. You may examine the MCAI on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–0395.

(2) For the British Aerospace Jetstream Series 3100 and 3200 service information related to this AD, contact BAE Systems (Operations) Ltd, Business Support Team-Technical Publications, Prestwick International Airport, Ayrshire, KA9 2RW, Scotland, United Kingdom; phone: +44 1292 675207; fax: +44 1292 675704; email: *RApublications@baesystems.com;* Internet: *https://www.regional-services.com/spares_and_support/support/aircraft-technical-publications/.* For the Heroux Devtek service information identified in this proposed AD, contact Heroux Devtek Product Support, Unit 1, Pembroke Court, Chancellor Road, Manor Park, Runcorn, Cheshire, WA7 1TG, England; phone: +44 01928 530530; fax: +44 01928 579454; email: *technical_support@herouxdevtek.com;* Internet: *http://www.herouxdevtek.com/aog-product-support.*

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

Issued in Kansas City, Missouri, on April 20, 2017.

Melvin Johnson,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2017–08536 Filed 4–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2016–9594; Airspace Docket No. 16–ASO–20]

Proposed Establishment of Temporary Restricted Areas R–2920A and R–2920B; Santa Rosa Island, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); withdrawal.

SUMMARY: This action withdraws the NPRM published in the **Federal Register** of February 23, 2017, proposing to establish temporary restricted areas R–2920A and R–2920B, Santa Rosa Island, FL, for the period May 11 to May 18, 2017. The proponent has informed the FAA that plans to conduct hazardous activities have been cancelled; therefore, a requirement no longer exists to establish temporary restricted areas.

DATES: The proposed rule published on February 23, 2017 at 82 FR 11415 is withdrawn as of 0901 UTC, April 28, 2017.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

An NPRM was published in the **Federal Register** of February 23, 2017 (82 FR 11415), Docket No. FAA–2016–9594, to establish temporary restricted areas, designated as R–2920A and R–2920B, south of the Elgin Air Force Base Range Complex, in the vicinity of Santa Sosa Island, FL. The temporary restricted areas were proposed to contain hazardous activities to be used for the testing of counter-unmanned aircraft systems capabilities in support of exercise Black Dart 2017, from May 11 to May 18, 2017. The comment period closed on March 27, 2017. The FAA received five comments on the proposal. The proponent has informed the FAA that hazardous testing activities have been cancelled. Therefore, the NPRM is being withdrawn. As a result, the comments received on the proposal are no longer relevant.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

The Withdrawal

Accordingly, pursuant to the authority delegated to me, the notice of proposed rulemaking, as published in the **Federal Register** on February 23, 2017 (82 FR 11415), FR Doc. 2017–03537, is hereby withdrawn.

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.

Issued in Washington, DC, on April 24, 2017.

Rodger A. Dean, Jr.,

Manager, Airspace Policy Group.

[FR Doc. 2017–08597 Filed 4–27–17; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2016–0514; FRL–9961–39–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Maryland; Removal of Clean Air Interstate Rule (CAIR) Program Regulations and Reference to CAIR, and Amendments to Continuous Emission Monitor (CEM) Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a

July 7, 2016 state implementation plan (SIP) revision submitted by the State of Maryland. The revision includes revised regulations which repealed Maryland's Clean Air Interstate Rule (CAIR) Program in its entirety, and which removed references to CAIR from other Maryland regulations that relate to general air quality definitions and to the control of emissions from pulp mills in Maryland. Additionally, the revision includes an amendment to a Maryland regulation regarding the use of continuous emission monitoring (CEM) systems at Kraft pulp mill boilers and combustion units in order to clarify that CEM systems must meet requirements beyond those only related to certification. The July 7, 2016 SIP submittal satisfies Maryland's obligation pursuant to an earlier rulemaking in which EPA granted final conditional approval of amendments regarding the control of emissions from Kraft pulp mills contingent upon Maryland addressing the monitoring issue. Final approval of the July 7, 2016 SIP revision will convert the prior conditional approval of the pulp mill regulations to a full approval. EPA is proposing to approve this revision to the Maryland SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: Written comments must be received on or before May 30, 2017.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2016–0514 at *http://www.regulations.gov,* or via email to *pino.maria@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, 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, 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ellen Schmitt, (215) 814–5787, or by email at *schmitt.ellen@epa.gov.*

SUPPLEMENTARY INFORMATION: On July 7, 2016, EPA received from the State of Maryland a formal submittal (#16–07) seeking a revision to its SIP.

I. Background

To help reduce interstate transport of ozone and fine particulate matter ($PM_{2.5}$) pollution in the eastern half of the United States, EPA finalized CAIR in May 2005.[1] CAIR addressed both the 1997 ozone and $PM_{2.5}$ national ambient air quality standards (NAAQS) and required 28 states, including Maryland, to limit emissions of nitrogen oxides (NO_X) and sulfur dioxide (SO_2).[2] For CAIR, EPA developed three separate cap and trade programs that could be used to achieve the required reductions: The CAIR NO_X ozone season trading program, the CAIR annual NO_X trading program, and the CAIR SO_2 trading program.

On December 23, 2008, CAIR was remanded to EPA by the United States Court of Appeals for the District of Columbia Circuit (D.C. Circuit) in *North Carolina* v. *EPA,* 531 F.3d 896 (D.C. Cir. 2008), *modified on reh'g,* 550 F.3d 1176. The December 2008 D.C. Circuit ruling allowed CAIR to remain in effect until a new interstate transport rule consistent with the Court's opinion was developed. While EPA worked on developing a new rule to address the interstate transport of air pollution, the CAIR program continued as planned with the NO_X annual and ozone season programs beginning in 2009 and the SO_2 annual program beginning in 2010.

In response to the remand of CAIR, EPA promulgated the Cross State Air Pollution Rule (CSAPR) on July 6, 2011.[3] CSAPR, which reduces emissions from electric generating units (EGUs), addresses the 1997 8-hour ozone NAAQS, the 1997 annual $PM_{2.5}$ NAAQS and the 2006 24-hour $PM_{2.5}$ NAAQS. The rule also contained provisions that would sunset CAIR-related obligations on a schedule coordinated with the implementation of CSAPR compliance requirements. CSAPR was to become effective January 1, 2012; however, the timing of CSAPR's implementation was impacted by a number of court actions. On December 30, 2011, the D.C. Circuit stayed CSAPR prior to its implementation, and EPA was ordered to continue administering CAIR on an interim basis.[4] In a subsequent decision on the merits, the Court vacated CSAPR based on a subset of petitioners' claims.[5] However, on April 29, 2014, the U.S. Supreme Court reversed that decision and remanded the case to the D.C. Circuit for further proceedings.[6] Throughout the initial round of D.C. Circuit proceedings and the ensuing Supreme Court proceedings, the stay on CSAPR remained in place, and EPA continued to implement CAIR.

Following the April 2014 Supreme Court decision, EPA filed a motion asking the D.C. Circuit to lift the stay in order to allow CSAPR to replace CAIR in an equitable and orderly manner while further D.C. Circuit proceedings were held to resolve remaining claims from petitioners. Additionally, EPA's motion requested to toll, by three years, all CSAPR compliance deadlines that had not passed as of the approval date of the stay. On October 23, 2014, the D.C. Circuit granted EPA's request, and on December 3, 2014 (79 FR 71663), in an interim final rule, EPA set the updated effective date of CSAPR as January 1, 2015 and tolled the implementation of CSAPR Phase I to 2015 and CSAPR Phase 2 to 2017. In accordance with the interim final rule, the sunset date for CAIR was December 31, 2014, and EPA began implementing CSAPR on January 1, 2015.[7]

II. Summary of SIP Revision

On July 7, 2016, EPA received from the State of Maryland a formal submittal (#16–07) seeking a revision to its SIP. As a result of CSAPR replacing CAIR, Maryland, in its July 7, 2016 submittal, requested that EPA remove from the Maryland SIP the CAIR program in its entirety, and references to CAIR located in other sections of the Code of Maryland Regulations (COMAR). Maryland's submittal seeks to remove the CAIR program by removing, in its entirety, COMAR 26.11.28 from Maryland's SIP because the CAIR program is now moot and has been replaced entirely by CSAPR. The July 7, 2016 SIP submittal also includes an amended definition of ''NO_X Ozone Season Allowance'' in COMAR 26.11.01.01B(24–1) which removed reference to CAIR, thereby directing

[1] 70 FR 25172 (May 12, 2005).

[2] SO_2 is a precursor to $PM_{2.5}$ formation, and NO_X is a precursor to both ozone and $PM_{2.5}$ formation.

[3] 76 FR 48208 (August 8, 2011).

[4] Order of December 30, 2011, in *EME Homer City Generation, L.P.* v. *EPA,* D.C. Cir. No. 11–1302.

[5] *EME Homer City Generation, L.P.* v. *EPA,* 696 F.3d 7 (D.C. Cir. 2012), cert. granted 133 U.S. 2857 (2013).

[6] *EPA* v. *EME Homer City Generation, L.P.,* 134 S. Ct. 1584, 1600–01 (2014).

[7] At the present time, CSAPR is implemented in Maryland via a federal implementation plan (FIP).

affected sources to the ''NO_X ozone season emission trading program,'' which is currently CSAPR. The SIP revision also includes a revised version of COMAR 26.11.14. In COMAR 26.11.14.07C(1), there was a specific reference to COMAR 26.11.28, Maryland's CAIR program, which is now moot and which Maryland requested EPA remove from the SIP. Maryland revised COMAR 26.11.14.07C(1) to remove reference to COMAR 26.11.28, while permitting the continued practice of allowing certain sources to use NO_X ozone season allowances as an alternative compliance method. Maryland has included revised COMAR 26.11.01.01 and 26.11.14.07, which includes 26.11.01.01B(24–1) and 26.11.14.07C(1), respectively, for incorporation by reference into the Maryland SIP.

Finally, the July 7, 2016 SIP submission includes an amended COMAR 26.11.14.07D(1) which removes the word ''certified'' in order to clarify that for Kraft pulp mill combustion units and boilers to meet the monitoring and reporting requirements, CEM systems must meet all the requirements of 40 CFR 75, subpart H, and not just the certification requirements for CEMs.

III. Summary of EPA Analysis

In this action, EPA proposes to approve the removal of COMAR 26.11.28, which incorporated the CAIR program, from the Maryland SIP. EPA also proposes to approve the removal of references to CAIR from other Maryland regulations located in the Maryland SIP that relate to general air quality definitions and to the control of emissions from pulp mills in Maryland. As mentioned previously in this preamble, the D.C. Circuit remanded CAIR to EPA in 2008; however, the Court left CAIR in place while EPA worked to develop a new interstate transport rule. CSAPR was promulgated to respond to the court's concerns and to replace CAIR. The implementation of CSAPR was delayed for several years beyond its originally expected implementation timeframe of 2012 and therefore the sunsetting of CAIR was also deferred. CAIR was implemented through the 2014 compliance periods and was sunset and replaced by CSAPR on January 1, 2015, thereby making CAIR moot and any reference to CAIR inconsequential. Additionally, as a result of CSAPR replacing CAIR and the removal of Maryland's CAIR program under COMAR 26.11.28, reference to CAIR in other Maryland regulations is inaccurate and misleading. Thus, removing reference to CAIR or COMAR 26.11.28 from the other Maryland regulations mentioned in this action does not affect the sources impacted by the federal cap and trade program. Additionally, although EPA's proposed action here removes the CAIR program from the Maryland SIP, this action is overall SIP strengthening as it removes a moot program no longer in operation. EPA has already replaced CAIR with CSAPR which operates through FIPs, and which yields overall NO_X and ozone reductions that are at least equal to or better than reductions from CAIR.[8] [9]

In addition, Maryland's amendments to COMAR 26.11.01.01 and COMAR 26.11.14 (to remove references to CAIR) are in response to EPA's conditional approval of a previous Maryland SIP submittal. Maryland SIP #14–04 was submitted on October 8, 2014 for inclusion in the Maryland SIP and included amendments to COMAR 26.11.14—Control of Kraft Pulp Mills.[10] In a letter dated September 18, 2015, the Maryland Department of the Environment (MDE) committed to removing references to CAIR, which sunset on December 31, 2014, through a SIP revision. The amendments to COMAR 26.11.01.01 and COMAR 26.11.14, provided by Maryland's SIP submittal #16–07, complete the actions required by EPA's conditional approval of Maryland SIP submittal #14–04. 81 FR 59486 (August 30, 2016). Pursuant to section 110(k) of the CAA and as stated in the August 30, 2016 final conditional approval of COMAR 26.11.14 for Maryland's October 8, 2014 SIP submittal, once EPA determines that MDE has satisfied the condition to remove references to CAIR, EPA shall remove the conditional nature of the August 30, 2016 approval. At that time, the October 8, 2014 SIP submission #14–04 will receive full approval status.[11]

Finally, regarding Maryland's amendments to COMAR 26.11.14.07D(1), the removal of the word ''certified'' from this portion of the Maryland regulation is merely an administrative action to make clear that CEMs used by Kraft pulp mill combustion units and boilers must meet all of the requirements of 40 CFR part 75, subpart H, and not just the certification requirements for CEMs.

Based upon its review, EPA finds Maryland's July 7, 2016 SIP submittal approvable under section 110 of the CAA as a SIP strengthening measure which removes moot provisions and makes minor administrative changes.

IV. Proposed Action

This action proposes to approve Maryland's July 7, 2016 SIP submittal which seeks removal of Maryland's CAIR program, in its entirety, from the SIP and also seeks the removal of references to CAIR from other Maryland regulations that relate to general air quality definitions and to the control of emissions from Kraft pulp mills in the State. EPA is also proposing to approve the amended version of COMAR 26.11.14.07D(1) for inclusion in the Maryland SIP as the amended version removes the word ''certified'' from COMAR 26.11.14.07D(1) in order to clarify the CEM system requirements for monitoring and reporting emissions from Kraft pulp mill boilers and combustion units.

Additionally, EPA proposes to find that Maryland's July 7, 2016 SIP submittal satisfies Maryland's obligation pursuant to EPA's August 30, 2016 (81 FR 59486) rulemaking in which the Agency granted final conditional approval of amendments regarding the control of NO_X emissions at Kraft pulp mills. For this reason, EPA also proposes to remove the conditional nature of the August 30, 2016 conditional approval and proposes to grant full approval to the Maryland SIP revision regarding the control Kraft pulp mill emissions from various processes and fuel-burning equipment, submitted as #14–04 on October 15, 2014.

EPA is proposing to approve the Maryland SIP revision which was submitted on July 7, 2016. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

V. Incorporation by Reference

In this proposed rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference portions of MDE regulations COMAR 26.11.01 and COMAR 26.11.14 regarding air quality definitions and

[8] 76 FR 48208 (August 8, 2011).

[9] According to section 110(l) of the CAA, the Administrator shall not approve a revision of a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress), or any other applicable requirement of the Act.

[10] The final rulemaking notice for EPA's conditional approval of SIP submission #14–04 was published on August 30, 2016 (81 FR 59486) and addressed NO_X reductions for pulp mills in Maryland.

[11] Thus, once this proposed action to approve the July 7, 2016 SIP submission #16–07 is finalized, thereby finding Maryland has met the conditions within our August 30, 2016 conditional approval (81 FR 59486), the conditional approval of Maryland's October 8, 2014 SIP submission #14–04 will be converted to full approval.

Kraft pulp mill emission controls to remove reference to CAIR which were discussed in section II (Summary of SIP Revision) of this preamble. EPA is also proposing to incorporate by reference the portion of COMAR 26.11.14 which removed the word ''certified'' from COMAR 26.11.14.07D(1). EPA has made, and will continue to make, these materials generally available through *http://www.regulations.gov* and/or at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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 CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rule, regarding the removal of the CAIR program under COMAR 26.11.28 from the Maryland SIP and amendments to COMAR 26.11.01 and 26.11.14, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

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

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

Dated: March 21, 2017.

Cecil A. Rodrigues,

Acting Regional Administrator, Region III.

[FR Doc. 2017–08664 Filed 4–27–17; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 82, No. 81

Friday, April 28, 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 AGRICULTURE

Submission for OMB Review; Comment Request

April 25, 2017.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are required regarding (1) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by May 30, 2017 will be considered. Written comments should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725—17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Copies of the submission(s) may be obtained by calling (202) 720–8958.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Farm Service Agency

Title: Farm Loan Program, General Program Administration.

OMB Control Number: 0560–0238.

Summary of Collection: Authority to establish the regulatory requirements contained in 7 CFR 761 and 7 CFR 763, is derived from 5 U.S.C. 301 which provides that ''The Head of an Executive department or military department may prescribe regulations for the government of his department, the distribution and performance of its business . . .'' The Secretary delegated authority to administer the provisions of the Act applicable to the Farm Loan Program (FLP) to the Under Secretary for Farm and Foreign Agricultural Service in section 2.16 of 7 CFR part 2. FLP provides loans to family farmers to purchase real estate equipment and finance agricultural production. The regulations covered by this information collection package describes, the policies and procedures the agency uses to provide supervised credit to direct FLP applicants and borrowers in accordance with the provisions of the Consolidated Farm and Rural Development Act (Pub. L. 87–128), as amended.

Need and use of the Information: Information collections are submitted by applicants and borrowers to the local FSA office serving the county in which their business is headquartered. The information is necessary to provide supervised credit as legislatively mandated and is used by Agency Officials to: (1) Ensure that when loan funds or insurance proceeds are used for construction and development, projects, work is completed according to applicable state and local requirements, and in a manner that protects the Agency's financial interest. (2) Ensure that the loan repayment plan is developed using realistic data, based on the actual history of the operation and any planned improvements. (3) Identify potential concerns limiting the success of the operation and develop a loan assessment outlining the course of action to be followed, to improve the operation so that commercial credit is available. The agency is mandated to provide supervised credit; therefore, failure to collect the information, or collecting it less frequently, could result in the failure of the farm operation or loss of agency security property.

Description of Respondents: Business or other for-profit; Farms.

Number of Respondents: 84,983.

Frequency of Responses: Reporting: On occasion; Annually.

Total Burden Hours: 229.237.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2017–08594 Filed 4–27–17; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0033]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Bovine Spongiform Encephalopathy; Importation of Animals and Animal Products

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with activities to prevent the introduction of bovine spongiform encephalopathy into the United States.

DATES: We will consider all comments that we receive on or before June 27, 2017.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0033.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2017–0033, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket

may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0033* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations to prevent the introduction of bovine spongiform encephalopathy into the United States, contact Dr. Alexandra MacKenzie, Senior Staff Veterinarian, Live Animal Imports, NIES, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737–1236; 301–851–3411; and Dr. Magde S. Elshafie, Senior Staff Veterinary Medical Officer, NIES, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737, 301–851–3300. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at 301–851–2483.

SUPPLEMENTARY INFORMATION:

Title: Bovine Spongiform Encephalopathy; Importation of Animals and Animal Products.

OMB Control Number: 0579–0393.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Animal Health Protection Act (7 U.S.C. 8301 *et seq.*) authorizes the Secretary of Agriculture to, among other things, prohibit or restrict the importation and interstate movement of animals and animal products into or through the United States to prevent the introduction and dissemination of animal diseases and pests.

To guard against the introduction of animal diseases, the Animal and Plant Health Inspection Service (APHIS) regulates the importation of animals and animal products into the United States. The regulations in 9 CFR parts 92, 93, 94, 95, and 96 govern the importation of certain animals, birds, poultry, meat, and other animal products and byproducts into the United States to prevent the introduction of various animal diseases, including bovine spongiform encephalopathy (BSE), a chronic degenerative disease that affects the central nervous system of cattle.

Section 92.5 of the regulations provides that all countries of the world are considered by APHIS to be in one of three BSE risk categories: Negligible risk, controlled risk, or undetermined risk. These risk categories are defined in § 92.1. Any region that is not classified by APHIS as presenting either negligible risk or controlled risk for BSE is considered to present an undetermined risk. Under the regulations, APHIS may classify a region for BSE in one of two ways. One way is for countries that have not received a risk classification from the World Organization for Animal Health (OIE) to request classification by APHIS. The other way is for APHIS to concur with the classification given to a country by the OIE.

To ensure BSE is not introduced into the United States, the regulations place specific conditions on the importation of animals and animal products. These requirements necessitate the use of several information collection activities, including, but not limited to, certifications, official identification, request for and retention of classification as negligible or controlled risk, declarations of importation, import and export certificates, applications, import and movement permits, agreements, certification statements, seals, notifications, and recordkeeping.

The information collection requirements above are currently approved by the Office of Management and Budget (OMB) under OMB control numbers 0579–0393 (Bovine Spongiform Encephalopathy; Importation of Bovines and Bovine Products) and 0579–0234 (Bovine Spongiform Encephalopathy; Importation of Animals and Animal Products). After OMB approves this combined information collection package (0579–0393), APHIS will retire OMB control number 0579–0234. We have also updated the title of this information collection to ''Bovine Spongiform Encephalopathy; Importation of Animals and Animal Products.''

We are asking the OMB to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.52 hours per response.

Respondents: Shippers, hunters, U.S. importers of regulated animal products, herd owners (including hobby farms), salaried veterinarians of foreign nations, foreign exporters of processed animal protein and other regulated materials and products, accredited veterinarians, and slaughter facility managers.

Estimated annual number of respondents: 2,225.

Estimated annual number of responses per respondent: 238.

Estimated annual number of responses: 529,236.

Estimated total annual burden on respondents: 275,743 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 25th day of April 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–08728 Filed 4–27–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0004]

Notice of Request for Reinstatement of an Information Collection; Importation of Ruminant and Swine Hides, Bird Trophies, and Deer Hides

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Reinstatement of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a reinstatement of an information collection associated with the importation of ruminant and swine hides, bird trophies, and deer hides.

DATES: We will consider all comments that we receive on or before June 27, 2017.

ADDRESSES: You may submit comments by either of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0004.*

• *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2017–0004, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0004* or in our reading Room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the importation of ruminant and swine hides, bird trophies, and deer hides, contact Dr. Lisa Dixon, Animal Products Import Director, NIES, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737; (301) 851–3373. Copies of this information collection can be obtained from Ms. Kimberly Hardy, the APHIS Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Importation of Ruminant and Swine Hides, Bird Trophies, and Deer Hides.

OMB Control Number: 0579–0307.

Type of Request: Reinstatement of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture is authorized, among other things, to prohibit or restrict the importation and interstate movement of animals and animal products to prevent the introduction into and dissemination within the United States of livestock diseases and pests. To carry out this mission, APHIS regulates the importation of animals and animal products into the United States. The regulations are contained in title 9, parts 91 through 99, of the Code of Federal Regulations (CFR).

The regulations in 9 CFR part 95 (referred to below as the regulations) prohibit or restrict the importation of specified animal products into the United States to prevent the introduction into the U.S. livestock population of certain contagious animal diseases. Sections 95.16 and 95.17 of the regulations contain, among other things, specific processing, recordkeeping, and certification requirements for untanned hides and skins and bird trophies.

The regulations require that shipments of hides be accompanied by certificates showing their origin and certifying that the hides are from areas free of certain animal diseases. Shipments of ruminant hides from Mexico must be accompanied by written statements indicating that the hides were frozen for 24 hours and treated for ticks. Shipments of bird trophies must be accompanied by certificates of origin certifying that the trophies are from regions free of exotic Newcastle disease and highly pathogenic avian influenza. These activities help ensure that the products do not harbor disease or ticks.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public reporting burden for this collection of information is estimated to average 0.2 hours per response.

Respondents: National government officials of the exporting country, owners of untanned ruminant and swine hides, and importers of untanned ruminant and swine hides.

Estimated number of respondents: 264.

Estimated number of responses per respondent: 2.59.

Estimated annual number of responses: 683.

Estimated total annual burden on respondents: 137 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 24th day of April 2017.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–08605 Filed 4–27–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0021]

General Conference Committee of the National Poultry Improvement Plan; Meeting

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of meeting.

SUMMARY: We are giving notice of a meeting of the General Conference Committee of the National Poultry Improvement Plan.

DATES: The General Conference Committee meeting will be held on May 18, 2017, from 7:30 a.m. to 12 p.m.

ADDRESSES: The General Conference Committee meeting will be held at the Doubletree by Hilton, 363 Maine Mall Road, Portland, ME 04106.

FOR FURTHER INFORMATION CONTACT: Dr. Denise Brinson, Senior Coordinator, National Poultry Improvement Plan, VS, APHIS, USDA, 1506 Klondike Road, Suite 101, Conyers, GA 30094; (770) 922–3496.

SUPPLEMENTARY INFORMATION: The General Conference Committee (the Committee) of the National Poultry Improvement Plan, representing cooperating State agencies and poultry industry members, serves an essential function by acting as liaison between the poultry industry and the Department in matters pertaining to poultry health.

Topics for discussion at the upcoming meeting include:

1. National Veterinary Services Laboratories (NVSL) Avian Influenza Update.
2. Animal and Plant Health Inspection Service/Veterinary Services Update.
3. Compartmentalization Program for Primary Breeders.
4. NVSL Salmonella Update.
5. New Diagnostic Tests.

The meeting will be open to the public. However, due to time constraints, the public will not be allowed to participate in the discussions during the meeting. Written statements on meeting topics may be filed with the Committee before or after the meeting by sending them to the person listed under **FOR FURTHER INFORMATION CONTACT**. Written statements may also be filed at the meeting. Please refer to Docket No. APHIS–2017–0021 when submitting your statements.

This notice of meeting is given pursuant to section 10 of the Federal Advisory Committee Act (5 U.S.C. App. 2).

Done in Washington, DC, this 24th day of April 2017.

Jere L. Dick,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–08601 Filed 4–27–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2017–0032]

Notice of Request for Extension of Approval of an Information Collection; Credit Account Approval for Reimbursable Services

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request an extension of approval of an information collection associated with credit account approval for reimbursable services.

DATES: We will consider all comments that we receive on or before June 27, 2017.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0032.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–20173–0032, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2017-0032* or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on credit account approval for reimbursable services, contact Mrs. Kris Caraher, Accountant, Financial Management Division, APHIS, 4700 River Road Unit 55, Riverdale, MD 20737; (301) 851–2834. For copies of more detailed information on the information collection, contact Ms. Kimberly Hardy, APHIS' Information Collection Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION:

Title: Credit Account Approval for Reimbursable Services.

OMB Control Number: 0579–0055.

Type of Request: Extension of approval of an information collection.

Abstract: The Animal and Plant Health Inspection Service (APHIS) provides the services of a Federal inspector to clear imported and exported agricultural commodities for animal and plant health purposes. These services are paid for by user fees during regular working hours. If an importer wishes to have shipments cleared at other hours, such services will usually be provided on a reimbursable overtime basis, unless already covered by a user fee. Exporters wishing cargo to be certified during nonworking hours may also utilize this procedure.

Many importers and exporters who require inspection services are repeat customers who request that APHIS bill them. The Agency needs to collect certain information to conduct a credit check on prospective applicants to ensure creditworthiness prior to extending credit services and to prepare billings. Also, the Debt Collection Improvement Act of 1996, as amended (31 U.S.C. 3332), requires that agencies collect tax identification numbers from all persons doing business with the Government for purposes of collecting delinquent debts. APHIS Form 192 (Application for Credit Account) is used to collect this information and must be completed before credit is extended.

We are asking the Office of Management and Budget (OMB) to approve our use of this information collection activity for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the 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, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of Burden: The public reporting burden for this collection of information is estimated to average 0.25 hours per response.

Respondents: Importers, exporters, or brokers who wish to set up an account for billing of inspection services provided during nonworking hours.

Estimated Annual Number of Respondents: 261.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Annual Number of Responses: 261.

Estimated Total Annual Burden on Respondents: 65 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 25th day of April 2017.

Michael C. Gregoire,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2017–08727 Filed 4–27–17; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

National Advisory Committee for Implementation of the National Forest System Land Management Planning Rule

AGENCY: Forest Service, USDA.

ACTION: Notice of meetings.

SUMMARY: The National Advisory Committee for Implementation of the National Forest System Land Management Planning Rule Committee (Committee) will meet in Houston, Texas. Attendees may also listen via webinar and conference call. The Committee operates in compliance with the Federal Advisory Committee Act (FACA). Committee information can be found by visiting the Committee's Web site at: *http://www.fs.usda.gov/main/planningrule/committee.*

DATES: The meetings will be held in-person and streamed via webinar/conference call on the following dates and times:

- Tuesday, May 9, 2017 from 8:30 a.m. to 5:00 p.m. CST.
- Wednesday, May 10, 2017 from 8:30 a.m. to 5:00 p.m. CST.
- Thursday, May 11, 2017 from 8:30 a.m. to 1:00 p.m. CST.

All meetings are subject to cancellation. For updated status of meetings prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Woodlands Waterway Marriott Hotel and Convention Center, 1601 Lake Robbins Drive, The Woodlands, Texas. For anyone who would like to attend via webinar and/or conference call, please visit the Web site listed above or contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the USDA Forest Service Washington Office—Yates Building. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Crystal Merica, Committee Coordinator by phone at 202–205–3562, or by email at *ckmerica@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to provide:

1. Continued deliberations on formulating advice for the Secretary,
2. Discussion of Committee work group findings,
3. Hearing public comments, and
4. Administrative tasks.

This meeting is open to the public. The agenda will include time for people to make oral comments of three minutes or less. Individuals wishing to make an oral comment should submit a request in writing by May 5, 2017, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Committee may file written statements with the Committee's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Crystal Merica, USDA Forest Service, Ecosystem Management Coordination, 201 14th Street SW., Mail Stop 1104, Washington, DC 20250–1104, or by email at *ckmerica@fs.fed.us.* The agenda and summary of the meeting will be posted on the Committee's Web site within 21 days of the meeting.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: April 13, 2017.

Glenn Casamassa,

Associate Deputy Chief, National Forest System.

[FR Doc. 2017–08555 Filed 4–27–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Black Hills National Forest Advisory Board (Board) will meet in Rapid City, South Dakota. The Board is established consistent with the Federal Advisory Committee Act of 1972, the Forest and Rangeland Renewable Resources Planning Act of 1974, the National Forest Management Act of 1976, and the Federal Public Lands Recreation Enhancement Act. Additional information concerning the Board, including the meeting summary/minutes, can be found by visiting the Board's Web site at: *http://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees.*

DATES: The meeting will be held on Wednesday, May 17, 2017, at 1:00 p.m.

All meetings are subject to cancellation. For updated status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Forest Service Center, 8221 Mount Rushmore Road, Rapid City, South Dakota.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses, when provided, are placed in the record and available for public inspection and copying. The public may inspect comments received at the Black Hills National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Scott Jacobson, Committee Coordinator, by phone at 605–440–1409 or by email at *sjjacobson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to provide:

(1) 2017 Recreation Event Permits;
(2) Information Topic: National Forest System Trails Stewardship Act;
(3) Black Hills Resilient Landscape Project update;
(4) Teckla Osage 230 kV Powerline Update;
(5) Non-motorized Trails—Working Group update; and
(6) Black Hills National Forest Mobile App;

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should submit a request in writing by May 8, 2017, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the Board may file written statements with the Board's staff before or after the meeting. Written comments and time requests for oral comments must be sent to Scott Jacobson, Black Hills National Forest Supervisor's Office, 1019 North Fifth Street, Custer, South Dakota 57730; by email to *sjjacobson@fs.fed.us,* or via facsimile to 605–673–9208.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices,

or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: April 13, 2017.

Glenn Casamassa,

Associate Deputy Chief, National Forest System.

[FR Doc. 2017–08556 Filed 4–27–17; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–122–858]

Certain Softwood Lumber Products From Canada: 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 certain softwood lumber products (softwood lumber) from Canada. The period of investigation is January 1, 2015, through December 31, 2015.

DATES: Effective April 28, 2017.

FOR FURTHER INFORMATION CONTACT: Lana Nigro (Tolko), Toby Vandall (Canfor), Justin Neuman (JDIL), Patricia Tran (West Fraser), and Kristen Johnson (Resolute), AD/CVD Operations, Offices I and III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–1779, (202) 482–1664, (202) 482–0486, (202) 482–1503, and (202) 482–4793, 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 December 22, 2017.[1] On February 2, 2017, the Department postponed the preliminary determination of this investigation and the revised deadline is now April 24, 2017.[2]

On April 13, 2017, the Department preliminarily determined that critical circumstances exist with respect to certain companies.[3] For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[4] 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 softwood lumber from Canada. 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,[5] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage, (*i.e.,* scope).[6] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice* as well as on additional language proposed by the Department. On March 29, 2017, a letter presenting a proposal for company exclusions was filed on behalf of the Government of Canada (GOC), Canadian provincial and territorial governments, as well as the Canadian industry associations.[7] The Department finds that it lacks the authority to conduct the requested company exclusion process in the context of this countervailing duty investigation (CVD) on softwood lumber from Canada.[8]

With respect to other proposed scope exclusions, including the request to exclude merchandise from certain provinces, the Department is inviting comments on those proposed exclusions and will incorporate the decisions into the final CVD and AD determinations after considering any relevant comments submitted in case and rebuttal briefs. Comments on any proposed scope exclusions are due no later than seven days of publication of this notice in the **Federal Register**. Please note that the Department will not accept any new factual information in these submissions. The Department intends to set the same deadline on the record of the companion AD investigation. For further information regarding proposed scope excusions, *see* the Preliminary Decision Memorandum accompanying this notice.

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.[9]

Alignment

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 determination in the companion AD

[1] *See Certain Softwood Lumber Products from Canada: Initiation of Countervailing Duty Investigation,* 81 FR 93897 (December 22, 2016) (*Initiation Notice).*

[2] *See Certain Softwood Lumber Products from Canada: Postponement of Preliminary Determination in the Countervailing Duty Investigation,* 82 FR 9055 (February 2, 2017).

[3] *See Antidumping and Countervailing Duty Investigations of Certain Softwood Lumber Products from Canada: Preliminary Determinations of Critical Circumstances,* signed April 13, 2017 (*Preliminary CC Determination*).

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Determination in the Countervailing Duty Investigation of Certain Softwood Lumber Products from Canada,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

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

[6] *See Initiation Notice.*

[7] *See* letter from the Government of Canada, ''Proposal for Company Exclusions,'' dated March 29, 2017; *see also* letter from the Government of New Brunswick, ''Softwood Lumber from Canada: Proposals for Product- or Company-Based Exclusions from the CVD Investigation,'' dated March 31, 2017; letter from Government of British Columbia, ''Certain Softwood Lumber Products from Canada: Comments in Support of Clarifying and Exclusionary Language Proposed by Canada Regarding the Scope of these Investigations,'' dated April 3, 2017.

[8] *See* Memorandum from Gary Taverman, Associate Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, dated April 24, 2017.

[9] *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.

investigation of softwood lumber from Canada based on a request made by the petitioner.[10] Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than September 6, 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 calculated individually estimated countervailable subsidy rates for Canfor Corporation (Canfor), J.D. Irving, Limited (JDIL),[11] Resolute FP Canada Inc. (Resolute), Tolko Marketing and Sales Ltd. (Tolko), and West Fraser Timber Co. Ltd. (West Fraser), that are not zero, *de minimis,* or based entirely on facts otherwise available. The Department calculated the all-others rate using a weighted-average of the individually estimated subsidy rates calculated for the examined respondents using each company's business proprietary data for the merchandise under consideration.[12]

Preliminary Determination

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

Company	Subsidy rate (%)
Canfor Corporation and its cross-owned affiliates [13]	20.26
J.D. Irving, Limited and its cross-owned affiliates [14]	3.02
Resolute FP Canada Inc. and its cross-owned affiliates [15]	12.82
Tolko Marketing and Sales Ltd. and its cross-owned affiliates [16]	19.50
West Fraser Mills Ltd. and its cross-owned affiliates [17]	24.12
All-Others:	19.88

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.

Section 703(e)(2) of the Act provides that, given an affirmative determination of critical circumstances, any suspension of liquidation shall apply to unliquidated entries of merchandise entered, or withdrawn from warehouse, for consumption on or after the later of (a) the date which is 90 days before the date on which the suspension of liquidation was first ordered, or (b) the date on which notice of initiation of the investigation was published. As discussed in *Preliminary CC Determination,* the Department preliminarily found that critical circumstances exist for imports of subject merchandise produced and/or exported by JDIL and the companies subject to the All-Others rate.[18] Accordingly, in accordance with section 703(e)(2)(A) of the Act, the suspension of liquidation shall apply to unliquidated entries of merchandise from the exporters/producers identified in this paragraph that were entered, or withdrawn from warehouse, for consumption on or after the date which is 90 days before the publication of this notice.

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 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.[19] 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

[10] *See* Letter from the petitioner, ''Certain Softwood Lumber Products from Canada: Request for Alignment of the Countervailing Duty Final Determination with the Companion Antidumping Duty Final Determination'' dated April 13, 2017.

[11] *See MacLean-Fogg Co.* v. *United States,* 753 F.3d 1237 (Fed. Cir. 2014) (holding that voluntary respondents are considered ''individually investigated'' for purposes of calculating the all-others rate). The Department accepted JDIL as a voluntary respondent in this investigation.

[12] *See* Memorandum to the File, ''Calculation of the ''All-Others'' Rate in the Preliminary Determination of the Countervailing Duty Investigation of Softwood Lumber Products from Canada'' (April 24, 2017).

[13] The Department preliminarily has found the following companies to be cross-owned with Canfor Corporation: Canadian Forest Products, Ltd., and Canfor Wood Products Marketing, Ltd.

[14] The Department preliminarily has found the following companies to be cross-owned with JDIL: Miramichi Timber Holdings Limited, The New Brunswick Railway Company, Rothesay Paper Holdings Ltd., St. George Pulp & Paper Limited, and Irving Paper Limted.

[15] The Department preliminarily has found the following companies to be cross-owned with Resolute: Resolute Growth Canada Inc., Resolute Sales Inc., Abitibi-Bowater Canada Inc., Bowater Canadian Ltd., Resolute Forest Products Inc., Produits Forestiers Maurice S.E.C., and 9192–8515 Quebec Inc.

[16] The Department preliminarily has found the following companies to be cross-owned with Tolko: Tolko Industries Ltd., and Meadow Lake OSB Limited Partnership.

[17] The Department preliminarily has found the following companies to be cross-owned with West Fraser: West Fraser Timber Co. Ltd., West Fraser Alberta Holdings, Ltd., Blue Ridge Lumber Inc., Manning Forest Products, Ltd., Sunpine Inc., and Sundre Forest Products Inc.

[18] *See Antidumping and Countervailing Duty Investigations of Certain Softwood Lumber Products from Canada: Preliminary Determinations of Critical Circumstances,* signed April 12, 2017 *(Preliminary CC Determination).*

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

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 and interested parties will be notified by the Department, via letter. 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: April 24, 2017.

Ronald K. Lorentzen,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is softwood lumber, siding, flooring and certain other coniferous wood (''softwood lumber products''). The scope includes:

- Coniferous wood, sawn, or chipped lengthwise, sliced or peeled, whether or not planed, whether or not sanded, or whether or not finger-jointed, of an actual thickness exceeding six millimeters.
- Coniferous wood siding, flooring, and other coniferous wood (other than moldings and dowel rods), including strips and friezes for parquet flooring, that is continuously shaped (including, but not limited to, tongued, grooved, rebated, chamfered, V-jointed, beaded, molded, rounded) along any of its edges, ends, or faces, whether or not planed, whether or not sanded, or whether or not end-jointed.
- Coniferous drilled and notched lumber and angle cut lumber.
- Coniferous lumber stacked on edge and fastened together with nails, whether or not with plywood sheathing.
- Components or parts of semi-finished or unassembled finished products made from subject merchandise that would otherwise meet the definition of the scope above.

Softwood lumber product imports are generally entered under Chapter 44 of the Harmonized Tariff Schedule of the United States (''HTSUS''). This chapter of the HTSUS covers ''Wood and articles of wood.'' Softwood lumber products that are subject to this investigation are currently classifiable under the following ten-digit HTSUS subheadings in Chapter 44: 4407.10.01.01; 4407.10.01.02; 4407.10.01.15; 4407.10.01.16; 4407.10.01.17; 4407.10.01.18; 4407.10.01.19; 4407.10.01.20; 4407.10.01.42; 4407.10.01.43; 4407.10.01.44; 4407.10.01.45; 4407.10.01.46; 4407.10.01.47; 4407.10.01.48; 4407.10.01.49; 4407.10.01.52; 4407.10.01.53; 4407.10.01.54; 4407.10.01.55; 4407.10.01.56; 4407.10.01.57; 4407.10.01.58; 4407.10.01.59; 4407.10.01.64; 4407.10.01.65; 4407.10.01.66; 4407.10.01.67; 4407.10.01.68; 4407.10.01.69; 4407.10.01.74; 4407.10.01.75; 4407.10.01.76; 4407.10.01.77; 4407.10.01.82; 4407.10.01.83; 4407.10.01.92; 4407.10.01.93; 4409.10.05.00; 4409.10.10.20; 4409.10.10.40; 4409.10.10.60; 4409.10.10.80; 4409.10.20.00; 4409.10.90.20; 4409.10.90.40; and 4418.90.25.00.

Subject merchandise as described above may also be classified as stringers, square cut box-spring-frame components, fence pickets, truss components, pallet components, flooring, and door and window frame parts under the following ten-digit HTSUS subheadings in Chapter 44: 4415.20.40.00; 4415.20.80.00; 4418.90.46.05; 4418.90.46.20; 4418.90.46.40; 4418.90.46.95; 4421.90.70.40; 4421.90.94.00; and 4421.90.97.80.

Although these HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments and Requests for Exclusion
IV. Scope of the Investigation
V. Subsidies Valuation
VI. Analysis of Programs
VII. Calculation of the All-Others Rate
VIII. ITC Notification
IX. Disclosure and Public Comment
X. Verification
XI. Conclusion

[FR Doc. 2017–08673 Filed 4–27–17; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE201

Deepwater Horizon Oil Spill; Notice of Intent To Conduct Strategic Restoration Planning That Considers Existing Projects for Barataria Bay, Louisiana and To Initiate Restoration Planning With Regard to the Mid-Barataria Sediment Diversion

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

ACTION: Notice of intent to prepare a Strategic Restoration Plan for Barataria Basin, Louisiana, and to initiate restoration planning with regard to the Mid-Barataria Sediment Diversion.

SUMMARY: NOAA, on behalf of the Federal and state natural resource trustees for the Louisiana Trustee Implementation Group (Louisiana TIG Trustees) for the *Deepwater Horizon* (DWH) oil spill, is initiating two actions with this notice.

First, the Louisiana TIG Trustees are announcing their intent to prepare a Strategic Restoration Plan for Barataria Basin, Louisiana, pursuant to the *Deepwater Horizon* Programmatic Damage Assessment and Restoration Plan and Programmatic Environmental Impact Statement (PDARP/PEIS) (Feb 2016). This Barataria Basin Strategic Restoration Plan, referred to herein as the Phase I Plan, will consider identifying habitat restoration components of the Louisiana Draft 2017 Coastal Master Plan (draft 2017 CMP) to serve as an Oil Pollution Act (OPA) Strategic Restoration Plan for restoring wetland, coastal, and nearshore habitat in Barataria Basin, Louisiana, consistent with OPA and with the Trustees' PDARP/PEIS. The Louisiana TIG Trustees will consider whether a combination of Barataria Basin habitat restoration projects in the draft 2017 CMP constitutes a preferred alternative, among other feasible alternatives, for fulfilling OPA's and the PDARP/PEIS's intent for the trustees to address ecosystem-level injuries and to restore, rehabilitate, replace, or acquire the equivalent of the injured wetland, coastal and nearshore habitat resources and services and compensate for interim losses of those resources from the *Deepwater Horizon* oil spill. Any projects or suites of projects that are ultimately included in the resulting Strategic Restoration Plan will be further analyzed in subsequent phased

restoration plans and their accompanying environmental impact analyses as required by OPA, NEPA, and the Trustees' PDARP/PEIS.

Second, the Louisiana TIG Trustees are providing notice of the initiation of restoration planning, including analysis of the Mid-Barataria Sediment Diversion and appropriate alternatives to partially restore ecosystem and wetland, coastal and nearshore habitat resources and services in Barataria Basin, and compensate for interim losses of those resources and services, injured by the *Deepwater Horizon* oil spill. This potential Mid-Barataria Sediment Diversion Restoration Plan is referred to herein as the Phase 2 Plan. The Louisiana TIG Trustees are evaluating whether the Mid-Barataria Sediment Diversion is an appropriate project for restoring injuries from the *Deepwater Horizon* oil spill, and the Louisiana TIG Trustees anticipate that their decision in that regard will be informed by the results of the Phase 1 Plan. Further, by separate Supplemental Notice of Intent, the U.S. Army Corps of Engineers (USACE) is announcing its intent, as part of its review under section 404 of the Clean Water Act, section 10 of the Rivers and Harbors Act of 1899 (''Section 10/404''), and section 408 of the Rivers and Harbors Appropriation Act of 1899, as amended (''Section 408''), to prepare a draft Environmental Impact Statement (''EIS'') pursuant to the National Environmental Policy Act of 1969 (NEPA). USACE will use the EIS, in conjunction with other relevant materials, to inform decision-making on the Department of the Army, section 10/404 and section 408 requests for permits and permissions for the Mid-Barataria Sediment Diversion. In order to capitalize on that ongoing environmental review, the Louisiana TIG Trustees are, at this time, requesting input on the scope of the USACE EIS via the process outlined in the coordinated USACE NOI. The LA TIG is supporting the development of the USACE EIS with the potential for the EIS to serve as the EIS for the Phase 2 Restoration Plan. The Louisiana TIG Trustees will additionally seek formal public involvement in the Phase 2 Draft Restoration Plan process in accordance with applicable Federal regulations and consistent with the PDARP/PEIS.

DATES: The date, time, and location of the formal public comment portion of this scoping period for the USACE EIS are yet to be determined. This information will be made available to the public on the DWH Trustees' Louisiana TIG Web page, (*http://www.gulfspillrestoration.noaa.gov/restoration-areas/louisiana*), the USACE–MVN's Web page (*http://www.mvn.usace.army.mil/Missions/Regulatory/Permits/Mid-Barataria-Sediment-Diversion-EIS/*), and via a future **Federal Register** notice. The Louisiana TIG Trustees will additionally seek formal public involvement in the Phase 2 Draft Restoration Planning process in accordance with applicable federal regulations and consistent with the PDARP/PEIS. The date, time, and location of the formal public involvement period for the Phase 2 Restoration Plan process are yet to be determined. This information will be made available to the public via a future **Federal Register** notice and on the DWH Trustees' Louisiana TIG Web page, (*http://www.gulfspillrestoration.noaa.gov/restoration-areas/louisiana*).

FOR FURTHER INFORMATION CONTACT:

- NOAA: Mel Landry, *gulfspill.restoration@noaa.gov.*
- LOUISIANA: Liz Williams, *LATIG@la.gov.*

SUPPLEMENTARY INFORMATION:

Background

On April 20, 2010, the mobile offshore drilling unit, *Deepwater Horizon,* which was being used to drill a well for BP Exploration and Production Inc. (BP), in the Macondo prospect (Mississippi Canyon 252—MC252), exploded, caught fire and subsequently sank in the Gulf of Mexico, resulting in an unprecedented volume of oil and other discharges from the rig and from the wellhead on the seabed. The *Deepwater Horizon* oil spill is the largest oil spill in U.S. history, discharging millions of barrels of oil over a period of 87 days. In addition, well over one million gallons of dispersants were applied to the waters of the spill area in an attempt to disperse the spilled oil. An undetermined amount of natural gas was also released to the environment as a result of the spill.

The *Deepwater Horizon* State and Federal natural resource trustees (DWH Trustees) conducted the natural resource damage assessment (NRDA) for the *Deepwater Horizon* oil spill under the Oil Pollution Act 1990 (OPA; 33 U.S.C. 2701 *et seq.*). Pursuant to OPA, Federal and State agencies act as trustees on behalf of the public to assess natural resource injuries and losses and to determine the actions required to compensate the public for those injuries and losses. OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship, including the loss of use and services from those resources from the time of injury until the time of restoration to baseline (the resource quality and conditions that would exist if the spill had not occurred) is complete.

Upon completion of the NRDA, the DWH Trustees reached and finalized a settlement of their natural resource damage claims with BP in a Consent Decree [1] approved by the United States District Court for the Eastern District of Louisiana. Pursuant to that Consent Decree, restoration projects in Louisiana are now chosen and managed by the Louisiana TIG. The Louisiana TIG is composed of the following Trustees:

- U.S. Department of the Interior, as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;
- National Oceanic and Atmospheric Administration, on behalf of the U.S. Department of Commerce;
- U.S. Department of Agriculture;
- U.S. Environmental Protection Agency;
- Louisiana Coastal Protection and Restoration Authority;
- Louisiana Department of Natural Resources;
- Louisiana Department of Environmental Quality;
- Louisiana Oil Spill Coordinator's Office; and
- Louisiana Department of Wildlife and Fisheries.

These restoration planning activities are proceeding in accordance with the PDARP/PEIS. Information on the Restoration Type: Restore Wetlands, Coastal, and Nearshore Habitats, as well as the OPA criteria against which projects will be evaluated, can be found in the PDARP/PEIS (*http://www.gulfspillrestoration.noaa.gov/restoration-planning/gulf-plan*) and in the Overview of the PDARP/PEIS (*http://www.gulfspillrestoration.noaa.gov/restoration-planning/gulf-plan*).

Overview of Action

The first action taken in this Notice is to inform the public that the Louisiana TIG Trustees intend to prepare a Strategic Restoration Plan for Barataria Basin pursuant to the PDARP/PEIS and OPA. The Trustees intend to consider the use of wetlands, coastal and nearshore habitat projects or suites of projects from the Draft 2017 CMP as the basis for that Strategic Restoration Plan. Those Draft 2017 CMP projects will be

[1] *https://www.justice.gov/enrd/file/838066/download.*

evaluated under applicable authorities in comparison to other feasible alternatives for restoring wetland, coastal and nearshore habitat and services injured by the *Deepwater Horizon* oil spill.

The PDARP/PEIS provides TIGs the option to prepare strategic restoration plans ''to focus and sequence priorities within a Restoration Area'' and to ''consider resources at the ecosystem level, while implementing restoration at the local level.'' (PDARP Section 7.3.1). In addition, the NRDA implementing regulations specifically allow trustees to consider the use of existing projects (15 CFR 990.56), such as those identified in the draft 2017 CMP. The Louisiana TIG is proposing that this Strategic Restoration Plan will focus on wetland, coastal, and nearshore habitat restoration type projects in the Barataria Basin restoration area because the PDARP/PEIS found that Barataria Basin experienced some of the heaviest and persistent oiling from the DWH spill and because the Basin supports very high primary and secondary production that contributes to the overall health of the northern Gulf of Mexico ecosystem.

The Louisiana TIG anticipates that the Strategic Restoration Plan for Barataria Basin will select for further funding and development most, if not all, of the remaining projects applicable under the ''Wetlands, Coastal, and Nearshore Habitats'' Restoration Type to be implemented in the Barataria Basin by the Louisiana TIG under the PDARP/PEIS. Developing such a strategic plan for much of Barataria Basin restoration for this Restoration Type will allow the Louisiana TIG to identify a suite of projects that, taken together, best achieve the ''integrated ecosystem restoration'' called for in Chapter 5 of the PDARP/PEIS. A decision in the strategic plan to fund further development of projects will not be a final decision by the Louisiana TIG to proceed with implementation of those projects. Information about the ''Wetlands, Coastal, and Nearshore Habitats'' Restoration Type as well as the OPA criteria against which projects will be evaluated can be found in the PDARP/PEIS.

The second action taken in this Notice is to inform the public of the Louisiana TIG Trustees' initiation of restoration planning, which will include the preparation of a restoration plan (the Phase 2 Plan) that evaluates the Mid-Barataria Sediment Diversion project as a means of restoring injured wetland, coastal and nearshore resources and services in Barataria Basin to restore for injuries resulting from the *Deepwater Horizon* oil spill. The Louisiana TIG began this restoration planning effort on March 28, 2017, by requesting project ideas from the public. At that time, the Louisiana TIG requested project ideas that could benefit wetlands, coastal, and nearshore habitats in the Barataria Basin, the estuary most heavily impacted by the DWH oil spill. That notice was published on the Louisiana TIG Web site: (*http://www.gulfspillrestoration.noaa.gov/restoration-areas/louisiana*).

The Mid-Barataria Sediment Diversion, a large-scale sediment diversion, is one of the projects proposed in the Draft 2017 CMP. While the Louisiana TIG Trustees have not yet decided to move forward with a restoration plan for a Mid-Barataria Sediment Diversion, the project currently is undergoing engineering and design and supplemental scoping for preparation of an EIS, led by the USACE based on permit applications submitted by the Louisiana Coastal Protection and Restoration Authority pursuant to the provisions of section 404 of the Clean Water Act, section 10 of the Rivers and Harbors Appropriation Act of 1899, and section 14 of the Rivers and Harbors Appropriation Act of 1899, as amended. To facilitate the potential consideration of this project under OPA, it is the intent of the state and Federal Louisiana TIG Trustees to assist the USACE in the preparation of the EIS for the Mid-Barataria Sediment Diversion. In addition, the Federal Louisiana TIG Trustees are cooperating agencies with the USACE for the preparation of that EIS. In a coordinated **Federal Register** notice, the USACE is issuing a supplemental Notice of Intent regarding the scope of the EIS for the project, including the potential for the EIS to inform a NRDA decision on restoration planning in which case the Louisiana TIG Trustees would adopt the EIS for such purposes. The Louisiana TIG is seeking to facilitate public involvement regarding the EIS, and encourages interested person and entities to submit comments in response to the USACE EIS process regarding the Mid-Barataria Sediment Diversion.

Next Steps

With regard to the Phase 1 Plan, the Louisiana TIG Trustees will proceed with consideration of whether a combination of projects in the Draft 2017 CMP provides a basis for a Strategic Restoration Plan for Barataria Basin.

With regard to the potential Phase 2 Plan, the Louisiana TIG Trustees will review all public input received as part of the USACE's scoping process for the preparation of an EIS for the proposed Mid-Barataria Sediment Diversion project as the Trustees work with the USACE to prepare an EIS that supports both the USACE regulatory decisions and OPA restoration planning decisions. The Louisiana TIG Trustees will additionally seek formal public involvement in the Phase 2 Draft Restoration Plan process in accordance with applicable federal regulations and consistent with the PDARP/PEIS.

Administrative Record

The documents included in the Administrative Record can be viewed electronically at the following location: *http://www.doi.gov/deepwaterhorizon/adminrecord.*

The Trustees opened a publicly available Administrative Record for the NRDA for the *Deepwater Horizon* oil spill, including restoration planning activities, concurrently with publication of the 2011 Notice of Intent (NOI) to Begin Restoration Scoping and Prepare a Gulf Spill Restoration Planning PEIS (pursuant to 15 CFR 990.45). The Administrative Record includes the relevant administrative records since its date of inception. This Administrative Record is actively maintained and available for public review.

Authority

The authority of this action is the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.)* and the implementing NRDA regulations found at 15 CFR part 990 and NEPA (42 U.S.C. 4321 *et seq.*).

Dated: April 21, 2017.

Carrie Selberg,

Deputy Director, Office of Habitat Conservation, National Marine Fisheries Service.

[FR Doc. 2017–08591 Filed 4–27–17; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Deletion from the Procurement List.

SUMMARY: This action deletes a product from the Procurement List previously furnished by a nonprofit agency employing persons who are blind or have other severe disabilities.

DATES: Effective May 28, 2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely

Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Deletion

On 3/24/2017 (82 FR 15047), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletion from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the product listed below is no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing a small entity to furnish the product to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the product deleted from the Procurement List.

End of Certification

Accordingly, the following product is deleted from the Procurement List:

Product

NSN(s)—Product Name(s): 4610–01–117–8271—Bag, Drinking Water Storage

Mandatory Source(s) of Supply: Huntsville Rehabilitation Foundation, Huntsville, AL

Contracting Activity: Defense Logistics Agency Land and Maritime

Amy B. Jensen,

Director, Business Operations.

[FR Doc. 2017–08614 Filed 4–27–17; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List: Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products to the Procurement List that will be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities, and deletes products and a service previously furnished by such agencies.

DATES: Comments must be received on or before May 28, 2017.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Amy B. Jensen, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products listed below from the nonprofit agency employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agency listed:

Products

NSN(s)—Product Name(s):
5180–01–563–6719—Kit, Urban Operation Tools, Squad
5180–01–631–3029—Kit, Urban Operations Tools, Platoon
Mandatory Source(s) of Supply: Wiscraft, Inc., Milwaukee, WI
Mandatory for: 100% of the requirements of the U.S. Army
Contracting Activity: U.S. Army TACOM LCMC ILSC—SKOT Group
Distribution: C-List

Deletions

The following products and service are proposed for deletion from the Procurement List:

Products:

NSN(s)—Product Name(s):
7530-01-368-3491—Index Dividers, White Tabs with Black Print, January–December
Mandatory Source(s) of Supply: South Texas Lighthouse for the Blind, Corpus Christi, TX
Contracting Activities: General Services Administration, New York, NY
Department of Veterans Affairs, Strategic Acquisition Center

NSN(s)—Product Name(s):
7930–00–NIB–0210 Cleaner, Phenolic Disinfectant, Concentrate, 2 Liter
7930–01–381–5957 Cleaner, Pretreatment Carpet, Concentrate, 2 Liter
7930–01–412–1031 Cleaner, Scotchgard Bonnet, Concentrate, 2 Liter
Mandatory Source(s) of Supply: Beacon Lighthouse, Inc., Wichita Falls, TX
Contracting Activity: Department of Veterans Affairs, Strategic Acquisition Center

NSN(s)—Product Name(s): 7350–01–359–9524—Cup, Paper, Recyclable, White, 9 oz.
Mandatory Source(s) of Supply: Clovernook Center for the Blind and Visually Impaired, Cincinnati, OH
Contracting Activity: General Services Administration, Fort Worth, TX

NSN(s)—Product Name(s):
7520–01–624–9379—Pen, Roller Ball, Liquid Ink, Retractable, Needle Point, Airplane Safe, 0.5mm, Refillable, Black, EA
7520–01–624–9383—Pen, Roller Ball, Liquid Ink, Retractable, Needle Point, Airplane Safe, 0.5mm, Refillable, Blue, EA
7520–01–624–9384—Pen, Roller Ball, Liquid Ink, Retractable, Needle Point, Airplane Safe, 0.7mm, Refillable, Black, EA
7520–01–624–9385—Pen, Roller Ball, Liquid Ink, Retractable, Needle Point, Airplane Safe, 0.7mm, Refillable, Blue, EA
Mandatory Source(s) of Supply: San Antonio Lighthouse for the Blind, San Antonio, TX
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s): 7520–01–466–0485—Tray, Desk, Plastic
Mandatory Source(s) of Supply: LC Industries, Inc., Durham, NC
Contracting Activity: General Services Administration, New York, NY

NSN(s)—Product Name(s):
891500–NSH–0145—Diced Green Peppers Diced Green Peppers
891500–NSH–0146—Sliced Yellow Onions Sliced Yellow Onions
891500–NSH–0147—Cole Slaw with Carrots
Mandatory Source(s) of Supply: Employment Solutions, Inc., Lexington, KY
Contracting Activity: Department of Justice, Federal Prison System

NSN(s)—Product Name(s): MR 942—Cloth, Dish, 2 pack
Mandatory Source(s) of Supply: Lions Services, Inc., Charlotte, NC
Contracting Activity: Defense Commissary

Agency

NSN(s)—Product Name(s): 1430–01–133–8435—Bag, Storage

Mandatory Source(s) of Supply: Huntsville Rehabilitation Foundation, Huntsville, AL

Contracting Activity: Defense Logistics Agency Land and Maritime

Service

Service Type: Customization & Distribution of NRPM Service Department of the Navy, FISC Norfolk: Detachment 1322 Patterson Ave. SE. Washington Navy Yard, Washington DC

Mandatory Source(s) of Supply: Industries for the Blind, Inc., West Allis, WI

Contracting Activity: Dept of Defense/Department of the Navy

Amy B. Jensen,

Director, Business Operations.

[FR Doc. 2017–08613 Filed 4–27–17; 8:45 am]

BILLING CODE 6353–01–P

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities: Proposed Collection Revision, Comment Request: Adoption of Revised Registration Form 8–R and Cancellation of Form 3–R

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (''CFTC'' or the ''Commission'') is announcing an opportunity for public comment on the proposed revision to the collection of certain information by the Commission. Under the Paperwork Reduction Act (''PRA''), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment. The Commission revised its Form 8–R, the application form that individuals use to register with the Commission or to be listed as a principal. This notice solicits comments on the PRA implications of the revisions to Form 8–R, including comments that address the burdens associated with the modified information collection requirements of the revised Form 8–R. Additionally, this notice also solicits comments on the PRA implications of reassigning the burdens associated with the information collections requirements of Commission Form 3–R, which is no longer used, to Commission Forms 7–R and 8–R.

DATES: Comments must be submitted on or before June 27, 2017.

ADDRESSES: You may submit comments, identified by ''OMB control numbers 3038–0023 and 3038–0072; Adoption of Revised Registration Form 8–R and Cancellation of Form 3–R,'' by any of the following methods:

- The Commission's Web site, via its Comments Online process at *http://comments.cftc.gov/*. Follow the instructions for submitting comments through the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as Mail above.
- *Federal eRulemaking Portal: http://www.regulations.gov/*. Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *http://www.cftc.gov*. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in Regulation 145.9.[1]

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from *http://www.cftc.gov* that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the information collection request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

FOR FURTHER INFORMATION CONTACT: Laura Gardy, Associate Director, (202) 418–7645, *lgardy@cftc.gov;* or August A. Imholtz III, Special Counsel, (202) 418–5140, *aimholtz@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (''OMB'') for each collection of information they conduct or sponsor. ''Collection of Information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA, 44 U.S.C. 3506(c)(2)(A), requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed revision to the collections of information listed below. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.

Titles: Registration Under the Commodity Exchange Act (OMB control number 3038–0023); Registration of Swap Dealers and Major Swap Participants (OMB control number 3038–0072). This is a request for extension and revision of these currently approved information collections.

Abstract: The Commission recently revised its Form 8–R, the application form that individuals must use to register with the Commission as an associated person, floor broker, or floor trader, or to be listed as a principal. The collections of information related to Form 8–R were previously approved by OMB in accordance with the PRA and assigned OMB control numbers 3038–0023 and 3038–0072. Additionally, the Commission no longer requires individuals and entities to use Commission Form 3–R to update their registration information, which now can be updated directly on Forms 7–R or 8–R. The Commission therefore is reassigning to Forms 7–R and 8–R the information collection burdens previously associated with Commission Form 3–R. The collection of information related to Form 3–R was previously approved by OMB in accordance with the PRA and assigned OMB control number 3038–0023.

1. Form 8–R Revision

The revised Form 8–R contains several changes that increase the existing information collection burden, currently 0.8 hours, associated with Form 8–R. The Commission estimates that the changes, which are discussed below, when considered together in aggregate add a total of 0.1 burden hours to the information collection burdens associated with Form 8–R.

[1] 17 CFR 145.9.

First, in the ''Fingerprint Card Information'' section, revised Form 8–R adds two new questions. One new question addresses new requirements and exemptions thereto contained in Commission Regulation 3.21(e) applicable to non-U.S. persons. The other new question addresses the fingerprinting requirement exception for certain outside directors of registered firms. Second, in the section titled ''Disciplinary Information—Regulatory Disclosures,'' a new question was added to existing Question E. Among other things, Question E inquires whether the applicant (or an entity of which the applicant was a principal) violated, or aided and abetted the violation of, any investment-related statutes or regulations, a potential statutory basis for refusing or conditioning registration. The new question directs the applicant to disclose whether he or she has ever been found to have ''failed to supervise another person's activities under any investment-related statute or regulation.'' Third, in the section titled ''Disciplinary Information—Financial Disclosures,'' the Commission revised Question J. Prior to the revision, Question J asked whether the applicant has ''currently failed to comply with any order to pay any futures-related civil monetary penalties, restitution amounts, disgorgement amounts, reparation amounts or arbitration awards.'' As revised, Question J now inquires whether the applicant ''failed to pay any arbitration awards involving CFTC-regulated products, CFTC civil monetary penalties, CFTC restitution amounts, CFTC disgorgement amounts, or CFTC reparation amounts.''

The revised Form 8–R also contains several changes that do not alter the information collection burdens associated with Form 8–R. First, the revised Form 8–R combines into a single form two separate, existing versions of the Form 8–R, the Form 8–R ''Individual Application'' and the Form 8–R ''Floor Trader Order Enterer Individual Application,'' both of which were previously approved by OMB. In the section titled ''Sponsor Information and Registration Categories,'' the revised Form 8–R adds ''floor trader order enterer'' as a new category of persons that can be associated with a sponsor. Also in connection with this change, the revised Form 8–R includes two newly defined terms: ''entity floor trader'' and ''floor trader order enterer.'' Second, in the section titled ''Principal Information,'' the prior version of Form 8–R contained a blank space in which an applicant entered a title. In the revised Form 8–R, the space is replaced with a list of available titles for applicants to choose from. Third, NFA is simplifying the process by which it requests supplemental information and documentation regarding the applicant's criminal, regulatory or financial disclosures. The prior version of Form 8–R requested that applicants provide a written explanation of the facts and circumstances regarding any such disclosures. Applicants were also separately requested to provide NFA with copies of pertinent documents associated with each disclosure. To consolidate and modernize this process, the revised Form 8–R allows applicants to complete a separate ''Disclosure Matter Page'' for each matter, instance or event requiring disclosure and to simultaneously upload all pertinent documents associated with each disclosure. The Disclosure Matter Page provides applicants with an efficient and effective method of supplying the supplemental information and documentation that NFA requests in the normal course whenever an applicant responds affirmatively to any of the questions regarding criminal, regulatory or financial disclosures.

Lastly, the revised Form 8–R contains numerous changes to the language, formatting and organization of Form 8–R, all of which—individually and collectively—do not alter the information collection burdens associated with Form 8–R. The only changes to Form 8–R that affect the information collection burdens associated with the form are those discussed above.

2. Cancellation of Form 3–R

Commission Regulations 3.11 and 3.31 historically required entities and individuals to use Commission Form 3–R to update or correct certain types of information that originally was supplied on Commission Forms 7–R or 8–R, the registration forms for entities and individuals respectively. Regulations 3.11 and 3.31 were amended in 2012 to reflect a new practice whereby Forms 7–R and 8–R could be directly updated online, and the requirement to use Form 3–R for updates, or for any other purpose, was deleted from the Commission rules. At that time, however, the Commission did not reassign to Forms 7–R and 8–R the information collection burden associated with the Form 3–R. The Commission is doing so now.

The information collection burden associated with Form 3–R is 0.1 hours. In reassigning that burden to Forms 7–R and 8–R, the Commission believes that it is appropriate to adopt a conservative approach and assign an additional 0.1 hours each to the Form 7–R and 8–R. Accordingly, by virtue of cancelling Form 3–R, and reassigning to Forms 7–R and 8–R the information collection burdens associated with Form 3–R, the information collections burdens for Forms 7–R and 8–R each will increase by 0.1 hours. The reassignment of the information collection burden from Form 3–R to Forms 7–R and 8–R reallocates the information collection burdens within OMB control number 3038–0023, and does not increase or decrease the total information collection burden under that control number.

3. Invitation to Comment

With respect to the information collections discussed above, the CFTC invites comments on:

- Whether the proposed revision to the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed revision to the collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of collection of information on those who are to respond, including through the further use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology; *e.g.,* permitting electronic submission of responses.

Burden Statement: As explained above, the Commission believes that the revisions to Form 8–R increase the information collection burdens associated with that Form under OMB control numbers 3038–0023 and 3038–0072. Additionally, the Commission believes that reassigning to Forms 7–R and 8–R the information collection burdens formerly associated with Commission Form 3–R reallocates the information collection burdens within OMB control number 3038–0023, and therefore does not increase or decrease the total information collection burden under that control number.

The Commission estimates the burden of this collection of information under OMB control number 3038–0023 to be:

Respondents/Affected Entities: (1) Users of Form 7–R, specifically futures commission merchants, retail foreign exchange dealers, introducing brokers, commodity trading advisors, commodity pool operators, floor trader firms, and

leverage transaction merchants; and (2) users of Form 8–R, specifically (i) associated persons of futures commission merchants, retail foreign exchange dealers, introducing brokers, commodity trading advisors, commodity pool operators, and leverage transaction merchants; floor brokers; (ii) principals of futures commission merchants, retail foreign exchange dealers, introducing brokers, commodity trading advisors, commodity pool operators, floor trader firms, or leverage transaction merchants; (iii) floor brokers; (iv) floor traders; and (v) floor trader order enterers.

Estimated Number of Respondents: 78,109.

Estimated Total Annual Burden on Respondents: 7,210 hours.

Frequency of Collection: Periodically.

There are no capital costs or operating and maintenance costs associated with this collection.

The Commission estimates the burden of this collection of information under OMB control number 3038–0072 to be:

Respondents/Affected Entities: (1) Users of Form 7–R, specifically swap dealers and major swap participants; and (2) users of Form 8–R, specifically principals of swap dealers and of major swap participants.

Estimated Number of Respondents: 770.

Estimated Total Annual Burden on Respondents: 648 hours.

Frequency of Collection: Periodically.

There are no capital costs or operating and maintenance costs associated with this collection.

Authority: 44 U.S.C. 3501 *et seq.*

Dated: April 24, 2017.

Robert N. Sidman,

Deputy Secretary of the Commission.

[FR Doc. 2017–08559 Filed 4–27–17; 8:45 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Sunshine Act Meetings

TIME AND DATE: 11:00 a.m., Thursday, May 4, 2017.

PLACE: Three Lafayette Centre, 1155 21st Street NW., Washington, DC, 9th Floor Commission Conference Room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Surveillance, enforcement, and examinations matters. In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's Web site at *http://www.cftc.gov.*

CONTACT PERSON FOR MORE INFORMATION: Christopher Kirkpatrick, 202–418–5964.

Natise Allen,

Executive Assistant.

[FR Doc. 2017–08684 Filed 4–26–17; 11:15 am]

BILLING CODE 6351–01–P

COMMODITY FUTURES TRADING COMMISSION

Adoption of Revised Registration Form 8–R

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission (the ''Commission'' or ''CFTC'') is revising its Form 8–R, the application form that individuals must use to register with the Commission as an associated person of a registrant, floor broker, or floor trader, or to be listed as a principal of a registrant (collectively, ''applicants'').

DATES: *Effective Date:* The new, revised version of Form 8–R shall be effective (and the prior version shall cease to be effective) when the National Futures Association (''NFA'') makes the new, revised version of the Form 8–R available on the NFA Web site for use by individual applicants.

FOR FURTHER INFORMATION CONTACT: Erik F. Remmler, Deputy Director, (202) 418–7630, *eremmler@cftc.gov;* Laura Gardy, Associate Director, (202) 418–7645, *lgardy@cftc.gov;* or August A. Imholtz III, Special Counsel, (202) 418–5140, *aimholtz@cftc.gov,* Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581.

SUPPLEMENTARY INFORMATION:

I. Background

Individuals acting in certain capacities in the markets regulated by the Commission must file a completed Form 8–R with NFA.[1] These applicants include: Associated persons of futures commission merchants, retail foreign exchange dealers, introducing brokers, commodity trading advisors, commodity pool operators, and leverage transaction merchants; floor brokers; and floor traders.[2] Additionally, any individual acting in the capacity as principal of a futures commission merchant, retail foreign exchange dealer, introducing broker, commodity trading advisor, commodity pool operator, swap dealer, major swap participant, floor trader or leverage transaction merchant also must file a completed Form 8–R.[3] Lastly, individuals that enter orders for floor trader firms must file the Form 8–R as well.[4] Individual applicants have been required to use Form 8–R since 1977.[5]

Form 8–R requests information about the applicant that can be used to assess the applicant's fitness to engage in business as a derivatives professional. Form 8–R is a Commission form maintained and used primarily by the NFA. NFA is currently the only registered futures association authorized by the Commission in accordance with Section 17 of the Commodity Exchange Act (''Act'').[6] Pursuant to Section 17(o) of the Act,[7] Regulation 3.2,[8] and a series of orders, the Commission delegated to NFA certain registration functions including, among other things, the processing of all Form 8–R filings.[9] Since the first delegation to NFA in 1984, NFA has developed substantial expertise in registration matters, including reviewing and processing completed Forms 8–R. In 2002, with the approval of the Commission, NFA transitioned from a paper-based registration system to an online registration system that utilizes, among other things, an electronic version of Form 8–R.[10]

[1] 17 CFR 3.10(a)(2), 3.11(a), and 3.12(c).

[2] 17 CFR 3.11(a); 3.12(c).

[3] 17 CFR 3.1(a); 3.10(a)(2); 3.11(a)(1). While ''principal'' is not technically a registration class and principals do not apply for registration, for purposes of this Notice, the Form 8–R filings by principals will be referred to with the other Form 8–R filings as ''registration applications.''

[4] 17 CFR 3.11(a)(1).

[5] Revision of Registration Forms and Amendment of Related Rules, 42 FR 23988 (May 11, 1977) (Form 8–R replaced Forms 2–R, 4–R and 94).

[6] 7 U.S.C. 21 (2012).

[7] 7 U.S.C. 21(o) (2012).

[8] 17 CFR 3.2.

[9] *See, e.g.,* Introducing Brokers and Associated Persons of Introducing Brokers; Authorization of National Futures Association to Perform Commission Registration Functions, 48 FR 35158 (Aug. 3, 1983); Performance of Registration Functions by National Futures Association, 49 FR 39593 (Oct. 9, 1984) (futures commission merchants, commodity pool operators, commodity trading advisors, and associated persons thereof); Performance of Registration Functions by National Futures Association; Delegation of Authority, 51 FR 34490 (Sept. 29, 1986) (floor brokers); Performance of Registration Functions by National Futures Association with Respect to Floor Traders and Floor Brokers, 58 FR 19657 (Apr. 15, 1993); and Performance of Registration Functions by National Futures Association with Respect to Swap Dealers and Major Swap Participants, 77 FR 2708 (Jan. 19, 2012).

[10] Registration of Intermediaries, 67 FR 38869 (June 6, 2002). The transition to an online registration system has permitted greater efficiencies, including allowing individuals to update their existing Forms 8–R instead of completing a separate Form 3–R. To that end, in 2012, the Commission eliminated the requirement that registrants and individuals use Form 3–R to

Continued

II. Revisions To Commission Form 8–R

NFA has requested that the Commission make several changes to Form 8–R.[11] Upon consideration of NFA's request, the Commission is revising and updating Form 8–R. In addition, the Commission is updating the Form 8–R Privacy Act and Paperwork Reduction Act Statements. The Form 8–R revisions are described below.[12]

In the section titled ''Sponsor Information and Registration Categories,'' Form 8–R previously listed three categories of persons that could be associated with a sponsor: Associated persons, branch office managers, and principals.[13] The revised Form 8–R includes a fourth category, floor trader order enterer. This addition addresses the Form 8–R filing requirement for employees of an entity that is a registered floor trader who execute swap transactions on a swap execution facility for the floor trader's own account.[14] In connection with this change, the revised Form 8–R includes two newly defined terms: ''Entity floor trader'' and ''floor trader order enterer.'' ''Entity floor trader'' is defined as an entity that is ''an applicant or registrant that filed a Form 7–R for registration as a floor trader.'' [15] ''Floor trader order enterer'' is defined as ''an individual responsible for entry of orders from an entity floor trader's own account.'' [16]

In the section titled ''Principal Information,'' the prior version of Form 8–R contained a blank space in which an applicant entered a title. In the revised Form 8–R, the space is replaced with a menu of available titles.

In the ''Fingerprint Card Information'' section, revised Form 8–R adds two new questions. One new question addresses new requirements and exemptions thereto contained in Commission Regulation 3.21(e) applicable to non-U.S. persons. A non-U.S. natural person may now claim an exemption under Commission Regulation 3.21(e) from the fingerprint submission requirement where the applicant otherwise underwent a qualifying criminal history background check.[17] The other new question addresses the fingerprinting requirement exception for certain outside directors of registered firms.[18]

The sections in Form 8–R titled ''Disciplinary Information—Criminal Disclosures,'' ''Disciplinary Information—Regulatory Disclosures,'' and ''Disciplinary Information—Financial Disclosures'' contain a series of questions that inquire about the disciplinary history of the applicant. These questions are designed to identify and gather information that may reflect on the fitness of the applicant and whether he or she may be subject to a statutory disqualification from registration.[19] Among other things, these questions ask about the disciplinary history of ''any entity of which you [the applicant] were a principal at the time the [potentially reportable] activities occurred.'' The term ''principal'' as used in the Disciplinary History section of Form 8–R was sometimes understood by applicants to mean that only firms that were subject to Commission registration were relevant. The long-standing interpretation of the term ''principal'' as used in that context was not limited to the applicant's status as a principal only for Commission registrants, but also if the applicant served in one of the capacities included in the definition of ''principal'' for any firm. The definition of ''principal'' is revised to clarify this issue.[20]

In the section titled ''Disciplinary Information—Regulatory Disclosures,'' a new question was added to existing Question E. Among other things, Question E inquires whether the applicant (or an entity of which the applicant was a principal) violated, or aided and abetted the violation of, any investment-related statutes or regulations, a potential statutory basis for refusing or conditioning registration.[21] The new question directs the applicant to disclose whether he or she has ever been found to have failed to supervise another person's activities under any investment-related statute or regulation.[22] The new question is intended to ensure complete disclosure of conduct that may result in a refusal or limitation on registration.

In the section titled ''Disciplinary Information—Financial Disclosures,'' the Commission revised Question J, which asked whether the applicant has ''currently failed to comply with any order to pay any futures-related civil monetary penalties, restitution amounts, disgorgement amounts, reparation amounts or arbitration awards.'' As revised, Question J now inquires whether the applicant ''failed to pay any arbitration awards involving CFTC-regulated products, CFTC civil monetary penalties, CFTC restitution amounts, CFTC disgorgement amounts, or CFTC reparation amounts.'' The revision is designed to clarify that this question is not limited solely to unpaid monetary awards related to futures contracts, but also includes unpaid awards related to all products subject to the jurisdiction of the Commission.

Lastly, NFA is simplifying the process by which it requests supplemental information and documentation regarding the applicant's criminal, regulatory, financial, or employment disclosures. The prior version of Form 8–R requested that applicants provide a written explanation of the facts and circumstances regarding any such disclosures. Applicants were also separately requested to provide NFA with copies of pertinent documents associated with each disclosure. To consolidate and modernize this process, the revised Form 8–R allows applicants

update information in their existing Form 7–R or 8–R, and provided that an update to a registrant's online Form 7–R or 8–R would automatically create a record of changes equivalent to a completed Form 3–R. Registration of Intermediaries, 77 FR 51898 (Aug. 28, 2012); *see also,* Registration of Intermediaries, 76 FR 12888, 12891 (proposed Mar. 9, 2011).

[11] Request from NFA to CFTC, dated Sept. 8, 2016, as amended on Oct. 31, 2016. Both communications are on file with the Commission.

[12] This Notice describes the substantive changes to Form 8–R. The Commission also is making a number of minor, non-substantive, or technical changes to Form 8–R that are not described herein.

[13] Associated persons and principals must file Form 8–R. 17 CFR 1.3(aa), 3.1(a), 3.10(a) and 3.12. Branch Office Manager is a category that NFA utilizes to ensure proper oversight of branch offices. *See* NFA Interpretive Notice 9002, Registration Requirements; Branch Offices (Staff, Sept. 6, 1985; revised July 1, 2000; Dec. 9, 2005; and Sept. 30, 2010).

[14] 17 CFR 1.3(ggg)(6)(iv), 3.11(a)(1). Commission Regulation 3.11(a)(1) was amended in 2012 to require individuals that enter swap orders for the account of an entity floor trader to file a Form 8–R. 77 FR 51898. These individuals are required to file a Form 8–R, but are not required to register with the Commission in any specified capacity. Since 2012, NFA has required these individuals to file a separate, paper version of the Form 8–R titled Floor Trader Order Enterer Application. The revisions to the Form 8–R discussed in this paragraph result from combining the pre-existing, electronic Form 8–R with the paper version for floor trader order enterers.

[15] Entities that act as market participants or intermediaries must use the Commission Form 7–R to register with the Commission. 17 CFR 3.10 and 3.11.

[16] The revised Form 8–R includes additional conforming changes to incorporate entity floor traders and floor trader order enterers as appropriate.

[17] 17 CFR 3.21(e); Alternative to Fingerprinting Requirements for Foreign Natural Persons, 81 FR 18743 (Apr. 1, 2016).

[18] 17 CFR 3.21(c) (permitting an outside director to indicate that he or she will file the appropriate notice required by Commission Regulation 3.21(c) instead of supplying his or her fingerprints).

[19] *See* 7 U.S.C. 12a(2) and (3) (2012).

[20] A provision was added to the definition of ''principal'' that states, ''[f]or the purpose of answering Questions A, B, C, D, E, F, G, I and K of the Disciplinary History sections, principal also means an individual described in [paragraphs] (1), (2) or (4) above with respect to any entity whether or not the entity is an applicant, registrant, or a person required to be registered under the Act.''

[21] 7 U.S.C. 12(a)(3).

[22] *See* 7 U.S.C. 12(a)(3)(C).

to complete a separate ''Disclosure Matter Page'' for each matter, instance, or event requiring disclosure and to simultaneously upload all pertinent documents associated with each disclosure. The Disclosure Matter Page provides applicants with an efficient and effective method of supplying the supplemental information and documentation that NFA requests in the normal course whenever an applicant responds affirmatively to any of the questions regarding criminal, regulatory or financial disclosures.

A revised version of Form 8–R that incorporates the changes discussed above, as well as other non-substantive changes, is attached as Appendix A to this Notice.

III. Related Matters

Paperwork Reduction Act. Recordkeeping or information collection requirements under the Paperwork Reduction Act (''PRA'') related to Form 8–R exist under current law. The titles for the existing information collections are ''Registration Under the Commodity Exchange Act,'' OMB control number 3038–0023, and ''Registration of Swap Dealers and Major Swap Participants,'' OMB control number 3038–0072. The preliminary view of the Commission is that the revisions to Form 8–R may modify the existing recordkeeping or information collection requirements under the PRA. To ensure compliance with the PRA, the Commission will publish in the **Federal Register** a separate notice and request for comment on the amended PRA burden associated with the revised Form 8–R.[23] The Commission also will submit to OMB an information collection request to amend the information collection, in accordance with 44 U.S.C. 3506(c)(2)(A) and 5 CFR 1320.8(d).

[23] The notice and request for comment on the amended PRA burden will also address reassigning from Form 3–R to Form 8–R the PRA burden associated with providing updated information on Form 8–R.

Issued by the Commission on April, 24 2017, in Washington, DC.

Robert N. Sidman,

Deputy Secretary of the Commission.

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

Appendices to Adoption of Revised Registration Form 8–R

Appendix 1—Commission Voting Summary

On this matter, Acting Chairman Giancarlo and Commissioner Bowen voted in the affirmative. No Commissioner voted in the negative.

Appendix A—Individual Application (Form 8–R)

BILLING CODE 6351–01–P

Individual Application (Form 8-R)

COMMODITY FUTURES TRADING COMMISSION
NATIONAL FUTURES ASSOCIATION

Instructions for Completing the Individual Application

READ THESE INSTRUCTIONS CAREFULLY BEFORE COMPLETING OR REVIEWING THE APPLICATION. THE FAILURE TO ANSWER ALL QUESTIONS COMPLETELY AND ACCURATELY OR THE OMISSION OF REQUIRED INFORMATION MAY RESULT IN THE DENIAL OR REVOCATION OF REGISTRATION.

THE FAILURE TO DISCLOSE A DISCIPLINARY MATTER EITHER IN AN APPLICATION OR AN UPDATE WILL RESULT IN THE IMPOSITION OF A LATE DISCLOSURE FEE IN ACCORDANCE WITH NFA REGISTRATION RULE 210(c).

Not every section applies to every applicant. Certain sections apply depending on the registration category or categories being applied for. The text above these sections explains who must complete the section.

DEFINED TERMS
Words that are underlined in this form are either defined terms and have the meanings contained in the Definition of Terms section or links to the text of Commodity Exchange Act provisions, CFTC Regulations or NFA Rules.

GENERAL
Read the Instructions and Questions Carefully

A question that is answered incorrectly because it was misread or misinterpreted can result in severe consequences, including denial or revocation of registration. Although this applies to all questions in the application, it is particularly important to the questions in the Disciplinary Information Section.

Rely Only on Advice from NFA Staff

A question that is answered incorrectly because of advice received from a lawyer, employer, a judge or anyone else (other than a member of NFA's Registration Investigations or Legal ("RIL") staff) can result in severe consequences, including denial or revocation of registration. This also applies to all questions in the form, but is particularly important regarding the Disciplinary Information Section. If the language of a question in the Disciplinary Information Section requires disclosure of a matter, a "Yes" answer to the question is required no matter what other advice has been received from anyone other than NFA's RIL staff. Additionally, the applicant or registrant remains responsible for failures to disclose even if someone completes the form on the applicant's or registrant's behalf.

Update the Information on the Application

If information provided on the application changes or a matter that would have required disclosure on the application occurs after the application is filed, the new information must be promptly filed. APs and Principals should advise their Sponsors of the new information, and the Sponsor must file the update on their behalf. The failure to promptly update information can result in severe consequences, including denial or revocation of registration.

Compliance with Disclosure Requirements of Another Regulatory Body is not Sufficient

With some exceptions, which are described below in the Regulatory and Financial Disclosures sections, if any question requires the provision of information, that information must be provided. In particular, if a question in the Disciplinary Information Section requires disclosure of a matter, the question must be answered "Yes" and additional documents must be provided even if the matter has been disclosed to another regulatory body such as FINRA, an exchange or a state regulator. Similarly, disclosure is required even if another regulatory body does NOT require disclosure of the same matter.

Call NFA with Questions

If there is any question about whether particular information must be provided, whether a particular matter must be disclosed or whether a particular question requires a "Yes" answer, call the NFA Information Center at (800) 621-3570 or (312) 781-1410. Representatives are available from 8:00 a.m. to 5:00 p.m., Central Time, Monday through Friday. If the advice of NFA staff is sought, a written record containing the date of the conversation, the name of the NFA staff person giving the advice and a description of the advice should be made during the conversation and kept in the event an issue concerning disclosure of the matter arises later.

DISCIPLINARY INFORMATION SECTION

Criminal Disclosures

Some common mistakes in answering the criminal disclosure questions involve expungements, diversion programs and similar processes. The Commodity Futures Trading Commission requires a "Yes" answer even if the matter has been expunged or the records sealed, there was no adjudication or finding of guilt, the guilty plea was vacated or set aside or the matter was dismissed upon completion of the diversion program.

Another common error regarding criminal matters concerns matters that do not involve the futures industry. All criminal matters must be disclosed, even if a matter is unrelated to the futures industry, unless the case was decided in a juvenile court or under a Youth Offender law.

Regulatory Disclosures

Regulatory actions taken by the Commodity Futures Trading Commission, NFA or U.S. futures exchanges do not need to be disclosed since NFA is already aware of them once they are entered into NFA's BASIC system.

Financial Disclosures

It is not necessary to disclose arbitration awards or CFTC reparations matters unless the applicant or registrant has failed to pay an award related to a CFTC-related product or an order entered in a reparations matter.

Only adversary actions that a bankruptcy trustee files must be disclosed. Adversary actions that creditors file are not disclosable. A person named as a party to an adversary action in a bankruptcy proceeding must disclose the action, even if the person is not the bankrupt person.

ADDITIONAL DOCUMENTS

For each matter that caused a "Yes" answer, a Disclosure Matter Page ("DMP"), which is accessible using NFA's DMP Filing System, must be filed. In addition to the required DMP, other documents about the matter must be provided to NFA. If court documents are unavailable, a letter from the court verifying that must be sent to NFA. If documents other than court documents are unavailable, the person must provide a written explanation for their unavailability. Electronic copies of the documents can be uploaded using NFA's DMP Filing System or you can send documents to NFA by emailing electronic documents to registration@nfa.futures.org, faxing documents to (312) 559-3411 or mailing documents to NFA Registration Department, 300 S. Riverside Plaza, Suite 1800, Chicago IL 60606.

Like answering the questions correctly, providing all documents to NFA is important. Failure to do so will delay the registration process and may result in a denial of the application.

DEFINITION OF TERMS (The following terms are defined solely for the purpose of using NFA's Online Registration System.)

10% OR MORE INTEREST: direct or indirect ownership of 10% or more of an entity's stock; entitlement to vote or empowered to sell 10% or more of an entity's voting securities; contribution of 10% or more of an entity's capital; or entitlement to 10% or more of an entity's net profits.

ADJUDICATION: in a criminal case, a determination by the court that the defendant is guilty or not guilty.

ADVERSARY ACTION: a lawsuit arising in or related to a bankruptcy case commenced by a creditor or bankruptcy trustee by filing a complaint with the bankruptcy court.

ALIAS: another name utilized by an individual or previously used by an entity.

CHARGE: a formal complaint, information, indictment or equivalent instrument containing an accusation of a crime.

DBA: abbreviation for Doing Business As. The firm is doing its futures, retail off-exchange forex or swaps business by this name.

DESIGNATED SUPERVISOR: solely for the purpose of determining whether the Branch Manager Examination (Series 30) is required, Designated Supervisor means a person who is registered with FINRA (formerly known as NASD) as a General Securities Representative and has been designated to act as the supervisor of an office that is not an Office of Supervisory Jurisdiction ("non-OSJ"), provided that:

- either the futures activity conducted in the non-OSJ that is subject to the Designated Supervisor's supervision is limited to activity not requiring the Series 3 Examination and both the Designated Supervisor and the Branch Manager of the Office of Supervisory Jurisdiction to which the non-OSJ reports have otherwise satisfied NFA's Proficiency Requirements appropriate to their supervisory activities; or

- the activity that is conducted in the non-OSJ that requires the Series 3 Examination is supervised by the Branch Manager of the Office of Supervisory Jurisdiction to which the non-OSJ reports and both the Designated Supervisor and Branch Office Manager have passed the Series 3 Examination.

ENJOINED: subject to an injunction.

ENTITY: any person other than an individual.

ENTITY FLOOR TRADER: an applicant that files or registrant that filed a Form 7-R to apply for registration as a floor trader.

FELONY: any crime classified as a felony and for states and countries that do not differentiate between a felony or misdemeanor, an offense that could result in imprisonment for any period of more than one year. The term also includes a general court martial.

FINANCIAL SERVICES INDUSTRY: the commodities, securities, accounting, banking, finance, insurance, law or real estate industries.

FLOOR TRADER ORDER ENTERER: an individual responsible for entry of orders from an Entity Floor Trader's own account.

FOUND: subject to a determination that conduct or a rule violation has occurred. The term applies to dispositions of any type, including but not limited to consent decrees or settlements in which the findings are neither admitted nor denied or in which the findings are for settlement or record purposes only.

INDIRECT OWNER: an individual who through agreement, holding companies, nominees, trusts or otherwise:

- is the owner of 10% or more of the outstanding shares of any class of an entity's equity securities, other than non-voting securities;
- is entitled to vote 10% or more of the outstanding shares of any class of an entity's equity securities, other than non-voting securities;
- has the power to sell or direct the sale of 10% or more of the outstanding shares of any class of an entity's equity securities, other than non-voting securities;
- is entitled to receive 10% or more of an entity's net profits; or
- has the power to exercise a controlling influence over an entity's activities that are subject to regulation by the Commission.

INTERNAL REVENUE CODE:
Section 7203: Willful Failure to File Return, Supply Information or Pay Tax
Section 7204: Fraudulent Statement or Failure to Make Statement
Section 7205: Fraudulent Withholding Exemption Certificate or Failure to Supply Information
Section 7207: Fraudulent Returns, Statements or Other Documents

INVESTMENT RELATED STATUTES:

- The Commodity Exchange Act
- The Securities Act of 1933
- The Securities Exchange Act of 1934
- The Public Utility Holding Company Act of 1935
- The Trust Indenture Act of 1939
- The Investment Advisers Act of 1940
- The Investment Company Act of 1940
- The Securities Investors Protection Act of 1970
- The Foreign Corrupt Practices Act of 1977
- Chapter 96 of Title 18 of the United States Code

- Any similar statute of a State or foreign jurisdiction
- Any rule, regulation or order under any such statutes; and
- The rules of the Municipal Securities Rulemaking Board

MISDEMEANOR: any crime classified as a misdemeanor and for states and countries that do not differentiate be-tween a felony or misdemeanor, an offense that could result in imprisonment for any period of at least six days but not more than one year. By way of example, an offense for which the maximum period of imprisonment is 60 days would be considered a misdemeanor. The term also includes a special court martial.

NON-U.S.NATURAL PERSON: an individual who has not resided in the U.S. since reaching the age of 18 years.

OTHER NAME: For firms or sole proprietors, any other name that the applicant uses or has used in the past for its futures, retail off-exchange forex or swaps business but not the name of any other legal entity that the applicant has an affiliation or association with (see DBA). For individuals, this is any name the person is or has been known by. For example, a maiden name, an alias name that you use or are known by, or a previous name if you have changed your legal name.

OUTSIDE DIRECTOR: an individual who is director of an applicant or registrant and who

- is not an officer or employee of the applicant or registrant;
- is not engaged in or have direct supervisory responsibility over persons engaged in the solicitation of
    - or acceptance of customers' orders or retail forex customers' orders;
    - funds, securities or property for participation in a commodity pool;
    - a client's or prospective client's discretionary account;
    - leverage customers' orders for leverage transactions;
    - or acceptance of a swap agreement; or
- does not regularly have access to the keeping, handling or processing of:
    - transactions involving "commodity Interests", as that term is defined in CFTC Regulation 1.3(yy);
    - customer funds, retail forex customer funds, leverage customer funds, foreign futures or foreign options secured amount, or adjusted net capital.

PERSON: an individual, association, partnership, corporation, limited liability company, limited liability partnership, trust, or other form of business organization.

PRINCIPAL - means, with respect to an applicant, a registrant, or a person required to be registered under the Act:

(1) an individual who is:

- a sole proprietor of a sole proprietorship;
- a general partner of a partnership;
- a director, president, chief executive officer, chief operating officer, chief financial officer, or a person in charge of a business unit, division or function subject to regulation by the Commission of a corporation, limited liability company or limited liability partnership;
- a manager, managing member or a member vested with the management authority for a limited liability company or limited liability partnership; or
- a chief compliance officer; or

(2) an individual who directly or indirectly, through agreement, holding companies, nominees, trusts or otherwise:

- is the owner of 10% or more of the outstanding shares of any class of an applicant or registrant's equity securities, other than non-voting securities;
- is entitled to vote 10% or more of the outstanding shares of any class of an applicant or registrant's equity securities, other than non-voting securities;
- has the power to sell or direct the sale of 10% or more of the outstanding shares of any class of an applicant or registrant's equity securities, other than non-voting securities;
- is entitled to receive 10% or more of an applicant or registrant's net profits; or
- has the power to exercise a controlling influence over an applicant or registrant's activities that are subject to regulation by the Commission; or

(3) an entity that:

- is a general partner of a partnership; or
- is the direct owner of 10% or more of the outstanding shares of any class of an applicant or registrant's equity securities, other than non-voting securities; or

(4) an individual who or an entity that:

- has contributed 10% or more of an applicant or registrant's capital unless such capital contribution consists of subordinated debt contributed by:
  - an unaffiliated bank insured by the Federal Deposit Insurance Corporation;
  - an unaffiliated "foreign bank," as defined in 12 CFR 211.21(n) that currently operates an "office of a foreign bank," as defined in 12 CFR 211.21(t), which is licensed under 12 CFR 211.24(a);
  - such office of an unaffiliated, licensed foreign bank; or
  - an insurance company subject to regulation by any State,

provided such debt is not guaranteed by an individual who or entity that is not a principal of the applicant or registrant.

For the purpose of answering Questions A, B, C, D, E, F, G, I and K of the Disciplinary Information sections, PRINCIPAL also means an individual described in (1), (2) or (4) above with respect to any entity whether or not the entity is an applicant, registrant, or a person required to be registered under the Act.

SELF-REGULATORY ORGANIZATION (SRO): a private, non-governmental organization authorized to set and enforce standards or conduct for an industry. NFA, FINRA (formerly known as NASD) and the securities and futures exchanges in the U.S. are examples of domestic SROs.

UNITED STATES CRIMINAL CODE:

Section 152: Concealment of assets, making false claims or bribery in connection with a bankruptcy
Sections 1341,1342, or 1343: Mail fraud
Chapter 25: Counterfeiting and forgery
Chapter 47: Fraud or false statements in a matter within the jurisdiction of a United States department or agency
Chapter 95 or 96: Racketeering and Racketeering Influence.

Completing the Proficiency Requirements Section

Individuals who are applying for registration as an AP or who are principals of a sole proprietorship must satisfy proficiency requirements. Individuals who have already satisfied the proficiency requirements do not need to complete the Proficiency Requirements section. An individual will have satisfied the proficiency requirements if:

- NFA has evidence that the individual has taken and passed the National Commodity Futures Examination (Series 3) or the Limited Futures Examination-Regulations (Series 32):
  - within two years prior to the date the application is filed; or
  - more than two years prior to the date the application is filed and since that date there has not been a period of two consecutive years during which the individual was not registered as an AP or FB or was not an approved principal of a registrant; or
- The individual is registered as a Floor Broker on the date the application is filed.

Individuals who must complete the Proficiency Requirements section must indicate whether they intend to use the Series 3 examination or one or more alternative means to satisfying proficiency requirements. Some of the alternatives require that an individual limit the activities that he or she intends to engage in and to pass an alternative examination. Individuals who have already passed an alternative examination do not complete the questions related to alternative examinations if:

- NFA has evidence that the individual has taken and passed the examination that the individual intends to use to satisfy the alternative proficiency requirement:
  - within two years prior to the date the application is filed; or
  - more than two years prior to the date the application is filed and since that date there has not been a period of two consecutive years during which the individual was not registered as an AP or FB or was not an approved principal of a registrant.

Individuals seeking approval as a forex associated person or as a sole proprietor forex firm must satisfy proficiency requirements before engaging in off-exchange forex business with retail customers. Individuals who have already satisfied the proficiency requirements do not need to complete the Proficiency Requirements section. An individual will have satisfied the proficiency requirements if:

- NFA has evidence that the individual has passed the Series 3 or Series 32 exam requirement (as described above) and
  - NFA has received satisfactory evidence that the applicant has passed the Series 34 within two years of the date the application is filed or
  - since the date the applicant last passed the Series 34 there has not been a period of two consecutive years during which the applicant has not been either registered as an AP or FB or was not an approved principal of a registrant; or

- The individual was registered as an AP, FB or an approved sole proprietor principal on May 22, 2008, and there has not been a period of two consecutive years since that date during which the applicant has not been either registered as an AP or FB or was not an approved principal of a registrant.

Individuals filing as Branch Office Managers must indicate whether they will satisfy the Branch Manager proficiency requirements using the Branch Manager Examination (Series 30) or an alternative. The individual does not complete the Branch Manager proficiency section if the individual has already satisfied the Branch Manager proficiency requirements. An individual will

have already satisfied the Branch Manager proficiency requirements if NFA has evidence that the individual has taken and passed the Series 30 and since the date the individual last ceased acting as a branch office manager, there has not been a period of two consecutive years during which he or she has not been registered as an AP.

Additional Assistance

Additional information regarding registration requirements and specific topics can be found on the Registration page of NFA's web site at www.nfa.futures.org. NFA's Information Center, (800-621-3570 or 312-781-1410), is also available to provide assistance. Its normal hours are Monday through Friday, from 8:00 AM to 5:00 PM, CT.

Name

Enter all required information.

Enter the individual's full legal name. Do not use nicknames or abbreviations. For example, if the individual's name is Charles, enter Charles, not Chuck.

First & Middle Name*_____Last Name (Surname)_____Suffix__
NFA ID#_____

Sponsor Information and Registration Categories

Indicate sponsor and office where applicant is located and check category(ies).

Sponsor Information

Sponsor*_____
Main/Branch Office_____

Categories*

- ☐ Associated Person
- ☐ Branch Office Manager
- ☐ Principal
- ☐ Floor Trader Order Enterer

Applicants whose sponsor is designated as a Forex Firm answer this question

Will your activities involve the solicitation of customers for managed accounts, pooled investment vehicles, or individual accounts or transactions in off-exchange foreign currency transactions as described in Sections 2(c)(2)(B) or 2(c)(2)(C) of the Act, or the supervision of persons involved in such solicitation activities?*

Yes ○ No ○

Applicants whose sponsor is designated as a Swap Firm answer these questions

Will your activities involve the solicitation of customers for swaps transactions subject to the jurisdiction of the Commodity Futures Trading Commission or the supervision of persons involved in such solicitation activities?*

Yes ○ No ○

Individual's activities involve:

- ○ Swaps transactions only
- ○ Swaps, futures and options on futures and/or retail off-exchange foreign currency transactions

*Required to file application

Associated Person applicants who are registered with other sponsors complete this section.

Current Sponsor Information

Our records indicate that the applicant is currently an Associated Person of the following sponsor(s). If the applicant is no longer an Associated Person of any sponsor(s) listed below, check all that apply.

□ [Sponsor Name]
□ [Sponsor Name]

*Required to file application

Floor broker and floor trader applicants complete this section

Registration Categories

Select category(ies)

Categories*

Floor Broker ☐
Floor Trader ☐

Are you requesting a change from floor broker to floor trader? ○ Yes ○ No

Are you requesting a change from floor trader to floor broker? ○ Yes ○ No

*Required to file application

Individuals filing as principals complete this section

Principal Information

Check all that apply.

Principal Title*

☐	SOLE PROPRIETOR	☐	CHIEF COMPLIANCE OFFICER
☐	GENERAL PARTNER	☐	HEAD OF A BUSINESS UNIT, DIVISION OR FUNCTION
☐	DIRECTOR	☐	MANAGER – LLC OR LLP
☐	PRESIDENT	☐	MANAGING MEMBER – LLC OR LLP
☐	CHIEF EXECUTIVE OFFICER	☐	VESTED WITH MANAGEMENT AUTHORITY – LLC OR LLP
☐	CHIEF OPERATING OFFICER	☐	OWNER
☐	CHIEF FINANCIAL OFFICER	☐	INDIRECT OWNER
		☐	NO LISTED TITLE

10% or more interest* ○ Yes ○ No

*Required to file application

Personal Information

Enter all required information.

Other Names

Enter any other name by which you are or have been known.

First and Middle Name_____Last Name (Surname) and Suffix_____

Birth Information

Enter information about applicant's date and location of birth

Date of Birth* (Month)_____(Day)_____Year (YYYY)_____

City**_____ State* (US Only)_____

Province_____ Country*_____

Residential Address
P.O. Box address is not acceptable.

Street Address 1*_____

Street Address 2_____

Street Address 3_____

City**_____State* (US Only)_____

Province_____Zip/Postal Code**_____

Country*_____

U.S. Social Security #_____

*Required to file application
**Required to file application for United States address

Floor broker and floor trader applicants complete this section

Business Mailing Address

Street Address 1*_____

Street Address 2_____

Street Address 3_____

City**_____State* (US Only)_____

Province_____Zip/Postal Code**_____

Country*_____

E-mail _____

CRD ID_____

Fingerprint Card Information

○ The applicant's properly signed fingerprint cards will be sent to NFA.

○The applicant is a non-U.S. natural person and:

Pursuant to CFTC Regulation 3.21(e), the sponsor has caused a criminal history background check to be performed for the applicant and the criminal history background check:

A) Is of a type that would reveal all matters listed under Sections 8a(2)(D) or 8a(3)(D), (E) or (H) of the Act;

B) Does not reveal any matters that constitute a disqualification under Sections 8a(2)(D) or 8a(3)(D), (E) or (H) of the Act, other than those disclosed to NFA; and

C) Was completed not more than one calendar year prior to the date this application is filed.

○The applicant is an outside director and the sponsor will file with NFA a notice pursuant to CFTC Regulation 3.21(c).

○The applicant's fingerprint card was sent to FINRA within the past 90 days.

*Required to file application

**Required to file application for United States address

Fingerprint Card Demographic Information

Individuals submitting a fingerprint card or who sent a fingerprint card to FINRA within the past 90 days complete this section.

The following information is used to conduct a criminal background check with the U.S. Federal Bureau of Investigations. The FBI requires this information to be submitted with your fingerprints to perform this check.

Gender* _____ Race* _____
Eye Color* _____ Hair Color* _____
Height* _____feet _____inch(es) Weight* _____pounds
Country of Citizenship _____

Floor broker and floor trader applicants complete this section

Exchange Affiliation

Select the exchange(s) at which you have been granted membership or trading privileges or at which you have an application pending.

Chicago Board of Trade ☐
Commodity Exchange Inc. ☐
CBOE Futures Exchange LLC ☐
Chicago Mercantile Exchange ☐
ICE Futures US Inc. ☐
Minneapolis Grain Exchange ☐
NASDAQ Futures Inc. ☐
New York Mercantile Exchange ☐

*Required to file application

Disciplinary Information – Criminal Disclosures

For additional assistance and information on completing this page refer to the Instructions and Definition of Terms at the beginning of this document.

Answer the following questions.

YOU MUST ANSWER "YES" TO THE QUESTIONS ON THIS PAGE EVEN IF:

• ADJUDICATION OF GUILT WAS WITHHELD OR THERE WAS NO CONVICTION; OR

• THERE WAS A CONDITIONAL DISCHARGE OR POST-CONVICTION DISMISSAL AFTER SUCCESSFUL COMPLETION OF A SENTENCE; OR

• A STATE CERTIFICATE OF RELIEF FROM DISABILITIES OR SIMILAR DOCUMENT WAS ISSUED RELIEVING THE HOLDER OF FORFEITURES, DISABILITIES OR BARS RESULTING FROM A CONVICTION; OR

• THE RECORD WAS EXPUNGED OR SEALED; OR

• A PARDON WAS GRANTED.

YOU MAY ANSWER "NO" IF THE CASE WAS DECIDED IN A JUVENILE COURT OR UNDER A YOUTH OFFENDER LAW.

For each matter that requires a "Yes" answer to Questions A, B or C below, you must provide additional information by filing a Criminal Disclosure Matter Page ("DMP") for each criminal matter using NFA's DMP Filing system that requests:

- who was involved;
- when it occurred;
- what the allegations were;
- what the final determination was, if any; and
- the date of the determination.

You must also provide documents regarding each criminal matter requiring a "Yes" answer, that show

- the charges;
- the classification of the offense, i.e., felony or misdemeanor;
- the plea, sentencing and probation information, as applicable;
- the final disposition; and
- a summary of the circumstances surrounding the criminal matter.

You may provide these documents electronically using the upload function in the DMP Filing System or sending them to NFA (See Instruction).

Question A.*

(1) Have you personally or

*Required to file application

(2) has any entity of which you were a Principal at the time the activities occurred

ever pled guilty or nolo contendere ("no contest") to or been convicted or found guilty of any felony in any U.S., non-U.S. or military court?

○Yes ○ No

Question B.*

(1) Have you personally or

(2) has any entity of which you were a Principal at the time the activities occurred

ever pled guilty to or been convicted or found guilty of any misdemeanor in any U.S., non-U.S. or military court which involves:

- embezzlement, theft, extortion, fraud, fraudulent conversion, forgery, counterfeiting, false pretenses, bribery, gambling, racketeering or misappropriation of funds, securities or property;
- violation of sections 7203, 7204, 7205 or 7207 of the Internal Revenue Code of 1986; or
- violation of sections 152, 1341, 1342, or 1343 or chapters 25, 47, 95 or 96 of the U.S. Criminal Code; or
- any transaction in or advice concerning futures, options, leverage transactions or securities?

○ Yes ○ No

Question C.*

(1) Are you personally or

(2) is any entity of which you were a Principal at the time the activities occurred

a party to any action, or is there a charge pending, the resolution of which could result in a "Yes" answer to the above questions?

○ Yes ○ No

Applicants with all "No" answers above answer this question

Even though you answered "No" to all of the above questions, would you like to provide a Criminal DMP?*

○ Yes ○ No

*Required to file application

Applicants with "Yes" answers above answer this question

Will you be filing a Criminal DMP with respect to a new matter?*

○ Yes ○ No

*Required to file application

Disciplinary Information - Regulatory Disclosures

For additional assistance and information on completing this page refer to the Instructions and Definition of Terms at the beginning of this document.

For each matter that requires a "Yes" answer to Questions D, E, F, G, H or I below, you must provide additional information by filing a Regulatory DMP for each regulatory matter using NFA's DMP Filing system that requests:

- who was involved;
- when it occurred;
- what the allegations were;
- what the final determination was, if any;
- the date of the determination; and
- a summary of the circumstances surrounding the regulatory matter.

You must also provide documents regarding each regulatory matter requiring a "Yes" answer, that show

- the allegations; and
- the final disposition.

You may provide these documents electronically using the upload function in the DMP Filing System or sending them to NFA (See Instruction).

Answer the following questions.

Question D.*

In any case brought by a U.S. or non-U.S. governmental body (other than the CFTC),

(1) have you personally or

(2) has any entity of which you were a Principal at the time the activities occurred

ever been permanently or temporarily enjoined after a hearing or default or as the result of a settlement, consent decree or other agreement, from engaging in or continuing any activity involving:

• any transaction in or advice concerning futures, options, leverage transactions or securities; or

• embezzlement, theft, extortion, fraud, fraudulent conversion, forgery, counterfeiting, false pretenses, bribery, gambling, racketeering or misappropriation of funds, securities or property?

○ Yes ○ No

*Required to file application

Question E.*

In any case brought by a U.S. or non-U.S. governmental body (other than the CFTC),

(1) have you personally or

(2) has any entity of which you were a Principal at the time the activities occurred

ever been found after a hearing or default or as the result of a settlement, consent decree or other agreement, to:

- have violated any provision of any investment-related statute or regulation thereunder; or
- have violated any statute, rule, regulation or order which involves embezzlement, theft, extortion, fraud, fraudulent conversion, forgery, counterfeiting, false pretenses, bribery, gambling, racketeering or misappropriation of funds, securities or property; or
- have willfully aided, abetted, counseled, commanded, induced or procured such violation by any other person; or
- have failed to supervise another person's activities under any investment-related statute or regulation thereunder?

○ Yes ○ No

Question F.*

(1) Have you personally or

(2) has any entity of which you were a Principal at the time the activities occurred

ever been debarred by any agency of the U. S. from contracting with the U. S.?

○ Yes ○ No

Question G.*

(1) Have you personally or

(2) has any entity of which you were a Principal at the time the activities occurred

ever been the subject of any order issued by or a party to any agreement with a U.S. or non-U.S. regulatory authority (other than the CFTC), including but not limited to a licensing authority, or self-regulatory organization (other than NFA or a U.S. futures exchange) that prevented or restricted your ability to engage in any business in the financial services industry?

○ Yes ○ No

*Required to file application

Question H.*

Are any of the orders or other agreements described in Question G currently in effect against you personally?

○ Yes ○ No

Question I.*

(1) Are you personally or

(2) is any entity of which you were a Principal at the time the activities occurred

a party to any action, or is there a charge pending, the resolution of which could result in a "Yes" answer to the above questions?

○ Yes ○ No

Applicants with all "No" answers above answer this question

Even though you answered "No" to all of the above questions, would you like to provide a Regulatory DMP?*

○ Yes ○ No

Applicants with "Yes" answers above answer this question

Will you be filing a Regulatory DMP with respect to a new matter?*

○ Yes ○ No

*Required to file application

Disciplinary Information - Financial Disclosures

For additional assistance and information on completing this page refer to the Instructions and Definition of Terms at the beginning of this document.

For each matter that requires a "Yes" answer to Questions J and K below, you must provide additional information by filing a Financial DMP for each financial matter using NFA's DMP Filing system that requests:

- who was involved;
- when it occurred;
- what the allegations were;
- what the final determination was, if any;
- the date of the determination; and
- a summary of the circumstances surrounding the financial matter.

For actions filed with bodies other than NFA or the CFTC, you must also provide documents regarding each financial matter requiting a "Yes" answer that show

- the allegations; and
- the final disposition.

You may provide these documents electronically using the upload function in the DMP Filing System or sending them to NFA (See Instruction).

Answer the following questions.

Question J.*

Have you failed to pay any arbitration awards involving CFTC-regulated products, CFTC civil monetary penalties, CFTC restitution amounts, CFTC disgorgement amounts, or CFTC reparation amounts?

○ Yes ○ No

Question K.*

(1) Have you personally or

(2) has any entity of which you were a Principal at the time the activities occurred

ever been the subject of an adversary action brought by a U.S. bankruptcy trustee?

○ Yes ○ No

*Required to file application

Applicants with all "No" answers above answer this question

Even though you answered "No" to all of the above questions, would you like to provide a Financial DMP?*

○ Yes ○ No

Applicants with "Yes" answers above answer this question

Will you be filing a Financial DMP with respect to a new matter?*

○ Yes ○ No

*Required to file application

Disciplinary Information - Employment Disclosures

For additional assistance and information on completing this page refer to the Instructions and Definition of Terms at the beginning of this document.

For each matter that requires a "Yes" answer to Question L below, you must provide additional information by filing an Employment DMP for each employment matter using NFA's DMP Filing system that requests:

- who was involved;
- when it occurred;
- what the allegations were;
- what the final determination was, if any;
- the date of the determination; and
- a summary of the circumstances surrounding the employment matter.

You must also provide documents regarding each employment matter requiring a "Yes" answer that show

- the allegations; and
- the final disposition.

You may provide documents regarding each employment matter electronically using the upload function in the DMP Filing System or sending them to NFA (See Instruction).

Answer the following question.

Question L.*

Have you ever been discharged or permitted to resign for cause as a result of allegations of:

• embezzlement, theft, extortion, fraud, fraudulent conversion, forgery, counterfeiting, false pretenses, bribery, gambling, racketeering or misappropriation of funds, securities or property; or

• failure to supervise another person in the conduct of such person's activities as a registrant of the CFTC, SEC, NFA, FINRA or other U.S. or non-U.S. self-regulatory organization?

○ Yes ○ No

Applicants with a "No" answer above answer this question

Even though you answered "No" to all of the above questions, would you like to provide an Employment DMP?*

○ Yes ○ No

*Required to file application

Applicants with "Yes" answers above answer this question

Will you be filing an Employment DMP with respect to a new matter?*

○ Yes ○ No

*Required to file application

Employment, Education and Residential History

Employment and Education History

The CFTC requires that the sponsor attempt to communicate with all of the applicant's previous employers and educational institutions for the past three years and to maintain documentation in their files that includes the names of the persons contacted and the dates of contact or, if no contact was made, the reason why.

Enter your employment and personal history, working back 10 years. All time must be accounted for, including self-employment, part-time employment, unemployment, military service and full-time education. If more spaces are needed, complete the information in another document and attach it to this document.

Month and Year Employment/School

From*: _____ Name*:_____
To: _____ Location:_____
(leave blank if current) (City, state or country)
Position Held and
Reason for Leaving: _____

Month and Year Employment/School

From*: _____ Name*:_____
To: _____ Location:_____
(leave blank if current) (City, state or country)
Position Held and
Reason for Leaving: _____

Month and Year Employment/School

From*: _____ Name*:_____
To: _____ Location:_____
(leave blank if current) (City, state or country)
Position Held and
Reason for Leaving: _____

Month and Year Employment/School

From*: _____ Name*:_____
To: _____ Location:_____
(leave blank if current) (City, state or country)
Position Held and
Reason for Leaving: _____

*Required to file application

Residential History

List your residential addresses, working back five (5) years. All time must be accounted for. Post office box address is not acceptable. If more spaces are needed, complete the information in another document and attach it to this document.

Month and Year _____ Residential Address _____

From:* _____ _____

To: _____
(leave blank if current)

Month and Year _____ Residential Address _____

From:* _____ _____

To: _____
(leave blank if current)

Month and Year _____ Residential Address _____

From:* _____ _____

To: _____
(leave blank if current)

Month and Year _____ Residential Address _____

From:* _____ _____

To: _____
(leave blank if current)

Month and Year _____ Residential Address _____

From:* _____ _____

To: _____
(leave blank if current)

*Required to file application

Associated Person applicants and principals of sole proprietors complete this section

Proficiency Requirements

Answer the following questions.

Have you passed the Series 3 Examination within the past two years?* ○ Yes ○ No

Only individuals intending to use an alternative(s) to satisfy the proficiency requirements complete this section.

Check one of the following, if applicable

If you are a registered General Securities Representative of the sponsor, and your futures activity will be limited to any of the two following activities, check each that applies:

- □ You limit futures activities to those activities covered in the Futures Managed Funds Examination (Series 31): the solicitation of pool participants and/or the solicitation of discretionary accounts managed by a CTA, or the supervision of others engaged in such solicitations.

  Have you passed the Series 31 Examination within the past two years?* ○ Yes ○ No

- □ You limit your futures activity as provided in Registration Rule 401(b) to referring clients to another AP of the sponsor or to supervising others who make such referrals.

□ Check here if you have been registered or licensed to solicit futures business by a foreign regulatory authority located in Canada or the United Kingdom within the past two years and are therefore eligible to satisfy the proficiency requirements by passing the Limited Futures Examination – Regulations (Series 32).

Have you passed the Series 32 Examination within the past two years?* ○ Yes ○ No

□ Check here if your sponsor is a CPO that trades swaps subject to the jurisdiction of the CFTC in a commodity pool that but for the trading of such swaps would be eligible for the exclusion under CFTC Regulation 4.5(c)(2)(iii)(A) or (B) or the exemption under CFTC Regulations 4.13(a)(3) and the sponsor has been granted or is seeking a waiver from the Series 3 for its APs pursuant to NFA Registration Rule 401(e)(2)(ii) or if your sponsor is a CTA that provides advice on behalf of the sponsor to a commodity pool as described above.

□ Check here if your sponsor is a CPO that operates pools primarily engaged in securities transactions or a CTA that provides futures trading advice solely incidental to its securities advisory services and your sponsor has been granted or is seeking a waiver from the Series 3 for its APs pursuant to the Interpretive Notices to Registration Rule 402.

*Required to file application

Only individuals filing as a forex associated person complete this section.

Have you passed the Series 34 Examination within the past two years?* ○ Yes ○ No

Only individuals filing as a branch office manager complete this section

Have you passed the Series 30 Examination within the past two years?* ○ Yes ○ No

Are you eligible to be a Branch Office Manager or Designated Supervisor under FINRA rules?* ○ Yes ○ No

*Required to file application

Paperwork Reduction Act Notice

OMB Numbers 3038-0023 and 3038-0072

You are not required to provide the information requested on a form subject to the Paperwork Reduction Act unless the form displays a valid OMB Control Number.

The time needed to complete and file Form 7-R, Form 7-W, Form 8-R and Form 8-T may vary depending upon individual circumstances. The estimated average times are:

Form 7-R

FCM	0.6 hours	IB	0.5 hours	Form 7-W	0.1 hours
SD	1.1 hour	CPO	0.5 hours	Form 8-R	1.0 hour
MSP	1.1 hour	CTA	0.5 hours	Form 8-T	0.2 hours
RFED	0.6 hours	FT	0.6 hours		

Privacy Act Notice

The information in Forms 7-R, 7-W, 8-R and 8-T and on the fingerprint card is being collected pursuant to authority granted in Sections 2(c), 4f, 4k, 4n, 4s, 8a and 19 of the Commodity Exchange Act, 7 U.S.C. 2(c), 6f, 6k, 6n, 6s, 12a and 23. Under Section 2(c), it is unlawful for anyone to engage in off-exchange foreign currency futures transactions or off-exchange foreign currency leveraged, margined or financed transactions with persons who are not eligible contract participants without registration, or exemption from registration, as a retail foreign exchange dealer, futures commission merchant, introducing broker, commodity pool operator or commodity trading advisor, as appropriate. Under Section 4d of the Commodity Exchange Act, 7 U.S.C. 6d, it is unlawful for anyone to act as a futures commission merchant or introducing broker without being registered in that capacity under the Act. Under Section 4m of the Commodity Exchange Act, 7 U.S.C. 6m, it is unlawful for a commodity trading advisor or commodity pool operator to make use of the mails or any means or instrumentality of interstate commerce in connection with his business as a commodity trading advisor or commodity pool operator without being registered in the appropriate capacity under the Act, except that a commodity trading advisor who, during the course of the preceding 12 months, has not furnished commodity trading advice to more than 15 persons and does not hold himself out generally to the public as a commodity trading advisor, need not register. Under Section 4s of the Commodity Exchange Act, 7 U.S.C. 6s, it is unlawful for anyone to act as a swap dealer or major swap participant without being registered in that capacity under the Act. Under Section 19 of the Commodity Exchange Act, 7 U.S.C. 23, and Section 31.5 of the CFTC's regulations, it is unlawful for anyone to act as a leverage transaction merchant without being registered in that capacity under the Act.

The information requested in Form 7-R is designed to assist NFA and the CFTC, as appropriate, in determining whether the application for registration should be granted or denied and to maintain the accuracy of registration files. The information in Form 7-W is designed to assist NFA and the CFTC in determining whether it would be contrary to the requirements of the Commodity Exchange Act, or any rule, regulation or order thereunder, or the public interest to permit withdrawal from registration.

The information requested in Form 8-R and on the fingerprint card will be used by the CFTC or NFA, as appropriate, as a basis for conducting an inquiry into the individual's fitness to be an associated person, floor broker or floor trader or to be a principal of a futures commission merchant, swap dealer, major swap participant, retail foreign exchange dealer, introducing broker, commodity

trading advisor, commodity pool operator, leverage transaction merchant or non-natural person floor trader.

Portions of the information requested in Form 8-R will be used by the CFTC and, in appropriate cases, by NFA, to confirm the registration of certain associated persons. The information requested in Form 8-T will be used by the CFTC, and, in appropriate cases, by NFA, to record the registration status of the individual and, in appropriate cases, as a basis for further inquiry into the individual's fitness to remain in business subject to the CFTC's jurisdiction.

With the exception of the social security number and Federal employer identification number, all information in Forms 8-R and 8-T must be furnished. Disclosure of the social security number and Federal employer identification number is voluntary. The social security number and the Federal employer identification number are sought pursuant to the Debt Collection Improvement Act of 1996, which allows the CFTC to use the social security number or taxpayer identifying number furnished to the CFTC as part of the registration process for purposes of collecting and reporting on any debt owed to the U.S. Government, including civil monetary penalties. Although voluntary, the furnishing of a social security number or Federal employer identification number assists the CFTC and NFA in identifying individuals and firms, and therefore expedites the processing of those forms.

The failure by an applicant, registrant or principal to timely file a properly completed Form 7-R and all other related required filings may result in the denial of an application for registration or withdrawal thereof or, in the case of an annual records maintenance fee, treating the registrant as having petitioned for withdrawal. Failure by an applicant, registrant or principal to timely file or cause to be filed a properly completed Form 8-R or 8-T, any other required related filings, or a fingerprint card may result in the lapse, denial, suspension or revocation of registration, withdrawal of the application or other enforcement or disciplinary action by the CFTC or NFA.

NFA makes available to the public on NFA website(s), including the Background Affiliation Status Information Center (BASIC), firm directories, business addresses, telephone numbers, registration categories, effective dates of registration, registration status, and disciplinary action taken concerning futures commission merchants, introducing brokers, commodity pool operators, commodity trading advisors, swap dealers, major swap participants and retail foreign exchange dealers and their associated persons and principals; non-natural person floor traders and their principals; and floor trader order enterers.

Additional information on Forms 7-R, 7-W, 8-R and 8-T is publicly available, and may be accessed by contacting the National Futures Association, Registration Department, Suite 1800, 300 S. Riverside Plaza, Chicago, IL 60606-6615, except for the following information, which is generally not available for public release unless required under the Freedom of Information Act (FOIA) :

- The fingerprint card, including its demographic information;
- social security number;
- date of birth;
- location of birth;
- current residential address; and
- any supplementary information filed in response to the Form 8-R "Personal Information," "Disciplinary Information," "Matter Information," or "Disclosure Matter" sections, Form 8-T "Withdrawal Reasons," "Disciplinary Information," or "Matter Information" sections, and Form 7-W, "Additional Customer Information" sections.

The CFTC, or NFA acting in accordance with rules approved by the CFTC, may disclose to third parties any information provided on Forms 7-R, 7-W, 8-R and 8-T pursuant to the Commodity Exchange Act, 7 U.S.C. 1 et. seq., Privacy Act of 1974, 5 U.S.C. 552a (Privacy Act), and the Commission's Privacy Act routine uses published in the Federal Register, which may include, but is not limited to, disclosure to Federal, state, local, or foreign law enforcement or regulatory authorities acting within the scope of their jurisdiction or for their use in meeting responsibilities assigned to them by law. The information will be maintained and disclosures will be made in accordance with CFTC Privacy Act System of Records Notice CFTC-12, National Futures Association (NFA) Applications Suite System (Exempted), CFTC-10, Investigatory Records (Exempted), or another relevant System of Records Notice, available from the CFTC "Privacy Program" page, http://www.cftc.gov/Transparency/PrivacyOffice.

If an individual believes that information on the forms is confidential, the individual may petition the CFTC, pursuant to 17 CFR 145.9, to treat such information as confidential in response to requests under FOIA. 5 U.S.C. 552. The filing of a petition for confidential treatment, however, does not guarantee that the information will be treated confidentially in response to a FOIA request. The CFTC will make no determination as to confidential treatment of information submitted unless and until the information is the subject of an FOIA request.

This notice is provided in accordance with the requirements of the Privacy Act, 5 U.S.C. 552a(e)(3), and summarizes some of an individual's rights under the Privacy Act, 5 U.S.C. 552a. Individuals desiring further information should consult the CFTC's regulations under the Privacy Act, 17 CFR Part 146, and under the Freedom of Information Act, 17 CFR Part 145, and the CFTC's published System of Records Notices, which describe the existence and character of each system of records maintained by the CFTC, available at the CFTC "Privacy Program" page.

Forms which have not been prepared and executed in compliance with applicable requirements may not be acceptable for filing. Acceptance of this form shall not constitute any finding that the information is true, current or complete. Misstatements or omissions of fact may constitute federal criminal violations [7 U.S.C. 13 and 18 U.S.C. 1001] or grounds for disqualification from registration.

Sponsor Agreement

Sponsor certifies that:

the Form 8-R is, to the best of the Sponsor's knowledge, information and belief, true, complete and accurate and that in light of the circumstances under which the Sponsor has given them, the answers and statements in the Form 8-R are not misleading in any material respect;

the AP applicant, Forex AP applicant, Swap AP applicant, principal or Floor Trader Order Enterer has authorized the Sponsor to electronically file the Form 8-R on the AP applicant's, Forex AP applicant's or Swap AP applicant's behalf, the principal's behalf or the Floor Trader Order Enterer's behalf and that the Sponsor has authorized the person who files the application to file the Form 8-R and to make the certifications and acknowledgements contained in this Sponsor Agreement;

the Sponsor has communicated or has attempted to communicate with all of the applicant's previous employers and educational institutions for the past three years and has documentation on file with the names of the persons contacted and the dates of contact or, if no contact was

made, the reason therefor;

the applicant has been hired or is employed by the Sponsor or that it is the intention of the Sponsor to hire or otherwise employ the applicant as an AP, Forex AP or Swap AP within 30 days after receipt of notification that the applicant has received a temporary license or has been registered;

the applicant will not be permitted to act as an AP until the applicant has received a temporary license or has been registered as an AP, to act as a Forex AP until the applicant has been approved as a Forex AP or to act as a Swap AP until the applicant has been approved as a Swap AP;

if the Sponsor is a new sponsor filing an application for registration of the applicant as an AP pursuant to the provisions of NFA Registration Rule 207(a), that the Sponsor has verified that the applicant is not subject to a disqualification from registration under Section 8a(2) of the Commodity Exchange Act, 7 U.S.C. 12(a)(2), and that the Sponsor meets the requirements set forth in NFA Registration Rule 509(b)(5);

if the applicant is applying for a temporary license pursuant to NFA Registration Rule 301(a)(2), that the Sponsor has reviewed the information concerning the applicant in NFA's BASIC system and has received a copy of the notice of the institution of any proceeding in the BASIC system that is pending and was brought against the applicant under Sections 6(c), 6(d), 6c, 6d, 8a or 9 of the Commodity Exchange Act, 7 U.S.C. 9, 13b, 13a-1, 13a-2, 12a, and 13, CFTC regulations 3.55 or 3.60 or NFA or exchange rules or that was instituted in accordance with the procedures provided in CFTC regulation 3.51 or Part 500 of the NFA Registration Rules and, within the prior 12 months, resulted in the Commission or NFA permitting the withdrawal of such person's application for registration in any capacity;

if the applicant is subject to any current NFA or Commission order imposing conditions on the registration of the applicant, that the Sponsor meets the requirements set forth in NFA Registration Rule 509(b)(5) to sponsor a conditioned registrant, that it has reviewed the conditions contained in any current NFA or Commission order imposing conditions on the registration of the applicant and that the Sponsor will supervise the applicant in accordance with the conditions contained in the order; and

the Sponsor has taken, and will take, such measures as are necessary to prevent the unwarranted dissemination of any of the information contained in the Form 8-R and the records and documents retained in support of the Form 8-R.

Sponsor acknowledges that:

the Sponsor is subject to the imposition of criminal penalties under Section 9(a) of the Commodity Exchange Act, 7 U.S.C. 13(a), and 18 U.S.C. 1001 for any false statements or omissions Sponsor made in the Form 8-R;

while the individual is an AP, forex AP or Swap AP sponsored by or a principal of the Sponsor or is responsible for entering orders on behalf of the Floor Trader's own account, the Sponsor is responsible for maintaining the information in the Form 8-R in a complete, accurate and current manner by electronically filing updates to the information contained therein;

it is the duty and obligation of the Sponsor not to employ an individual as an AP with a statutory disqualification under Section 8a(2) of the Commodity Exchange Act, 7 U.S.C. 12(a)(2),to notify the Commission when any individual associated with the Sponsor is subject to a statutory disqualification under Section 8a(2) of the Act and to supervise any individual for whom the Sponsor files a Form 8-R, once the Sponsor employs him or her, with a view toward preventing him or her from committing violations of the Commodity Exchange Act and the rules, regulations and orders thereunder; and

the information contained in the Form 8-R has been supplied to the Sponsor for the sole purpose of allowing it to verify the information contained in the Form 8-R.

Individual Agreement

The applicant, principal or Floor Trader Order Enterer verifies that:

the answers and statements in the application or Form 8-R are true, complete and accurate and that in light of the circumstances under which the applicant, principal or Floor Trader Order Enterer has given them, the answers and statements in the Form 8-R are not misleading in any material respect.

The applicant certifies that

if applying for a temporary license pursuant to the provisions of NFA Registration Rule 301(a)(2), that the applicant has advised the Sponsor of and has provided the Sponsor with a copy of the notice of the institution of any pending adjudicatory proceeding that was brought against the applicant under Sections 6(c), 6(d), 6c, 6d, 8a or 9 of the Commodity Exchange Act, 7 U.S.C. 9, 13b, 13a-1, 13a-2, 12a, and 13, CFTC regulations 3.55 or 3.60 or NFA or exchange rules or any proceeding that was brought against the applicant under CFTC regulation 3.51 or Part 500 of the NFA Registration Rules and, within the prior 12 months, resulted in the Commission or NFA permitting the withdrawal of such person's application for registration in any capacity.

The applicant, principal or Floor Trader Order Enterer acknowledges that:

the applicant, principal or Floor Trader Order Enterer is subject to the imposition of criminal penalties under Section 9(a) of the Commodity Exchange Act, 7 U.S.C. 13(a), and 18 U.S.C. 1001 for any false statements or omissions made in the Form 8-R;

the applicant, principal or Floor Trader Order Enterer is responsible at all times for maintaining the information in the Form 8-R in a complete, accurate and current manner by promptly notifying the Sponsor whenever any of the information on the Form 8-R is no longer complete, accurate or current and authorizing the Sponsor to electronically file updates to correct the information;

the residential address provided on the Form 8-R may be deemed to be the address for delivery to the applicant, principal or Floor Trader Order Enterer of any written communications from the Commission and NFA, including any notice of intent to deny, revoke or otherwise affect the applicant's registration or individual's status as principal; any summons, complaint, reparations claim, arbitration claim, order or subpoena; request for information; or any other written communication

unless the applicant, principal or Floor Trader Order Enterer specifies another address for this purpose;

the applicant or principal must keep current the residential address provided on the Form 8-R while registered as an AP or affiliated as a principal and for two years after termination of registration or affiliation; and

the applicant is not registered and may not act as an AP until a notice has been issued that registration or a TL has been granted; if applicable, the applicant is not approved as a Forex AP and may not act as a Forex AP until approval has been granted; and, if applicable, the applicant is not approved as a Swap AP and may not act as a Swap AP until approval has been granted.

The applicant, principal or Floor Trader Order Enterer authorizes that:

NFA, and any contract market of which the applicant's or principal's Sponsor or any current or future guarantor (under CFTC regulation 1.10(j)) of the applicant's or principal's Sponsor is or may become a member, may conduct an investigation to determine the applicant's or principal's fitness for registration, and if applicable, for Associate status and NFA may conduct a background investigation of the Floor Trader Order Enterer;

and requests that any person, including but not limited to contract markets, or non-U.S. regulatory or law enforcement agencies, furnish upon request to NFA or any agent acting on behalf of NFA any information requested by NFA in connection with any investigation conducted by NFA to determine the applicant's fitness for registration or fitness of the principal or any background investigation of the Floor Trader Order Enterer;

The applicant, principal or Floor Trader Order Enterer agrees that:

the applicant, principal or Floor Trader Order Enterer will cooperate promptly and fully, consistent with applicable Federal law, in any investigation in connection with the applicant's or principal's fitness for registration or Associate status or any background investigation of the Floor Trader Order Enterer, which may include contacting non-U.S. regulatory and law enforcement authorities, including the submission of documents and information to NFA that NFA, in its discretion, may require in connection with the applicant's or principal's fitness for registration or Associate status or the background investigation of the Floor Trader Order Enterer;

the applicant or principal submits to the jurisdiction of any contract market, of which the applicant's or principal's Sponsor or any current or future guarantor (under CFTC regulation 1.10(j)) of the applicant's or principal's Sponsor is or may become a member, which has or may adopt rules which apply to the applicant as an associated person or principal, and the applicant or principal shall abide by all such rules and to comply with, be subject to, and abide by all requirements, rulings, orders, directives and decisions of and any penalties, prohibitions and limitations imposed by any such contract market;

any person furnishing information to NFA or any agent acting on behalf of NFA in connection with the investigation so authorized is released from any and all liability of whatever nature by reason of furnishing such information to NFA or any agent acting on behalf of NFA;

if the applicant is applying to obtain registration as an associated person, the applicant is also applying for registration with NFA as an Associate if the applicant's Sponsor is or becomes a Member of NFA; and

if the applicant is granted registration as an Associate of a Member of NFA, the applicant shall become and remain bound by all applicable NFA requirements, including without limitation all applicable NFA Bylaws, Compliance Rules, Financial Requirements, Registration Rules, Code of Arbitration and Member Arbitration Rules, as then and thereafter in effect, and that this agreement shall apply each time that the applicant is granted registration as an Associate.

Floor Broker/Floor Trader Agreement

The applicant certifies that:

the answers and statements in the Form 8-R are true, complete and accurate and that in light of the circumstances under which the applicant has given them, the answers and statements in the Form 8-R are not misleading in any material respect.

The applicant acknowledges that:

the applicant is subject to the imposition of criminal penalties under Section 9(a) of the Commodity Exchange Act, 7 U.S.C. 13(a), and 18 U.S.C. 1001 for any false statements or omissions made in the Form 8-R;

the applicant is responsible at all times for maintaining the information in the Form 8-R in a complete, accurate and current manner by electronically filing updates to the information contained therein;

the business address provided on the Form 8-R may be deemed to be the address for delivery to the applicant of any written communications from the Commission and NFA, including any notice of intent to deny, revoke or otherwise affect the applicant's registration; any summons, complaint, reparations claim, arbitration claim, order or subpoena; request for information; or any other written communication unless the applicant specifies another address for this purpose;

the applicant must keep current the business address provided on the Form 8-R while registered and for two years after termination of registration; and

the applicant is not registered and may not act as an FB or FT until a notice has been issued that registration or a temporary license has been granted.

The applicant authorizes that:

NFA may conduct an investigation to determine the applicant's fitness for registration;

and requests that any person, including but not limited to contract markets or non-U.S. regulatory or law enforcement agencies, furnish upon request to NFA or any agent acting on behalf of NFA any information requested by NFA in connection with any investigation conducted by NFA to

determine the applicant's fitness for registration;

The applicant agrees that:

the applicant will cooperate promptly and fully, consistent with applicable Federal law, in any investigation in connection with the applicant's application for registration, which investigation may include contacting non-U.S. regulatory and law enforcement authorities, including the submission of documents and information to NFA that NFA, in its discretion, may require in connection with the applicant's application for registration;

any person furnishing information to NFA or any agent acting on behalf of NFA in connection with the investigation so authorized is released from any and all liability of whatever nature by reason of furnishing such information to NFA or any agent acting on behalf of NFA; and

if the applicant ever applies for and is granted registration as an Associate of a Member of NFA, the applicant shall become and remain bound by all applicable NFA requirements, including without limitation all applicable NFA Bylaws, Compliance Rules, Financial Requirements, Registration Rules, Code of Arbitration and Member Arbitration Rules, as then and thereafter in effect, and that this agreement shall apply each time that that the applicant is granted registration as an Associate.

THE APPLICANT, PRINCIPAL OR FLOOR TRADER ORDER ENTERER ALSO AGREES TO THE PRIVACY ACT NOTICE ABOVE, AND THE COLLECTION, PROCESSING, DISCLOSURE, AND USE OF HIS OR HER PERSONAL INFORMATION BY NFA, THE CFTC, AND THIRD PARTIES AS STATED IN THE NOTICE.

Agree	Cancel

[FR Doc. 2017–08558 Filed 4–27–17; 8:45 am]
BILLING CODE 6351–01–C

BUREAU OF CONSUMER FINANCIAL PROTECTION

Academic Research Council Meeting

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the announcement of a public meeting of the Academic Research Council (ARC or Council) of the Consumer Financial Protection Bureau (Bureau). The notice also describes the functions of the Council. Notice of the meeting is permitted by section 8 of the ARC Charter.

DATES: The meeting date is Wednesday, May 17, 2017, 9:00 a.m. to 12:00 p.m. eastern standard time.

ADDRESSES: The meeting location is Consumer Financial Protection Bureau, 1275 First Street NE., Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Emily Turner, Director's Financial Analyst, 202–435–7730, *CFPB_AcademicResearchCouncil@cfpb.gov,* Academic Research Council, Office of Research, 1275 First Street NE., Washington, DC 20002.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1013(b)(1) of the Consumer Financial Protection Act, 12 U.S.C. 5493(b)(1), establishes the Office of Research (OR) and assigns to it the responsibility of researching, analyzing, and reporting on topics relating to the Bureau's mission, including developments in markets for consumer financial products and services, consumer awareness, and consumer behavior. The Academic Research Council is a consultative body comprised of scholars that help the Office of Research perform these responsibilities. Section 3 of the ARC Charter states: The Council will provide the Office of Research advice and feedback on research methodologies, framing research questions, data collection, and analytic strategies. Additionally, the Council will provide both backward- and forward-looking feedback on the Office of Research's research work and will offer input into its research strategic planning process and research agenda. Specifically, Section 8(d) of the ARC Charter states:

> (1) The Council will convene in person from time to time at the call of the Assistant Director or the Assistant Director's designee, but at a minimum shall meet annually. Council members may also make additional visits to the Bureau or participate in additional meetings for educational or other research-related purposes.

II. Agenda

The Academic Research Council will discuss methodology and direction for consumer finance research at the Bureau.

Persons who need a reasonable accommodation to participate should

contact *CFPB_504Request@cfpb.gov,* 202–435–9EEO, 1–855–233–0362, or 202–435–9742 (TTY) at least ten business days prior to the meeting or event to request assistance. The request must identify the date, time, location, and title of the meeting or event, the nature of the assistance requested, and contact information for the requester. CFPB will strive to provide, but cannot guarantee that accommodation will be provided for late requests.

Individuals who wish to attend the Academic Research Council meeting must RSVP to CFPB_504 *Request@cfpb.gov* by noon, May 8, 2017. Members of the public must RSVP by the due date and must include ''ARC'' in the subject line of the RSVP.

III. Availability

The Council's agenda will be made available to the public on May 1, 2017, via *consumerfinance.gov.* Individuals should express in their RSVP if they require a paper copy of the agenda.

A recording and transcript of this meeting will be available after the meeting on the CFPB's Web site *consumerfinance.gov.*

Dated: April 24, 2017.

Leandra English,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2017–08611 Filed 4–27–17; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committee

AGENCY: Department of Defense.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is renewing the charter for the Board of Regents, Uniformed Services University of the Health Sciences (''the Board'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Board's charter is being renewed pursuant to 10 U.S.C. 2113a and in accordance with the Federal Advisory Committee Act (FACA) of 1972 (5 U.S.C., Appendix, as amended) and 41 CFR 102–3.50(a). The Board's charter and contact information for the Board's Designated Federal Officer (DFO) can be found at *http://www.facadatabase.gov/.*

The Board shall assist the Secretary of Defense in an advisory capacity in carrying out the Secretary's responsible to conduct the business of the Uniformed Services University of the Health Sciences (''the University''). The Board shall provide advice and recommendations on academic and administrative matters critical to the full accreditation and successful operation of the University.

Under the provisions of 10 U.S.C. 2113a(b), the Board shall be composed of 15 members. All members of the Board are appointed to provide advice on behalf of the Government on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Pursuant to 10 U.S.C. 2113a(e), Board members (other than ex-officio members), while attending conferences or meetings or while otherwise performing their duties as members, shall be entitled to receive compensation at a rate to be fixed by the Secretary of Defense. All members are entitled to reimbursement for official Board-related travel and per diem.

The public or interested organizations may submit written statements to the Board membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board. All written statements shall be submitted to the DFO for the Board, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: April 25, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–08661 Filed 4–27–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Industry Information Day; Amendment

AGENCY: DoD Chief Information Officer, Department of Defense (DoD).

ACTION: Notice of meeting; extension of period for public to submit questions prior to meeting.

SUMMARY: DoD is extending the period for organizations to submit questions prior to the public ''Industry Information Day'' where DoD will present a briefing, and receive and address industry feedback on the implementation of Defense Federal Acquisition Regulation Supplement (DFARS) Case 2013–D018, ''*Network Penetration Reporting and Contracting for Cloud Services.*'' The period for organizations to submit questions is extended until Friday, June 2, 2017.

DATES: The public meeting will be held on June 23, 2017, from 9:00 a.m. to 1:00 p.m., EDT. Registration to attend this meeting must be received by Monday, June 12, 2017.

ADDRESSES: The public meeting will be held at the Mark Center Auditorium, 4800 Mark Center Drive, Alexandria, VA 22350–3603. The auditorium is located on level B–1 of the building.

FOR FURTHER INFORMATION CONTACT: Ms. Vicki Michetti, at (703)604–3167.

SUPPLEMENTARY INFORMATION:

Background

On April 5, 2017 (82 FR 16577), DoD published a notice of meeting in the **Federal Register** to announce that DoD is hosting an ''Industry Information Day'' to present a briefing, and receive and address industry feedback on the implementation of Defense Federal Acquisition Regulation Supplement (DFARS) Case 2013–D018, ''*Network Penetration Reporting and Contracting for Cloud Services.*''

The period for organizations to submit questions prior to DoD hosting an ''Industry Information Day'' is extended from May 1, 2017 to June 2, 2017, to provide additional time for parties to request information on the implementation of DFARS Case 2013–D018, ''*Network Penetration Reporting and Contracting for Cloud Services.*'' Questions should be sent by email to *OSD.DIBCSIAEvents@mail.mil* with the subject line of the email stating, ''Industry Information Day.''

Dated: April 25, 2017.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2017–08589 Filed 4–27–17; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Availability of Record of Decision for the Gulf of Alaska Navy Training Activities Final Supplemental Environmental Impact Statement/ Overseas Environmental Impact Statement

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy (DoN), after carefully weighing the

strategic, operational, and environmental consequences of the proposed action, announces its decision to continue military readiness activities as identified in Alternative 1 in the Gulf of Alaska Navy Training Activities Final Supplemental Environmental Impact Statement/Overseas Environmental Impact Statement. This alternative includes one large-scale Carrier Strike Group exercise annually, Anti-Submarine Warfare activities, and the use of active sonar for up to 21 consecutive days between April and October. Implementation of Alternative 1 will enable the DoN to meet current and future training requirements and manage and mitigate environmental impacts.

SUPPLEMENTARY INFORMATION: The complete text of the Record of Decision is available at *http://www.GOAEIS.com.* Single copies of the Record of Decision are available upon request by contacting: GOA Supplemental EIS/OEIS Project Manager, Naval Facilities Engineering Command Northwest, 1101 Tautog Circle, Suite 203, Silverdale, Washington 98315–1101.

Dated: April 25, 2017.

A.M. Nichols,

Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2017–08606 Filed 4–27–17; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2017–ICCD–0007]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; 2017–18 National Teacher and Principal Survey (NTPS 2017–18)

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of an existing information collection.

DATES: Interested persons are invited to submit comments on or before May 30, 2017.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2017–ICCD–0007. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW, LBJ, Room 224–84, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact NCES Information Collections at *NCES.Information.Collections@ed.gov.*

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: 2017–18 National Teacher and Principal Survey (NTPS 2017–18).

OMB Control Number: 1850–0598.

Type of Review: A revision of an existing information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 101,383.

Total Estimated Number of Annual Burden Hours: 46,749.

Abstract: The National Teacher and Principal Survey (NTPS), conducted biennially by the National Center for Education Statistics (NCES), is a system of related questionnaires that provides descriptive data on the context of elementary and secondary education. Redesigned from the Schools and Staffing Survey (SASS) with a focus on flexibility, timeliness, and integration with other ED data, the NTPS system allows for school, principal, and teacher characteristics to be analyzed in relation to one another. NTPS is an in-depth, nationally representative survey of first through twelfth grade public school teachers, principals, and schools. Kindergarten teachers in schools with at least a first grade are also surveyed. NTPS utilizes core content and a series of rotating modules to allow timely collection of important education trends as well as trend analysis. Topics covered include characteristics of teachers, principals, schools, teacher training opportunities, retention, retirement, hiring, and shortages. Preliminary activities for NTPS 2017–18, namely: (a) Contacting and seeking research approvals from public school districts with an established research approval process (''special contact districts''), (b) notifying districts that their school(s) have been selected for NTPS 2017–18, and (c) notifying sampled schools of their selection for the survey and verifying their mailing addresses, were approved in November 2016 with revisions in March 2017 (OMB# 1850–0598 v.16–17). This request is to conduct NTPS 2017–18, including all of its recruitment and data collection activities. Because of the overlap in time, this request also carries over the burden and materials for the approved preliminary activities.

Dated: April 25, 2017.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2017–08590 Filed 4–27–17; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

DOE/NSF High Energy Physics Advisory Panel

AGENCY: Department of Energy, Office of Science.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the DOE/NSF High Energy Physics Advisory Panel (HEPAP). The Federal Advisory Committee Act requires that public notice of these

meetings be announced in the **Federal Register**.

DATES: Monday, June 5, 2017 8:30 a.m. to 6:00 p.m.

Tuesday, June 6, 2017 8:30 a.m. to 4:00 p.m.

ADDRESSES: Hilton Washington DC North/Gaithersburg, 620 Perry Parkway, Gaithersburg, MD 20877.

FOR FURTHER INFORMATION CONTACT: John Kogut, Executive Secretary, High Energy Physics Advisory Panel (HEPAP), U.S. Department of Energy, Office of Science, SC–25/Germantown Building, 1000 Independence Avenue SW., Washington, DC 20585; Telephone: (301) 903–1298.

SUPPLEMENTARY INFORMATION:

Purpose of Meeting: To provide advice and guidance to the Department of Energy and the National Science Foundation on scientific priorities within the field of high energy physics research.

Tentative Agenda: Agenda will include discussions of the following: June 5–6, 2017

- Discussion of Department of Energy High Energy Physics Program.
- Discussion of National Science Foundation Elementary Particle Physics Program.
- Reports on and Discussions of Topics of General Interest in High Energy Physics.
- Public Comment (10-minute rule).

Public Participation: The meeting is open to the public. A webcast of this meeting will be available. Please check the Web site below for updates and information on how to view the meeting. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact John Kogut, (301) 903–1298 or by email at: *John.Kogut@science.doe.gov*. You must make your request for an oral statement at least five business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Panel will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

Minutes: The minutes of the meeting will be available on the U.S. Department of Energy's Office of High Energy Physics Advisory Panel Web site: *http://science.energy.gov/hep/hepap/meetings/*.

Issued at Washington, DC, on April 21, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017–08621 Filed 4–27–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Northern New Mexico

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Northern New Mexico. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 17, 2017 1:00 p.m.–5:15 p.m.

ADDRESSES: The Lodge at Santa Fe, Kachina Ballroom, 750 North St. Francis Drive, Santa Fe, New Mexico 87501.

FOR FURTHER INFORMATION CONTACT: Menice Santistevan, Northern New Mexico Citizens' Advisory Board (NNMCAB), 94 Cities of Gold Road, Santa Fe, NM 87506. Phone (505) 995–0393; Fax (505) 989–1752 or Email: *Menice.Santistevan@em.doe.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Call to Order
- Welcome and Introductions
- Approval of Agenda and Meeting Minutes of March 29, 2017
- Old Business
- New Business
- Update from Co-Deputy Designated Federal Officers and Executive Director
- Break
- Presentation on Wildfire Mitigation
- Public Comment Period
- Updates from EM Los Alamos Field Office and New Mexico Environment Department
- Wrap-Up Comments from NNMCAB Members
- Adjourn

Public Participation: The EM SSAB, Northern New Mexico, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Menice Santistevan at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Menice Santistevan at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Menice Santistevan at the address or phone number listed above. Minutes and other Board documents are on the Internet at: *http://energy.gov/em/nnmcab/northern-new-mexico-citizens-advisory-board.*

Issued at Washington, DC, on April 21, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017–08619 Filed 4–27–17; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

Orders Granting Authority To Import and Export Natural Gas, To Import and Export Liquefied Natural Gas, and Vacating Authority During March 2017

	FE Docket Nos.
Talisman Energy USA Inc	15–117–NG
New England NG Supply Limited.	16–103–NG
RBC Energy Services, L.P	17–26–NG
ST. Lawrence Gas Company, Inc.	17–27–NG
Dersa Oil & Gas Corporation.	17–16–NG
Gulf LNG Energy, L.L.C	17–19–LNG
Puget Sound Energy, Inc ..	17–24–NG
Nextera Energy Marketing, LLC and Nextera Energy Power Marketing, LLC.	17–25–NG
Koch Energy Services, LLC.	17–20–NG
Pilot Power Group, Inc	17–28–NG
Maritimes & Northeast Pipeline, L.L.C.	17–29–NG
Chevron U.S.A., Inc	16–141–LNG
Ferus Natural Gas Fuels Inc.	17–30–LNG

	FE Docket Nos.
Excelerate Energy Gas Marketing, Limited Partnership.	17–31–LNG

AGENCY: Office of Fossil Energy, Department of Energy.

ACTION: Notice of orders.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy gives notice that during March 2017, it issued orders granting authority to import and export natural gas, to import and export liquefied natural gas (LNG), and vacating authority. These orders are summarized in the attached appendix and may be found on the FE Web site at *http://energy.gov/fe/listing-doefe-authorizationsorders-issued-2017.*

They are also available for inspection and copying in the U.S. Department of Energy (FE–34), Division of Natural Gas Regulation, Office of Regulation and International Engagement, Office of Fossil Energy, Docket Room 3E–033, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478. The Docket Room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on April 20, 2017.

John A. Anderson,

Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.

APPENDIX

DOE/FE ORDERS GRANTING IMPORT/EXPORT AUTHORIZATIONS

3701–A	03/17/17	15–117–NG	Talisman Energy USA Inc	Order 3701–A vacating blanket authority to import/export natural gas from/to Canada.
3995	03/07/17	16–103–NG	New England NG Supply Limited.	Order 3995 granting Long-term authority to export natural gas to Mexico.
3996	03/09/17	17–26–NG	RBC Energy Services, L.P	Order 3996 granting blanket authority to import/export natural gas from/to Canada.
3997	03/09/17	17–27–NG	St. Lawrence Gas Company, Inc.	Order 3997 granting blanket authority to export natural gas to Canada.
3998	03/17/17	17–16–NG	Dersa Oil & Gas Corporation	Order 3998 granting blanket authority to export natural gas to Mexico.
4001	03/17/17	17–19–LNG	Gulf LNG Energy, L.L.C	Order 3984 granting blanket authority to import LNG from various international sources by vessel.
4002	03/17/17	17–24–NG	Puget Sound Energy, Inc	Order 4002 granting blanket authority to import/export natural gas from/to Canada, and vacating prior authority.
4003	03/20/17	17–25–NG	NextEra Energy Marketing, LLC and NextEra Energy Power Marketing, LLC.	Order 4003 granting blanket authority to import/export natural gas from/to Canada/Mexico, and vacating prior authority.
4004	03/17/17	17–20–NG	Koch Energy Services, LLC	Order 4004 granting blanket authority to import/export natural gas from/to Canada, and vacating prior authority.
4005	03/17/17	17–28–NG	Pilot Power Group, Inc	Order 4005 granting blanket authority to import/export natural gas from/to Canada/Mexico.
4006	03/17/17	17–29–NG	Maritimes & Northeast Pipeline, L.L.C.	Order 4006 granting blanket authority to import/export natural gas from/to Canada.
4007	03/28/17	16–141–LNG	Chevron U.S.A., Inc	Order 4007 granting blanket authority to export previously imported LNG to Non-free Trade Agreement Nations by vessel.
4008	03/31/17	17–30–LNG	Ferus Natural Gas Fuels Inc	Order 4008 granting blanket authority to import/export LNG from/to Canada by truck.
4009	03/31/17	17–31–LNG	Excelerate Energy Gas Marketing, Limited Partnership.	Order 4009 granting blanket authority to import LNG from various international sources by vessel.

[FR Doc. 2017–08623 Filed 04–27–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

DOE/NSF Nuclear Science Advisory Committee

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the DOE/NSF Nuclear Science Advisory Committee (NSAC). The Federal Advisory Committee Act requires that public notice of these meetings be announced in the **Federal Register**.

DATES: Friday, June 2, 2017; 8:45 a.m.–4:45 p.m.

ADDRESSES: Hilton Washington DC/Rockville Hotel & Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland 20852, 301–468–1100.

FOR FURTHER INFORMATION CONTACT: Brenda L. May, U.S. Department of Energy; SC–26/Germantown Building, 1000 Independence Avenue SW., Washington, DC 20585–1290; Telephone: 301–903–0536 or email: *brenda.may@science.doe.gov*

The most current information concerning this meeting can be found on the Web site: *http://science.gov/np/nsac/meetings/.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and guidance on a continuing basis to the Department of Energy and the National Science Foundation on scientific priorities within the field of basic nuclear science research.

Tentative Agenda: Agenda will include discussions of the following:

Friday, June 2, 2017

- Perspectives from Department of Energy and National Science Foundation
- Update from the Department of Energy and National Science Foundation's Nuclear Physics Office's
- LRP Presentations on CEBAF, FRIB, Theory Initiatives, RHIC

Note: The NSAC Meeting will be broadcast live on the Internet. You may find out how to access this broadcast by

going to the following site prior to the start of the meeting. A video record of the meeting including the presentations that are made will be archived at this site after the meeting ends: *http://www.tvworldwide.com/events/DOE/170602/*.

Public Participation: The meeting is open to the public. If you would like to file a written statement with the Committee, you may do so either before or after the meeting. If you would like to make oral statements regarding any of these items on the agenda, you should contact Brenda L. May, 301–903–0536 or *Brenda.May@science.doe.gov* (email). You must make your request for an oral statement at least five business days before the meeting. Reasonable provision will be made to include the scheduled oral statements on the agenda. The Chairperson of the Committee will conduct the meeting to facilitate the orderly conduct of business. Public comment will follow the 10-minute rule.

The minutes of the meeting will be available for review on the U.S. Department of Energy's Office of Nuclear Physics Web site at *http://science.gov/np/nsac/meetings/*.

Issued in Washington, DC, on April 21, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017–08622 Filed 4–27–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Oak Ridge Reservation

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Oak Ridge Reservation. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, May 10, 2017, 6:00 p.m.

ADDRESSES: Department of Energy Information Center, Office of Science and Technical Information, 1 Science.gov Way, Oak Ridge, Tennessee 37831.

FOR FURTHER INFORMATION CONTACT: Melyssa P. Noe, Alternate Deputy Designated Federal Officer, U.S. Department of Energy, Oak Ridge Office of Environmental Management, P.O. Box 2001, EM–942, Oak Ridge, TN 37831. Phone (865) 241–3315; Fax (865) 241–6932; E-Mail: *Melyssa.Noe@orem.doe.gov.* Or visit the Web site at *www.energy.gov/orssab.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

- Welcome and Announcements
- Comments from the Deputy Designated Federal Officer (DDFO)
- Comments from the DOE, Tennessee Department of Environment and Conservation and Environmental Protection Agency Liaisons
- Public Comment Period
- Presentation by DOE: Key Materials Disposition Activities
- Motions/Approval of February 8, 2017 Meeting Minutes
- Status of Outstanding Recommendations
- Alternate DDFO Report
- Committee Reports
- Adjourn

Public Participation: The EM SSAB, Oak Ridge, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Melyssa P. Noe at least seven days in advance of the meeting at the phone number listed above. Written statements may be filed with the Board either before or after the meeting. Individuals who wish to make oral statements pertaining to the agenda item should contact Melyssa P. Noe at the address or telephone number listed above. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comments will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling Melyssa P. Noe at the address and phone number listed above. Minutes will also be available at the following Web site: *https://energy.gov/orem/services/community-engagement/oak-ridge-site-specific-advisory-board/oak-ridge-site-specific-0.*

Issued at Washington, DC, on April 21, 2017.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2017–08620 Filed 4–27–17; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–1438–000]

Radford's Run Wind Farm, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Radford's Run Wind Farm, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 11, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by

clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08569 Filed 4–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–141–000]

Texas Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on April 11, 2017, Texas Gas Transmission, LLC (Texas Gas), 9 Greenway Plaza, Suite 2800, Houston, Texas 77046, filed a prior notice application pursuant to sections 157.205, and 157.216(b) of the Federal Energy Regulatory Commission's (Commission) regulations under the Natural Gas Act (NGA), and Texas Gas' blanket certificate issued in Docket No. CP82–407–000. Texas Gas requests authorization to abandon certain natural gas pipeline assets, ancillary auxiliary facilities and appurtenances, located in Terrebonne Parish, Louisiana and Louisiana State waters. Specifically, Texas Gas proposes to: (1) Abandon in place 3.61 miles of 8-inch-diameter pipeline known as the Bay Junop to Bay Round 8-inch pipeline; (3) abandon in place approximately 10.05 miles and abandon by removal approximately 0.24 miles of 8-inch-diameter pipeline, known as the Bay Round to Block 8 8-inch pipeline; and (3) abandon by removal the Bay Round Platform and the Brammer Old Camp Pass Platform, all as more fully set forth in the application, which is open to the public for inspection. The filing may also 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, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (866) 208–3676 or TTY, (202) 502–8659.

Any questions regarding this application should be directed to Kathy D. Fort, Manager, Certificates and Tariffs, Texas Gas Transmission, LLC, 610 West 2nd Street, Owensboro, Kentucky 42301 or phone (270) 688–6825, or by email *kathy.fort@bwpmlp.com.*

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenter will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Dated: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08567 Filed 4–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Commission Staff Attendance

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of the Commission's staff may attend the following meetings related to the transmission planning activities of the New York Independent System Operator, Inc. (NYISO):

NYISO Electric System Planning Working Group Meeting

May 5, 2017, 10:00 a.m.–3:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=bic_espwg&directory=2017-05-05.*

NYISO Business Issues Committee Meeting

May 17, 2017, 10:00 a.m.–12:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=bic&directory=2017-05-17.*

NYISO Operating Committee Meeting

May 18, 2017, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=oc&directory=2017-05-18*.

NYISO Electric System Planning Working Group Meeting

May 25, 2017, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=bic_espwg&directory=2017-05-25*.

NYISO Management Committee Meeting

May 31, 2017, 10:00 a.m.–4:00 p.m. (EST)

The above-referenced meeting will be via web conference and teleconference.

The above-referenced meeting is open to stakeholders.

Further information may be found at: *http://www.nyiso.com/public/committees/documents.jsp?com=mc&directory=2017-05-31*.

The discussions at the meetings described above may address matters at issue in the following proceedings:

New York Independent System Operator, Inc., Docket No. ER13–102.

New York Independent System Operator, Inc., Docket No. ER15–2059.

New York Transco, LLC, Docket No. ER15–572.

For more information, contact James Eason, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (202) 502–8622 or *James.Eason@ferc.gov*.

Dated: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08571 Filed 4–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER17–1442–000]

Axiall, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Axiall, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is May 11, 2017.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov*. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov*. or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08570 Filed 4–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–6–000]

Texas Eastern Transmission, LP; Notice of Availability of the Environmental Assessment for the Proposed Idle Line 1 Abandonment Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Idle Line 1 Abandonment Project, proposed by Texas Eastern Transmission, LP (Texas Eastern) in the above-referenced docket. Texas Eastern requests authorization to abandon in place and by removal approximately 165 miles of existing, idle, Line 1 pipeline that runs from Fayette County, Ohio, to Greene County, Pennsylvania. Specifically, Texas Eastern is proposing to abandon portions of the Line 1 pipeline that were placed into idle service in 1989 including three segments of 24-inch pipeline, associated lateral lines 10–L and 10–M, metering and regulating facilities, and other related aboveground facilities.

The EA assesses the potential environmental effects of the abandonment of the Idle Line 1 in accordance with the requirements of the National Environmental Policy Act (NEPA). The FERC staff concludes that approval of the proposed project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The U.S. Army Corps of Engineers participated as a cooperating agency in the preparation of the EA. Cooperating agencies have jurisdiction by law or special expertise with respect to resources potentially affected by the proposal and participate in the NEPA analysis. The U.S. Army Corps of Engineers may adopt and use the EA in its decision-making process on whether to issue a Section 404 or Section 10 permit to Texas Eastern for abandonment activities in waters of the United States.

The proposed Idle Line 1 Abandonment Project includes abandoning in place the following facilities:

- 5.03 miles of 24-inch-diameter Line 1 from milepost 837.05 in Fayette County, Ohio to milepost 842.08 in Pickaway County, Ohio (Segment 1);
- 155.37 miles of 24-inch-diameter Line 1 from milepost 848.33 in Pickaway County, Ohio to milepost 1003.7 in Green County, Pennsylvania (Segment 2);
- 5.48 miles of 24-inch-diameter Line 1 from milepost 1004.35 to 1009.83 in Greene County, Pennsylvania (Segment 3);
- 0.5 miles of 8-inch Line 10–M in Marshall County, West Virginia;
- 0.07 miles of 4.5-inch Line 10–L in Greene County, Pennsylvania; and

Metering and Regulation facilities, and related launcher/receiver barrels, mainline valves, and other appurtenances would also be removed.

The FERC staff mailed copies of the EA to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; libraries in the project areas; potentially affected landowners and other interested individuals and groups; and parties to this proceeding.

In addition, the EA is available for public viewing on the FERC's Web site (*www.ferc.gov*) using the eLibrary link. A limited number of copies of the EA are available for distribution and public inspection at: Federal Energy Regulatory Commission, Public Reference Room, 888 First Street NE., Room 2A, Washington, DC 20426, (202) 502–8371.

Any person wishing to comment on the EA may do so. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this project, it is important that we receive your comments in Washington, DC on or before May 22, 2017.

For your convenience, there are three methods you can use to file your comments to the Commission. In all instances, please reference the project docket number (CP17–6–000) with your submission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

(1) You can file your comments electronically using the eComment feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's Web site (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214).[1] Only intervenors have the right to seek rehearing of the Commission's decision. The Commission grants affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site (*www.ferc.gov*) using the eLibrary link. Click on the eLibrary link, click on ''General Search,'' and enter the docket number excluding the last three digits in the Docket Number field (*i.e.,* CP17–6). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

[1] See the previous discussion on the methods for filing comments.

Dated: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08566 Filed 4–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP17–212–000]

Transcontinental Gas Pipe Line Company, LLC; Notice of Amendment

On April 19, 2017, Transcontinental Gas Pipe Line Company, LLC (Transco), P.O. Box 1396, Houston, TX 77251–1396, filed a variance request in Docket No. CP15–138–000. The Commission is treating the variance request as an application to amend its Atlantic Sunrise Project under section 7(c) of the Natural Gas Act (NGA) and Part 157 of the Commission's regulations, and herby gives notice of the proposed amendment. Specifically, Transco requests authorization to modify the pipeline route in Luzerne and Wyoming counties, Pennsylvania, from milepost (MP) M–0166–0.29 to MP 30.20 (totaling 6.48 miles), identified as Central Penn Line (CPL) North Alternative 13 (Amendment). Transco proposes this amendment to address landowner concerns, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing 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, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions regarding the proposed amendment should be directed to Bill Hammons at Transcontinental Gas Pipe Line Company, LLC, Post Office Box 1396, Houston, TX 77251 or at (713) 215–2130 or Scott Turkington, Director, Rates & Regulatory, Transcontinental Gas Pipe Line Company, LLC, Post Office Box 1396, Houston, TX 77251–1396 or at (713) 215–3391 (phone), or *scott.c.turkington@williams.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental analysis (EA) and place it into the Commission's public record (eLibrary) for this proceeding, or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 5 copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on May 12, 2017.

Dated: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08568 Filed 4–27–17; 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: EC17–106–000.
Applicants: ITC Midwest LLC.
Description: Application of ITC Midwest LLC for Approval of Acquisition of Assets Pursuant to Section 203 of the FPA.
Filed Date: 4/21/17.
Accession Number: 20170421–5243.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: EC17–107–000.
Applicants: Decatur Energy Center, LLC, Capital Power Investments LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Action, Confidential Treatment, and Waivers of Capital Power Investments LLC, et al.
Filed Date: 4/21/17.
Accession Number: 20170421–5246.
Comments Due: 5 p.m. ET 5/12/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–1458–000.
Applicants: PacifiCorp.
Description: § 205(d) Rate Filing: BPA AC Intertie Agreement 14th Revised to be effective 6/21/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5239.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1459–000.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2017–04–21 Market Redesign and Technology Upgrade Directives to be effective N/A.
Filed Date: 4/21/17.
Accession Number: 20170421–5241.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1460–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1636R18 Kansas Electric Power Cooperative, Inc. NITSA and NOA to be effective 4/1/2017.
Filed Date: 4/24/17.
Accession Number: 20170424–5128.
Comments Due: 5 p.m. ET 5/15/17.

Docket Numbers: ER17–1461–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC-Greenwood RS No. 334 Revised PPA to be effective 7/1/2017.
Filed Date: 4/24/17.
Accession Number: 20170424–5134.
Comments Due: 5 p.m. ET 5/15/17.

Docket Numbers: ER17–1462–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC-Concord RS No. 327 Revised PPA to be effective 7/1/2017.
Filed Date: 4/24/17.
Accession Number: 20170424–5136.
Comments Due: 5 p.m. ET 5/15/17.

Docket Numbers: ER17–1463–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original SA No. 4682, First Revised SA Nos. 4332 and 4333, Queue No. AA1–139 to be effective 10/26/2016.
Filed Date: 4/24/17.
Accession Number: 20170424–5167.
Comments Due: 5 p.m. ET 5/15/17.

Docket Numbers: ER17–1464–000.
Applicants: World Fuel Services, Inc.
Description: Baseline eTariff Filing: World Fuel Services—Baseline Filing to be effective 4/24/2017.
Filed Date: 4/24/17.
Accession Number: 20170424–5174.

Comments Due: 5 p.m. ET 5/15/17.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF17–852–000.
Applicants: Newberry Solar 1, LLC.
Description: Refund Report of Newberry Solar 1, LLC.
Filed Date: 4/21/17.
Accession Number: 20170421–5242.
Comments Due: 5 p.m. ET 5/12/17.

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: April 24, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08573 Filed 4–27–17; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. EL17–67–000]

New York Power Authority; New York Independent System Operator, Inc.; Notice of Institution of Section 206 Proceeding

On April 21, 2017, a letter order was issued in Docket No. EL17–67–000 by the Director, Division of Electric Power—East, Office of Energy Market Regulation, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into whether the updated depreciation rates of New York Power Authority, which were included in New York Independent System Operator, Inc.'s Open Access Transmission Tariff may be unjust, unreasonable, unduly discriminatory or preferential. *New York Power Authority and New York Independent System Operator, Inc.,* 159 FERC 62,075 (2017).

Any interested person desiring to be heard in Docket No. EL17–67–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08574 Filed 4–27–17; 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: EC17–105–000.
Applicants: CP Bloom Wind LLC.
Description: Application for Authorization under Section 203 of the Federal Power Act of CP Bloom Wind LLC.
Filed Date: 4/20/17.
Accession Number: 20170420–5237.
Comments Due: 5 p.m. ET 5/11/17.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER17–335–002.
Applicants: PJM Interconnection, L.L.C.
Description: Compliance filing: Erata to Compliance Filing in Docket No. ER17–335–001 to be effective 1/9/2017.
Filed Date: 4/20/17.
Accession Number: 20170420–5202.
Comments Due: 5 p.m. ET 5/11/17.

Docket Numbers: ER15–794–004.
Applicants: Catalyst Paper Operations Inc.
Description: Compliance filing: Change in Status Filing to be effective 1/27/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5223.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1445–000.
Applicants: Tucson Electric Power Company.
Description: § 205(d) Rate Filing: Concurrence to PNM RS No. 45 PETA (TEP RS No. 47) to be effective 6/11/2017.
Filed Date: 4/20/17.
Accession Number: 20170420–5190.
Comments Due: 5 p.m. ET 5/11/17.

Docket Numbers: ER17–1446–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Notification of Tariff Discrepancy and Request for Limited Tariff Waiver of Midcontinent Independent System Operator, Inc.
Filed Date: 4/20/17.
Accession Number: 20170420–5241.
Comments Due: 5 p.m. ET 5/11/17.

Docket Numbers: ER17–1447–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 1630R7 The Empire District Electric Company NITSA and NOA to be effective 4/1/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5036.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1448–000.
Applicants: DifWind Farms Limited I.
Description: § 205(d) Rate Filing: CIS and SW Category 2 Seller Request to be effective 4/22/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5063.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1449–000.
Applicants: DifWind Farms Limited II.
Description: § 205(d) Rate Filing: CIS and SW Category 2 Seller Request to be effective 4/22/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5064.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1450–000.
Applicants: DifWind Farms Limited V.
Description: § 205(d) Rate Filing: CIS and SW Category 2 Seller Request to be effective 4/22/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5065.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1451–000.
Applicants: VPI Enterprises, LLC.
Description: § 205(d) Rate Filing: CIS and SW Category 2 Seller Request to be effective 4/22/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5066.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1452–000.
Applicants: Southern California Edison Company.
Description: § 205(d) Rate Filing: Amended SGIA SEPV Mojave West Project SA No. 560 to be effective 6/21/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5067.
Comments Due: 5 p.m. ET 5/12/17.

Docket Numbers: ER17–1453–000.
Applicants: New York Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 205 filing re: transmission constraint pricing revisions to be effective 6/20/2017.

Filed Date: 4/21/17.
Accession Number: 20170421–5070.
Comments Due: 5 p.m. ET 5/12/17.
Docket Numbers: ER17–1454–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2017–04–21_SA 3012 Wisconsin Power & Light-ATC GIA (J390) to be effective 4/7/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5092.
Comments Due: 5 p.m. ET 5/12/17.
Docket Numbers: ER17–1455–000.
Applicants: Public Service Electric and Gas Company, PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: PSEG submits revisions to OATT, Attachment M–2 (PSEG) to Update to General Proc. to be effective 6/21/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5102.
Comments Due: 5 p.m. ET 5/12/17.
Docket Numbers: ER17–1456–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Rate Schedule No. 217, Exhibit D to be effective 6/21/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5129.
Comments Due: 5 p.m. ET 5/12/17.
Docket Numbers: ER17–1457–000.
Applicants: ITC Midwest LLC.
Description: § 205(d) Rate Filing: Cancellation of Maintenance Agreement with SMMPA to be effective 4/21/2017.
Filed Date: 4/21/17.
Accession Number: 20170421–5145.
Comments Due: 5 p.m. ET 5/12/17.

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: April 21, 2017.

Kimberly D. Bose,

Secretary.

[FR Doc. 2017–08572 Filed 4–27–17; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9032–8]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information (202) 564–7146 or *http://www.epa.gov/nepa.*

Weekly Receipt of Environmental Impact Statements (EISs)

Filed 04/17/2017 through 04/21/2017
Pursuant to 40 CFR 1506.9.

Notice

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *http://www.epa.gov/compliance/nepa/eisdata.html.*

EIS No. 20170064, Draft, USFS, CA, Horse Creek Community Protection and Forest Restoration Project, Comment Period Ends: 06/13/2017, Contact: Lisa Bousfield 530–493–1766.

EIS No. 20170065, Draft, FHWA, TXDOT, TX, North Houston Highway Improvement Project, Comment Period Ends: 06/27/2017, Contact: Carlos Swonke 512–416–2734.

The Texas Department of Transportation is the Lead Agency for the above project.

EIS No. 20170066, Final Supplement, USFS, OR, Ochoco Summit Trail System, Review Period Ends: 05/30/2017, Contact: Marcy Anderson 541–416–6463.

EIS No. 20170067, Final, VA, KY, Replacement Robley Rex VA Medical Center, Review Period Ends: 05/30/2017, Contact: Glenn Wittman 224–610–3531.

EIS No. 20170068, Final, DOE, Other, ADOPTION—Delfin LNG Deepwater Port, Contact: Kyle Moorman 202–586–7970, The Department of Energy (DOE) has adopted the U.S. Coast Guard and the U.S. Maritime Administration's FEIS #20160277, filed with EPA on 11/18/2016. The DOE was a cooperating agency for this project. Therefore, recirculation of the EIS is not deemed necessary under Section 1506.3(c) of the CEQ Regulations.

Amended Notices

EIS No. 20170011, Draft, APHIS, Other, Revisions to USDA–APHIS 7 CFR part 340 Regulations Governing the Importation, Interstate Movement, and Environmental Release of Genetically Engineered Organisms, Comment Period Ends: 06/19/2017, Contact: Cindy Eck 301–851–3892, Revision to **Federal Register** Notice Published 01/23/2017; Extending Comment Period from 05/22/2017 to 06/19/2017.

Dated: April 25, 2017.

Dawn Roberts,

Management Analyst, NEPA Compliance Division Office of Federal Activities.

[FR Doc. 2017–08639 Filed 4–27–17; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Radio Broadcasting Services; AM or FM Proposals To Change the Community of License

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: The following applicants filed AM or FM proposals to change the community of License: Chehalis Valley Educational Foundation, Station KBSG, Facility ID 174954, BPED–20170329ABV, From Westport, WA, To Raymond, WA; Cochise Broadcasting, LLC, Station KKYZ, Facility ID 2185, BMPH–20170224AAW, From Sierra Vista, AZ, To Catalina Foothills, AZ; Educational Media Foundation, Station KWAO, Facility ID 121867, BPED–20170213AAP, From Ocean Park, WA, To Vashon, WA; Educational Media Foundation, Station KLOY, Facility ID 93999, BPED–20170213AAQ, From Astoria, OR, To Ocean Park, WA; Educational Media Foundation, Station KILV, Facility ID 87226, BPED–20170317AAB, From Castana, IA, To Whiting, IA; Evans Broadcasting, Inc., Station KCUA, Facility ID 13483, BPH–20170223ABR, From Naples, UT, To Maeser, UT; Gateway Radio Work, Inc., Station WGWM, Facility ID 24221, BP–20170206ABA, From London, KY, To Winchester, KY; Inspiration Time, Inc., Station WCTL, Facility ID 28774, BPH–20170221ACH, From Union City, PA, To Erie, PA; Mercyhurst University, Station WMCE, Facility ID 26610, BP–20170221ACI, From North East, PA, To Union City, PA; Mid-West Management, Inc., Station WECL, Facility ID 64011, BPH–20170303ABG, From Elk Mound, WI, To Lake Hallie, WI; Mid-West Management, Inc., Station WIAL, Facility ID 7063, BPH–20170303ABH, From Eau Claire, WI, To Elk Mound, WI; Radio License Holding SRC, LLC., Station KFFG, Facility ID 58843, BPH–20170216ABR, From Los Altos, CA, To San Jose, CA; Wifredo G. Blanco-PI,

Station WVOZ, Facility ID 72452, BP–20170327AAF, From Morovis, PR, To Aguadilla, PR.

DATES: The agency must receive comments on or before June 27, 2017.

ADDRESSES: Federal Communications Commission, 445 Twelfth Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Tung Bui, 202–418–2700.

SUPPLEMENTARY INFORMATION: The full text of these applications is available for inspection and copying during normal business hours in the Commission's Reference Center, 445 12th Street SW., Washington, DC 20554 or electronically via the Media Bureau's Consolidated Data Base System, *http://licensing.fcc.gov/prod/cdbs/pubacc/prod/cdbs_pa.htm.*

Federal Communications Commission.

James D. Bradshaw,

Deputy Chief, Audio Division, Media Bureau.

[FR Doc. 2017–08585 Filed 4–27–17; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Submission for OMB Review; Comment Request (3064–0006 & –0184)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of existing information collections, as required by the Paperwork Reduction Act of 1995. On January 11, 2017, the FDIC requested comment for 60 days on a proposal to renew the information collections described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of these collections, and again invites comment on this renewal.

DATES: Comments must be submitted on or before May 30, 2017.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767), Counsel, MB–3007, or Jennifer Jones (202–898–6768), Counsel, MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza or Jennifer Jones, at the FDIC address above.

SUPPLEMENTARY INFORMATION: On January 11, 2017, (82 FR 3315), the FDIC requested comment for 60 days on a proposal to renew the information collections described below. No comments were received. The FDIC hereby gives notice of its plan to submit to OMB a request to approve the renewal of these collections, and again invites comment on this renewal.

Proposal to renew the following currently approved collections of information:

1. *Title:* Interagency Biographical and Financial Report.

OMB Number: 3064–0006.

Form Number: Interagency Biographical and Financial Report.

Affected Public: Insured State Nonmember Banks and State Savings Associations.

Burden Estimate:

Type of burden	Estimated number of respondents	Estimated time per response	Frequency of response	Total annual estimated burden
Reporting	574	4	On Occasion	2,296 hours

General Description of Collection: The Report is submitted to the FDIC by: (1) Each individual director, officer or individual or group of shareholders acting in concert that will own or control 10% or more of a proposed or operating depository institution applying for FDIC deposit insurance; (2) a person proposing to acquire control of an insured state nonmember bank or state savings association (FDIC-supervised institution); (3) each proposed new director or proposed new chief executive officer of an FDIC-supervised institution which has undergone a change in control within the preceding twelve months; and (4) each proposed new director or senior executive officer of an FDIC-supervised institution that is not in compliance with the applicable capital requirements or is otherwise in a troubled condition. The information is used by the FDIC to make an evaluation of the general character and financial condition of individuals who will be involved in the management or control of financial institutions, as required by statute. In order to lessen the burden on applicants, the FDIC cooperates with the other federal banking agencies to the maximum extent possible in processing the various applications. Notably, the Interagency Biographical and Financial Report will be amended to remove all references to the Office of Thrift Supervision as it appears on the form as well as changing the term ''thrift'' to ''savings association.'' These changes are technical and non-substantive in nature.

There is no change in the method or substance of the collection. The overall reduction in burden hours is a result of economic fluctuation. In particular, the number of respondents has decreased while the hours per response remain the same.

2. *Title:* Prohibitions and Restrictions on Proprietary Trading and Certain Interests In and Relationships With, Hedge Funds and Private Equity Funds.

OMB Number: 3064–0184.

Form Number: None.

Affected Public: Insured state nonmember banks not under a holding company; state savings associations and state savings banks not under a holding company; subsidiaries of state nonmember banks, state savings associations, and state savings banks not under a holding company; and foreign banks having an insured branch and their branches and agencies.

BURDEN ESTIMATE

	Type of burden	Estimated number of respondents	Estimated time per response	Frequency of response	Total annual estimated burden (hours)
Implementation					
§ 351.12(e)	Reporting	1	50	1	50
Total Reporting					50
§ 351.3(d)(3)	Recordkeeping	1	3	1	3
§ 351.4(b)(3)(i)(A)	Recordkeeping	1	2	4	8
§ 351.11(a)(2)	Recordkeeping	1	10	1	10
§ 351.20(b)	Recordkeeping	1	795	1	795
§ 351.20(e)	Recordkeeping	1	200	1	200
§ 351.20(f)(1)	Recordkeeping	1	8	1	8
§ 351.20(f)(2)	Recordkeeping	1	100	1	100
Total Recordkeeping					1,124
§ 351.11(a)(8)(i)	Disclosure	1	0.1	26	3
Total Disclosure					3
Total Implementation					1,177
Ongoing					
§ 351.12(e)	Reporting	18	20	10	3,600
Total Reporting					3,600
§ 351.3(d)(3)	Recordkeeping	18	1	1	18
§ 351.4(b)(3)(i)(A)	Recordkeeping	18	2	4	144
§ 351.11(a)(2)	Recordkeeping	18	10	1	180
§ 351.20(b)	Recordkeeping	5	265	1	1,325
§ 351.20(e)	Recordkeeping	5	200	1	1,000
§ 351.20(f)(1)	Recordkeeping	819	8	1	6,552
§ 351.20(f)(2)	Recordkeeping	18	40	1	720
Total Recordkeeping					9,939
§ 351.11(a)(8)(i)	Disclosure	18	0.1	26	47
Total Disclosure					47
Total Ongoing					13,586
Total Estimated Annual Burden.					14,763

General Description of Collection: Subject to certain exemptions, banking entities are generally prohibited from engaging in proprietary trading or from investing in, sponsoring, or having certain relationships with a hedge fund or private equity fund (''covered fund''). The Covered entities must retain certain records for a period that is no less than 5 years in a form that allows the prompt production of such records to the FDIC on request. The information collection requirements affecting FDIC-supervised institutions are summarized below.

Reporting Requirements

Section 351.12(e) states that, upon application, a banking entity may obtain an extension of the period of time to meet the requirements on ownership limitations in this section for up to 2 additional years.

Recordkeeping Requirements

Section 351.3(d)(3) requires covered entities to have a detailed written liquidity management plan that specifically contemplates and authorizes certain otherwise prohibited securities to be used for liquidity management purposes.

Section 351.4(b)(3)(i)(A) provides that a trading desk or other organizational unit of another entity with more than $50 billion in trading assets and liabilities is not a client, customer, or counterparty unless the trading desk documents how and why a particular trading desk or other organizational unit of the entity should be treated as a client, customer, or counterparty of the trading desk for purposes of § 351.4(b).

Section 351.11(a)(2) requires that covered funds generally must be organized and offered only in connection with the provision of bona fide trust, fiduciary, investment advisory, or commodity trading advisory services and only to persons that are customers of such services of the banking entity, pursuant to a written plan or similar documentation outlining how the banking entity intends to provide advisory or other similar services to its customers through organizing and offering the covered fund.

Section 351.20(b) specifies the contents of a required compliance program for a banking entity with total consolidated assets of $10 billion or more including a provision requiring that records sufficient to demonstrate compliance with section 13 of the BHC Act and applicable regulations be maintained and retained for a period of no less than 5 years or such longer period as required by FDIC.

Section 351.20(e) specifies that any banking entity that has more than $10 billion in total consolidated assets as reported on December 31 of the previous two calendar years shall maintain records documenting the determination that each fund sponsored by the banking entity (including all subsidiaries and affiliates) is not a covered fund. Banking entities must also maintain a written plan documenting the treatment of certain seeding vehicles described in the regulation and, under certain circumstances, documentation of the value of the ownership interests owned by the banking entity in certain foreign public fund and each jurisdiction in which any such foreign public fund is organized.

Section 351.20(f)(1) applies to banking entities with no covered activities. A banking entity that does not engage in activities or investments pursuant to subpart B or subpart C (other than trading activities permitted pursuant to § 351.6(a) of subpart B) may satisfy the requirements of this section by establishing the required compliance program prior to becoming engaged in such activities or making such investments (other than trading activities permitted pursuant to § 351.6(a) of subpart B).

Section 351.20(f)(2) applies to banking entities with modest activities. A banking entity with total consolidated assets of $10 billion or less as reported on December 31 of the previous two calendar years may satisfy the requirements of this section by including in its existing compliance policies and procedures appropriate references to the statutory and regulatory requirements and adjustments as appropriate given the activities, size, scope and complexity of the banking entity.

Disclosure Requirements

Section 351.11(a)(8)(i) requires that a banking entity make certain clear and conspicuous written disclosures to any prospective and actual investor in a covered fund (such as through disclosure in the covered fund's offering documents).

There is no change in the method or substance of this information collection. The annual burden estimate has been reduced from 28,234 hours to 17,763 hours primarily because the FDIC estimates that all FDIC-supervised institutions have now completed the implementation phase of the information collection and are no longer subject to that burden. FDIC is using one (1) respondent as a place-holder for implementation burden. Another reason for the reduction in burden is that fewer institutions are subject to reporting, recordkeeping and disclosure requirements. The foregoing reductions in burden more than offset a modest increase in burden attributable to: (i) One additional institution growing in size to a degree that now makes it subject to 12 CFR 351.20(b) and (e) recordkeeping requirements; and (ii) an agency adjustment in its estimate of respondents affected by the recordkeeping requirements in 12 CFR 351.20(f)(1) due to the inadvertent omission of a class of respondents in its prior estimate.

Request for Comment

Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 24th day of April 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2017–08604 Filed 4–27–17; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewals; Comment Request (3064–0099; –0118; –0148 and –0153)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of existing information collections, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35). Currently, the FDIC is soliciting comment on renewal of the information collections described below.

DATES: Comments must be submitted on or before June 27, 2017.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *http://www.FDIC.gov/regulations/laws/federal/notices.html.*
- *Email: comments@fdic.gov.* Include the name and number of the collection in the subject line of the message.
- *Mail:* Manny Cabeza (202–898–3767). Counsel, MB 3007 or Jennifer Jones (202–898–6768), Counsel, MB–3105, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza or Jennifer Jones, at the FDIC address noted above.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently approved collections of information:

1. *Title:* Application for Waiver of Prohibition on Acceptance of Brokered Deposits.

OMB Number: 3064–0099.

Form Number: None.

Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

Type of burden	Estimated number of respondents	Estimated time per response (hours)	Frequency of response	Total annual estimated burden (hours)
Reporting	30	6	On Occasion	180

General Description of Collection: Section 29 of the Federal Deposit Insurance Act prohibits undercapitalized insured depository institutions from accepting, renewing, or rolling over any brokered deposits. Adequately capitalized institutions may do so with a waiver from the FDIC, while well-capitalized institutions may accept, renew, or roll over brokered deposits without restriction. This information collection captures the burden associated with preparing and filing an application for a waiver of the

prohibition on the acceptance of brokered deposits.

There is no change in the method or substance of the collection. The overall reduction in burden hours is a result of economic fluctuation. In particular, the number of respondents has decreased while the hours per response remain the same.

2. *Title:* Management Official Interlocks.

OMB Number: 3064–0118.

Form Number: None.

Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

Type of burden	Estimated number of respondents	Estimated time per response	Frequency of response	Total annual estimated burden (hours)
Reporting	3	7	On Occasion	21

General Description of Collection: The FDIC's Management Official Interlocks regulation, 12 CFR 348, which implements the Depository Institutions Management Interlocks Act (DIMIA), 12 U.S.C. 3201–3208, generally prohibits bank management officials from serving simultaneously with two unaffiliated depository institutions or their holding companies but allows the FDIC to grant exemptions in appropriate circumstances. Consistent with DIMIA, the FDIC's Management Official Interlocks regulation has an application requirement requiring information specified in the FDIC's procedural regulation. The rule also contains a notification requirement.

There is no change in the method or substance of the collection. The overall reduction in burden hours is a result of economic fluctuation as well as the change in complexity of the reporting institutions. In particular, the number of respondents has decreased while the hours per response have increased due to the complexity of the reporting institutions.

3. *Title:* Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions.

OMB Number: 3064–0148.

Form Number: Interagency Statement on Sound Practices Concerning Elevated Risk Complex Structured Finance Activities.

Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

Type of burden	Estimated number of respondents	Estimated time per response	Frequency of response	Total annual estimated burden (hours)
Recordkeeping	4	25	On Occasion	100

General Description of Collection: The Interagency Statement on Sound Practices Concerning Complex Structured Finance Transactions describes the types of internal controls and risk management procedures that the Agencies believe are particularly effective in assisting financial institutions to identify, evaluate, assess, document, and control the full range of credit, market, operational, legal and reputational risks. A financial institution that engages in complex structured finance transactions should maintain a set of formal, written, firm-wide policies and procedures that are designed to allow the institution to identify and assess these risks.

There is no change in the method or substance of the collection. The overall reduction in burden hours is a result of economic fluctuation. In particular, the number of respondents has decreased while the hours per response remain the same.

4. *Title:* Regulatory Capital Rules.

OMB Number: 3064–0153.

Form Number: None.

Affected Public: State nonmember banks, state savings associations, and certain subsidiaries of those entities.

Burden Estimate:

ESTIMATED HOURLY BURDEN

	Type of burden	Estimated number of respondents	Estimated time per response	Frequency of response	Total annual estimated burden
BASEL III Advanced Approaches: Recordkeeping and disclosure					
Implementation plan—Section _.121(b): Ongoing	Recordkeeping	2	330.0	On Occasion	660
Documentation of advanced systems—Section _.122(j): Ongoing.	Recordkeeping	2	19.0	On Occasion	38
Systems maintenance—Sections _.122(a), _123(a), _.124(a): Ongoing.	Recordkeeping	2	27.9	On Occasion	56
Supervisory approvals—Sections _.122(d)–(h), _.132(b)(3), _.132(d)(1), _.132(d)(1)(iii): Ongoing.	Recordkeeping	2	16.8	On Occasion	34
Control, oversight and verification of systems—Sections _.122 to _.124: Ongoing.	Recordkeeping	2	11.1	On Occasion	22
(CCR)—Section _.132(b)(2)(iii)(A): One-time	Recordkeeping	1	80.0	On Occasion	80
(CCR)—Section _.132(b)(2)(iii)(A): Ongoing	Recordkeeping	2	16.0	On Occasion	32
(CCR)—Section _.132(d)(2)(iv): One-time	Recordkeeping	1	80.0	On Occasion	80
(CCR)—Section _.132(d)(2)(iv): Ongoing	Recordkeeping	2	40.0	On Occasion	80
(CCR)—Section _.132(d)(3)(vi): One-time	Recordkeeping	1	80.0	On Occasion	80

ESTIMATED HOURLY BURDEN—Continued

	Type of burden	Estimated number of respondents	Estimated time per response	Frequency of response	Total annual estimated burden
(CCR)—Section _.132(d)(3)(viii): One-time	Recordkeeping	1	80.0	On Occasion	80
(CCR)—Section _.132(d)(3)(viii): Ongoing	Recordkeeping	2	10.0	Quarterly	80
(CCR)—Section _.132(d)(3)(ix): One-time	Recordkeeping	1	40.0	On Occasion	40
(CCR)—Section _.132(d)(3)(ix): Ongoing	Recordkeeping	2	40.0	On Occasion	80
(CCR)—Section _.132(d)(3)(x): One-time	Recordkeeping	1	20.0	On Occasion	20
(CCR)—Section _.132(d)(3)(xi): One-time	Recordkeeping	1	40.0	On Occasion	40
(CCR)—Section _.132(d)(3)(xi): Ongoing	Recordkeeping	2	40.0	On Occasion	80
(OC)—Section _.141(b)(3), _.141(c)(1), _.141(c)(2)(i)–(ii), _.153: One-time.	Recordkeeping	1	40.0	On Occasion	40
(OC)—Section _.141(c)(2)(i)–(ii): Ongoing	Recordkeeping	2	10.0	Quarterly	80
Sections _.142 and _.171: Ongoing	Disclosure	2	5.8	On Occasion	12
(CCB and CCYB)—Section _.173, Table 4 (CR) _.173, Table 5 (Securitization) _.173, Table 9 (IRR) _.173, Table 12: Ongoing.	Disclosure	2	35.0	Quarterly	280
(CCB and CCYB)—Section _.173, Table 4 (CR) Section _.173, Table 5 (Sec.) Section _.173, Table 9 (IRR) Section _.173, Table 12: One-time.	Disclosure	1	280.0	On Occasion	280
Subtotal: One-time Recordkeeping and Disclosure.					740
Subtotal: Ongoing Recordkeeping and Disclosure.					1,533
Total Recordkeeping and Disclosure					2,273
Minimum Regulatory Capital Ratios: Recordkeeping					
(CCR Operational Requirements)—Sections _.3(c) and _.22(h)(2)(iii)(A): Ongoing.	Recordkeeping	3,787	16.0	On Occasion	60,592
Subtotal: One-time Recordkeeping					0
Subtotal: Ongoing Recordkeeping					60,592
Total Recordkeeping					60,592
Standardized Approach: Recordkeeping and Disclosure					
(QCCP)—Section _.35(b)(3)(i)(A): One-time	Recordkeeping	1	2.0	On Occasion	2
(QCCP)—Section _.35(b)(3)(i)(A): Ongoing	Recordkeeping	3,787	2.0	On Occasion	7,574
(CT)—Section _.37(c)(4)(i)(E): One-time	Recordkeeping	1	80.0	On Occasion	80
(CT)—Section _.37(c)(4)(i)(E): Ongoing	Recordkeeping	3,787	16.0	On Occasion	60,592
(SE)—Section _.41(b)(3) and _.41(c)(2)(i): One-time.	Recordkeeping	1	40.0	On Occasion	40
(SE)—Section _.41(c)(2)(i): Ongoing	Recordkeeping	3,787	2.0	On Occasion	7,574
(S.E.)—Section _ .42(e)(2), (C.R.) Sections_ .62(a), (b), & (c), (Q&Q) Sections_ .63(a) & (b): One-time.	Disclosure	1	226.3	On Occasion	226
(S.E.)—Section _.42(e)(2), (C.R.) Sections_ .62(a), (b), & (c), (Q&Q) Sections_. 63(a) & (b) and _ .63 Tables: Ongoing.	Disclosure	1	131.3	Quarterly	525
Subtotal: One-time Recordkeeping and Disclosure.					348
Subtotal: Ongoing Recordkeeping and Disclosure.					76,265
Total Recordkeeping and Disclosure					76,613
Total Burden Hours					139,478

General Description of Collection: This collection comprises the disclosure and recordkeeping requirements associated with minimum capital requirements and overall capital adequacy standards for insured state nonmember banks, state savings associations, and certain subsidiaries of those entities. The data is used by the FDIC to evaluate capital before approving various applications by insured depository institutions, to

evaluate capital as an essential component in determining safety and soundness, and to determine whether an institution is subject to prompt corrective action provisions.

There is no change in the method or substance of the collection. The overall reduction in burden hours is a result of economic fluctuation. In particular, the number of respondents has decreased while the hours per response remain the same.

Request for Comment

Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 25th day of April 2017.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2017–08667 Filed 4–27–17; 8:45 am]

BILLING CODE 6714–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than May 16, 2017.

A. *Federal Reserve Bank of Chicago* (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *James P Cravens Stock Trust, James P Cravens Trustee, Sanborn, Iowa, and Marilyn Lee Cravens Stock Trust, Marilyn Lee Cravens Trustee, Sanborn, Iowa, as individuals and as a group acting in concert the Cravens Family Control group consisting of James P Cravens Stock Trust, James P Cravens Trustee, Sanborn, Iowa, Marilyn Lee Cravens Stock Trust, Marilyn Lee Cravens Trustee, Sanborn, Iowa, Emilie G Cravens, Manhattan, Kansas, Catherine J Cravens, Arlington, Virginia, and Margaret Burr Porter, Godfrey, Illinois;* to acquire and retain shares of Milford Bancorporation, Milford, Iowa, and thereby indirectly acquire and retain shares of United Community Bank, Milford, Iowa.

Board of Governors of the Federal Reserve System, April 25, 2017.

Yao-Chin Chao,

Assistant Secretary of the Board.

[FR Doc. 2017–08662 Filed 4–27–17; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0292; Docket No. 2017–0001; Sequence 4]

Information Collection; FFATA Subaward and Executive Compensation Reporting Requirements

AGENCY: Office of the Integrated Award Environment, General Services Administration (GSA).

ACTION: Notice of request for comments regarding an extension to an existing OMB information collection.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of the currently approved information collection requirement regarding FFATA Subaward and Executive Compensation Reporting Requirements.

DATES: Submit comments on or before June 27, 2017.

ADDRESSES: Submit comments identified by Information Collection 3090–0292, FFATA Subaward and Executive Compensation Reporting Requirements by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number 3090–0292. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0292, FFATA Subaward and Executive Compensation Reporting Requirements''. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0292, FFATA Subaward and Executive Compensation Reporting Requirements'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: IC 3090–0292, FFATA Subaward and Executive Compensation Reporting Requirements.

Instructions: Please submit comments only and cite Information Collection 3090–0292, FFATA Subaward and Executive Compensation Reporting Requirements, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Dennis Harrison, Procurement Analyst, Office of the Integrated Award Environment, GSA, at telephone number 202–215–9767; or via email at *dennis.harrison@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Federal Funding Accountability and Transparency Act (P.L. 109–282, as amended by section 6202(a) of P.L. 110–252), known as FFATA or the Transparency Act requires information disclosure of entities receiving Federal financial assistance through Federal awards such as Federal contracts, sub-contracts, grants and sub-grants, FFATA 2(a), (2), (i), (ii). Beginning October 1, 2010, the currently approved Paperwork Reduction Act submission directed compliance with the Transparency Act to report prime and first-tier sub-award data. Specifically, Federal agencies and prime awardees of grants were to ensure disclosure of executive compensation of both prime and subawardees and sub-award data pursuant to the Transparency Act. This information collection requires reporting of only the information enumerated under the Transparency Act.

B. Annual Reporting Burden

Sub-award Responses: 107,614.
Hours Per Response: 1.
Total Burden Hours: 107,614.
Executive Compensation Responses: 41,298.
Hours Per Response: 1.

Total Burden Hours: 41,298.
Total Annual Burden Hours: 148,912.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0292, FFATA Subaward and Executive Compensation Reporting Requirements, in all correspondence.

Dated: April 18, 2017.

Steve Grewal,

Deputy Chief Information Officer, General Services Administration.

[FR Doc. 2017–08600 Filed 4–27–17; 8:45 am]

BILLING CODE 6820–WY–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0291; Docket No. 2017–0001; Sequence 3]

Information Collection; FSRS Registration Requirements for Prime Grant Awardees

AGENCY: Office of the Integrated Award Environment, General Services Administration (GSA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve a renewal of the currently approved information collection requirement regarding FSRS Registration Requirements for Prime Grant Awardees.

DATES: Submit comments on or before June 27, 2017.

ADDRESSES: Submit comments identified by Information Collection 3090–0291, FSRS Registration Requirements for Prime Grant Awardees by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching OMB control number 3090–0291. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0291, FSRS Registration Requirements for Prime Grant Awardees.'' Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0291, FSRS Registration Requirements for Prime Grant Awardees on your attached document.

• *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: IC 3090–0291, FSRS Registration Requirements for Prime Grant Awardees.

Instructions: Please submit comments only and cite Information Collection 3090–0291, FSRS Registration Requirements for Prime Grant Awardees, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: John Corro, Procurement Analyst, Office of the Integrated Award Environment, GSA, at telephone number 202–215–9767; or via email at *john.corro@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Federal Funding Accountability and Transparency Act (P.L. 109–282, as amended by section 6202(a) of P.L. 110–252), known as FFATA or the Transparency Act, requires information disclosure of entities receiving Federal financial assistance through Federal awards such as Federal contracts, sub-contracts, grants and sub-grants, FFATA 2(a),(2),(i),(ii). The system that collects this information is called the FFATA Sub-award Reporting System (FSRS, *www.fsrs.gov*). This information collection requires information necessary for prime awardee registration in FSRS to create a user log-in and enable sub-award reporting for their entity. To register in FSRS for a user log-in, an entity is required to provide their Data Universal Numbering System (DUNS) number. FSRS then pulls core data about the entity from their System for Award Management (SAM) registration to include the legal business name, physical address, mailing address and Commercial and Government Entity (CAGE) code. The entity completes the FSRS registration by providing contact information within the entity for approval.

If a prime awardee has already registered in FSRS to report contracts-related Transparency Act financial data, a new log-in will not be required. In addition, if a prime awardee had a user account in the Electronic Subcontract Reporting System (eSRS), a new log-in will not be required.

B. Annual Reporting Burden

Respondents: 5,678.
Responses Per Respondent: 1.
Total Annual Responses: 5,678.
Hours Per Response: .5.
Total Burden Hours: 2,839.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755.

Please cite OMB Control No. 3090–0291, FSRS Registration Requirements for Prime Grant Awardees, in all correspondence.

Dated: April 18, 2017.

Steve Grewal,

Deputy Chief Information Officer, General Services Administration.

[FR Doc. 2017–08602 Filed 4–27–17; 8:45 am]

BILLING CODE 6820–XY–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0118; Docket 2017–0001; Sequence 2]

Information Collection; Statement of Witness, Standard Form 94

AGENCY: Federal Vehicle Policy Division, General Services Administration (GSA).

ACTION: Notice of a request for comments regarding a reinstatement, with change, to an OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995, GSA has submitted to the Office of Management and Budget (OMB) a request to review and approve a reinstatement, with change, to an

information collection requirement concerning Standard Form 94, Statement of Witness.

DATES: Submit comments on or before June 27, 2017.

FOR FURTHER INFORMATION CONTACT: Ray Wynter, Federal Vehicle Policy Division, 202–501–3802, or via email at *ray.wynter@gsa.gov.*

ADDRESSES: Submit comments identified by Information Collection 3090–0118, Statement of Witness, SF 94, by any of the following methods: Regulations.gov: *http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0118, Statement of Witness, SF 94.'' Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 3090–0118, Statement of Witness, SF 94'' on your attached document.

- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Sosa/IC 3090–0118, Statement of Witness, SF 94.

Instructions: Please submit comments only and cite Information Collection 3090–0118, Statement of Witness, SF 94, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA is requesting the Office of Management and Budget (OMB) to review and approve information collection, 3090–0118, Statement of Witness, SF 94. This form is used by all Federal agencies to report accident information involving U.S. Government motor vehicles.

B. Annual Reporting Burden

Respondents: 874.
Responses per Respondent: 1.
Total Annual Responses: 874.
Hours per Response: .333.
Total Burden Hours: 291.

C. Public Comment

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 3090–0118, Statement of Witness, SF 94, in all correspondence.

Dated: April 18, 2017.

Steve Grewal,

Deputy Chief Information Officer, General Services Administration.

[FR Doc. 2017–08603 Filed 4–27–17; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed changes to the currently approved information collection project: ''*Developing a Registry of Registries.*''

DATES: Comments on this notice must be received by June 27, 2017.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Revision of a Currently Approved Collection Project: ''Developing a Registry of Registries.'' OMB Control Number 0935–0203

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection on the development of a registry of patient registries. Patient registries have received significant attention and funding in recent years. Similar to controlled studies, patient registries represent some burden to patients (*e.g.,* time to complete patient reported outcome measures, risk of loss of privacy), who often participate voluntarily in hopes of improving knowledge about a disease or condition. Patient registries also represent a substantial investment of health research resources. Despite these factors, patient registries are not required to be registered in *ClinicalTrials.gov*, presenting the potential for duplication of efforts and insufficient dissemination of findings that are not published in the peer-reviewed literature. To fulfill the obligation to patients and to ensure that resources are used in the most efficient manner, registries need to be listed in a manner similar to that of trials in *ClinicalTrials.gov*.

By providing a centralized point of collection for information about all patient registries in the United States, the Registry of Patient Registries (RoPR) enhances patient registry information, extracted from *ClinicalTrials.gov*, building on AHRQ's efforts to describe the quality, appropriateness, and effectiveness of health services (and patient registries in particular) in a more readily available, central location.

The RoPR database system aims to achieve the following objectives:

(1) Provide a searchable database of patient registries in the United States (to promote collaboration, reduce redundancy, and improve transparency);

(2) Facilitate the use of common data fields and definitions in similar health conditions (to improve opportunities for sharing, comparing, and linkage);

(3) Provide a public repository of searchable summary results (including results from registries that have not yet been published in the peer-reviewed literature);

(4) Offer a search tool to locate existing data that researchers can request for use in new studies; and

(5) Serve as a recruitment tool for researchers and patients interested in participating in patient registries.

To achieve the objectives of this project, the following data collections will be implemented:

(1) Collect information on registries from users who populate the RoPR database system.

AHRQ is proposing to add a self-registration option to the RoPR database so that registry owners do not need a National Library of Medicine Protocol Registration System (PRS) account to contribute. The current OMB-approved RoPR system requires users to have a PRS account. In the current data entry process, registry owners enter most of the registry information using the *ClinicalTrials.gov* PRS. If a user defines the ClinicalTrials.gov record as a patient registry, that user will have the option of following a link to the RoPR submission page to input additional information about the registry. Patient registry data entered in the PRS is uploaded to the RoPR system daily and is accessible (along with information entered directly into RoPR) to the public via the RoPR search function.

Under the AHRQ proposal, these users can complete a simple registration on the RoPR site, which would be less burdensome than the PRS registration process, and then enter all registry information directly on RoPR. The rationale behind this alternative registration pathway is that many registries are created for quality reporting, outcome tracking, and quality improvement purposes, rather than for research purposes. Registering in *ClinicalTrials.gov* implies a research purpose, so it is not necessarily appropriate for non-research registries to register in *ClinicalTrials.gov*, and many have expressed that they do not wish to do so. AHRQ anticipates that more than 75 percent of registries will still register through the *ClinicalTrials.com*. However, the remaining registries are extremely important for health policy, and providing them with a registration pathway furthers the goal of creating a central place where stakeholders can find information on research and non-research registries pertinent to a specific clinical topic.

The new self-registration pathway is being developed by AHRQ through its contractor, L&M Policy Research and subcontractor Truven Health Analytics, an IBM Company, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to database development. 42 U.S.C. 299a(a)(1) and (8).

AHRQ, in collaboration with the Centers for Medicare & Medicaid Services (CMS), is also proposing to add three fields to the self-registration pathway related to the CMS initiative to create a Centralized Repository for Public Health Agencies and Clinical Data Registry Reporting. The purpose of the repository is to assist eligible professionals, eligible hospitals, and critical access hospitals in finding entities that accept electronic public health data. By adding these fields to the existing RoPR database, AHRQ will further the goal of creating a central place where stakeholders can find all pertinent information on registries.

Method of Collection

The purpose and the use of the RoPR is to provide a readily available public resource strictly for patient registries, following the model of *ClinicalTrials.gov*, allowing for the increased availability and efficacy of patient registries. The information being collected in the RoPR Record is visible to the public visiting the RoPR Web site, and is readily available for public use.

The RoPR is an ongoing data collection initiative.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the RoPR. In 2016, 65 respondents manually entered a new RoPR record. It is expected that more than 75% of patient registries are research-focused and will continue to use the original *ClinicalTrials.gov* pathway described above. Thus, it is estimated that once the self-registration pathway is available, approximately 65 respondents will enter RoPR records through the *ClinicalTrials.gov* link annually, and an additional 16 respondents (roughly 25% of 65), representing non-research registries, will enter RoPR records through the new self-registration pathway.

Each respondent need enter his or her new RoPR record only once. The RoPR system sends an automated reminder to any registry owner who has not updated his or her RoPR record in the past year. In 2016, 132 RoPR entries were updated and released. Using the same logic as above, it is estimated that an additional 33 entries (25% of 132) might be updated annually once the self-registration pathway is available.

In January 2017, Truven Health Analytics used a sample of existing *ClinicalTrials.gov* registry entries to estimate the time needed to enter all additional fields added through the self-registration process. The sample included records representing a range of depth and complexity. For example, one registry record contained only one primary outcome measure. Another record contained three more detailed outcome measures (one primary, one secondary, and one other.)

As a result of the knowledge gained during these processes, it is estimated that it will take users 10 minutes, on average, to manually enter the additional fields added through the self-registration process. Adding this time to the estimated burden of completing the original RoPR fields (45 minutes), it is estimated that it will take users 55 minutes to complete all fields through the self-registration pathway.

It is estimated that it will take users 5 minutes to review and update the fields added through the self-registration pathway. Adding this time to the estimated burden of reviewing and updating the original RoPR fields (15 minutes), it is estimated that it will take 20 minutes for a person to review and make updates to an existing RoPR record created through the self-registration pathway.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
New RoPR Record entered manually through self-registration process	16	1	55/60	14.67
New RoPR Record entered through *ClinicalTrials.gov* pathway	65	1	45/60	48.75
Review/update existing RoPR Record created through self-registration process	33	1	20/60	11

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Number of respondents	Number of responses per respondent	Minutes per response	Total burden hours
Review/update existing RoPR Record created through *ClinicalTrials.gov* pathway	132	1	15/60	33
Total	246			107.42

Exhibit 2 shows the estimated cost burden associated with the respondent's time to participate in the RoPR. The total cost burden to respondents is estimated at an average of $4,017.51 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate † ($)	Total cost burden ($)
New RoPR Record entered manually through self-registration process	16	14.67	$37.40	$548.66
New RoPR Record entered through *ClinicalTrials.gov* pathway	65	48.75	37.40	1,823.25
Review/update existing RoPR Record created through self-registration process	33	11	37.40	411.40
Review/update existing RoPR Record created through *ClinicalTrials.gov* pathway	132	33	37.40	1,234.20
Total	246	107.42	37.40	4,017.51

* Based on the mean wages for Healthcare Practitioners and Technical Occupations, 29–0000. National Compensation Survey: Occupational wages in the United States May 2015, "U.S. Department of Labor, Bureau of Labor Statistics." Available at: *https://www.bls.gov/oes/current/oes290000.htm.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection.

All comments will become a matter of public record.

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–08650 Filed 4–27–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) reapprove the proposed information collection project: "*Medical Expenditure Panel Survey—Insurance Component.*"

DATES: Comments on this notice must be received by June 27, 2017.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov*.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Expenditure Panel Survey—Insurance Component

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. Employer-sponsored health insurance is the source of coverage for 84.4 million current and former workers, plus many of their family members, and is a cornerstone of the U.S. health care system. The Medical Expenditure Panel Survey—Insurance Component (MEPS–IC) measures the extent, cost, and coverage of employer-sponsored health insurance on an annual basis. These statistics for private industry are produced at the National, State, and sub-State (metropolitan area) level. Statistics are also produced for State and Local governments.

This research has the following goals:

(1) Provide data for Federal policymakers evaluating the effects of National and State health care reforms.

(2) Provide descriptive data on the current employer-sponsored health insurance system and data for modeling the differential impacts of proposed health policy initiatives.

(3) Supply critical State and National estimates of health insurance spending for the National Health Accounts and Gross Domestic Product.

The MEPS–IC is conducted pursuant to AHRQ's statutory authority to conduct surveys to collect data on the cost, use and quality of health care, including types and costs of private insurance, 42 U.S.C. 299b–2(a), and to conduct research on health care, 42 U.S.C. 299a.

Method of Collection

To achieve the goals of this project, following data collections will be implemented for both private sector and state and local government employers:

(1) Pre-screener Questionnaire—The purpose of the Pre-screener Questionnaire, which is collected via telephone, varies depending on the insurance status of the establishment contacted. Establishment is defined as a single, physical location in the private sector and a governmental unit in state and local governments. For establishments that do not offer health insurance to their employees, the Pre-screener Questionnaire is used to collect basic information, such as number of employees. For establishments that do offer health insurance, the Pre-screener Questionnaire collects contact name and address information for the person in the establishment best equipped to complete the full questionnaire.

(2) Establishment Questionnaire—The purpose of the mailed Establishment Questionnaire is to obtain general information from employers that provide health insurance to their employees, including total active enrollment in health insurance, other employee benefits, demographic characteristics of employees, and retiree health insurance.

(3) Plan Questionnaire—The purpose of the mailed Plan Questionnaire is to collect plan-specific information on each plan (up to four plans) offered by establishments. This questionnaire obtains information on total premiums, employer and employee contributions to the premium, and plan enrollment for each type of coverage offered—single, employee-plus-one, and family—within a plan. It also asks for information on deductibles, copays, and other plan characteristics.

The primary objective of the MEPS–IC is to collect information on employer-sponsored health insurance. Such information is needed in order to provide the tools for Federal, State, and academic researchers to evaluate current and proposed health policies and to support the production of important statistical measures for other Federal agencies.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondent's time to participate in the MEPS–IC. The Pre-screener Questionnaire will be completed by 30,041 respondents and takes about 5½ minutes to complete. The Establishment Questionnaire will be completed by 25,914 respondents and takes about 23 minutes to complete. The Plan Questionnaire will be completed by 22,943 respondents and will require an average of 2.2 responses per respondent. Each Plan Questionnaire takes about 11 minutes to complete. The total annualized burden hours are estimated to be 21,636 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this data collection. The annualized cost burden is estimated to be $691,703.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS FOR THE 2018–2019 MEPS–IC

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Pre-screener Questionnaire	30,041	1	0.09	2,704
Establishment Questionnaire	25,914	1	* 0.38	9,847
Plan Questionnaire	22,943	2.2	0.18	9,085
Total	78,898	na	na	21,636

* The burden estimate printed on the establishment questionnaire is 45 minutes which includes the burden estimate for completing the establishment questionnaire, an average of 2.2 plan questionnaires, plus the prescreener. The establishment and plan questionnaires are sent to the respondent as a package and are completed by the respondent at the same time.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR THE 2018–2019 MEPS–IC

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Pre-screener Questionnaire	30,041	2,704	31.97	$86,447
Establishment Questionnaire	25,914	9,847	31.97	314,809
Plan Questionnaire	22,943	9,085	31.97	290,447
Total	78,898	21,636	na	$691,703

* Based upon the mean hourly wage for Compensation, Benefits, and Job Analysis Specialists occupation code 13–1141, at *https://www.bls.gov/oes/current/oes131141.htm* (U.S. Department of Labor, Bureau of Labor Statistics).

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and

included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–08649 Filed 4–27–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*Generic Clearance for Questionnaire and Data Collection Testing, Evaluation, and Research for the Agency for Healthcare Research and Quality.*''

DATES: Comments on this notice must be received by June 27, 2017.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Generic Clearance for Questionnaire and Data Collection Testing, Evaluation, and Research for the Agency for Healthcare Research and Quality

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection. The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) reapprove generic pre-testing Clearance 0935–0124 for three years to facilitate AHRQ's efforts to (1) employ evaluation-type methods and techniques to improve AHRQ's current data collection and estimation procedures, (2) develop new collections and procedures, including toolkits, and (3) revise existing collections and procedures. AHRQ believes that developing, testing, and evaluating data collection and estimation procedures using survey methods and other techniques in anticipation of agency-sponsored studies can improve its information collection efforts, and the products it develops and allow AHRQ to be more responsive to fast-changing developments in the health care research field. AHRQ uses techniques to simplify data collection and estimation procedures, reduce respondent burden, and improve efficiencies to meet the needs of individuals and small business respondents who may have reduced budgets and staff.

This clearance request is limited to research on data collection, toolkit development, and estimation procedures and reports and does not extend to the collection of data for public release or policy formation. The current Clearance (0935–0124) was granted on November 12, 2014, and expires on November 30, 2017.

This generic clearance will allow AHRQ to draft and test toolkits, survey instruments and other data collection and estimation procedures more quickly and with greater lead time, thereby managing project time more efficiently and improving the quality of the data AHRQ collects. In some instances, the ability to test and evaluate toolkits, data collection and estimation procedures in anticipation of work or early in a project may result in the decision not to proceed with additional activities, which could save both public and private resources and eliminate respondent burden.

This generic clearance will facilitate AHRQ's response to a changing environment. Many of the tools AHRQ develops are made available to the private sector to assist in improving health care quality. The health and health care environment changes rapidly and requires a quick response from AHRQ to provide refined tools.

These preliminary research activities will not be used by AHRQ to regulate or sanction its customers. They will be entirely voluntary and the confidentiality of respondents and their responses will be preserved. Proposed information collections submitted under this generic clearance will be submitted for review by OMB with a response expected in 14 days.

Method of Collection

The information collected through preliminary research activities under this generic clearance will be used by AHRQ to employ techniques to (1) improve AHRQ's current data collection and estimation procedures, (2) develop new collections and procedures, including toolkits, and (3) revise existing collections and procedures in anticipation or in response to changes in the health or health care field. The end result will be improvement in AHRQ's data collections and procedures and the quality of data collected, a reduction or minimization of respondent burden, increased agency efficiency, and improved responsiveness to the public.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours, over the full 3 years of this clearance, for the respondents' time to participate in the research activities that may be conducted under this generic clearance. Mail surveys will be conducted with about 6,000 persons (2,000 per year for 3 years) and are estimated to average 20 minutes. Mail surveys may also be sent to respondents via email, and may include a telephone non-response follow-up. Telephone non-response follow-up for mailed surveys is not counted as a telephone survey in Exhibit 1. Not more than 600 persons, over 3 years, will participate in telephone surveys that will take about 40 minutes. Web-based surveys will be conducted with no more than 3,000 persons and will require no more than 10 minutes to complete. About 1,500 persons will participate in focus groups which may last up to two hours, while in-person interviews will be conducted with 600 persons and will take about 50 minutes. Automated data collection will be conducted for about 1,500 persons and could take up to 1 hour. Cognitive testing will be conducted with about 600 persons and is estimated to take 1½ hours to complete. The total burden over 3 years is estimated to be 8,900 hours (about 2,967 hours per year).

Exhibit 2 shows the estimated cost burden over 3 years, based on the respondent's time to participate in these research activities. The total cost burden is estimated to be $338,734.

EXHIBIT 1—ESTIMATED BURDEN HOURS OVER 3 YEARS

Type of information collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Mail/email *	6,000	1	20/60	2,000
Telephone	600	1	40/60	400
Web-based	3,000	1	10/60	500
Focus Groups	1,500	1	2.0	3,000
In-person	600	1	1.0	600
Automated **	1,500	1	1.0	1,500
Cognitive Testing ***	600	1	1.5	900
Totals	13,800	na	na	8,900

* May include telephone non-response follow-up in which case the burden will not change
** May include testing of database software, CAPI software or other automated technologies.
*** May include cognitive interviews for questionnaire or toolkit development, or ''think aloud'' testing of prototype Web sites.

EXHIBIT 2—ESTIMATED COST BURDEN OVER 3 YEARS

Type of information collection	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Mail/email	6,000	2,000	$38.06	$76,120
Telephone	600	400	38.06	15,224
Web-based	3,000	500	38.06	19,030
Focus Groups	1,500	3,000	38,06	114,180
In-person	600	600	38.06	22,836
Automated	1,500	1,500	38.06	57,090
Cognitive Testing	600	900	38.06	34,254
Totals	13,800	8,900	na	338,734

* Based upon the average wages for 29–000 (Healthcare Practitioner and Technical Occupations), ''National Compensation Survey: Occupational Wages in the United States, May 2016,'' U.S. Department of Labor, Bureau of Labor Statistics *https://www.bls.gov/oes/current/oes_nat.htm#29-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–08652 Filed 4–27–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Announcement of Requirements and Registration for Healthy Behavior Challenge

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) announces the launch of the Healthy Behavior Data Challenge. The Healthy Behavior Data Challenge responds to the call for new ways to address the challenges and limitations of self-reported health surveillance information and tap into the potential of innovative data sources and alternative methodologies for public health surveillance. Challenge participants will propose data sources and approaches for aggregating data from wearable devices, mobile applications and/or social media in the areas of nutrition, physical activity, sedentary behaviors, and/or sleep. Conducted in two phases, Phase I (Prototype Development) entails Challenge participants developing a concept proposal for obtaining data collected from wearable devices, mobile applications and/or social media for public health surveillance purposes. In Phase II (Prototype Implementation), a subset of submissions (up to 3) with promising concepts will be invited to test their proposed approaches for ongoing public health surveillance.

DATES: The Challenge is effective April 28, 2017 and will conclude December 31, 2017.

FOR FURTHER INFORMATION CONTACT: Dr. Machell Town, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, 4770 Buford Highway NE., MS F–78, Chamblee, Georgia 30341; Email: *BRFSSinnovations@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Award Approving Official: Anne Schuchat, MD, (RADM, USPHS) Acting Director, Centers for Disease Control and Prevention, and Acting Administrator, Agency for Toxic Substances and Disease Registry.

The Behavioral Risk Factor Surveillance System (BRFSS) is the nation's premier system of health-related telephone surveys that collect state data about U.S. residents regarding their health-related risk behaviors, chronic health conditions, and use of preventive services. Established in 1984 with 15 states, BRFSS now collects data in all 50 states as well as the District of

Columbia and three U.S. territories. BRFSS completes more than 400,000 adult interviews each year, making it the largest continuously conducted health survey system in the world.

The collection of health data through traditional surveillance modes including telephone and in-person interviewing, however, is becoming increasingly challenging and costly with declines in participation and changes in personal communications. In addition, the self-reported nature of responses particularly in the areas of nutrition, physical activity, sedentary behaviors, and sleep has been a major limitation in these surveillance systems, since self-reported data are subject to under/over reporting and recall bias. Meanwhile, the advent of new technologies and data sources including wearable devices (such as: Smart watches, activity trackers, sleep monitors, etc.), mobile health applications on smartphones or tablets, and data from social media represents an opportunity to enhance the ability to monitor health-related information and potentially adjust for methodological limitations in traditional self-reported data.

The Healthy Behavior Data (HBD) Challenge will be conducted concurrently with a similar challenge proposed by the Public Health Agency of Canada. This will enable the two countries to learn from their respective challenges and leverage information. We expect increased efficiency with a dual challenge.

Submissions will be accepted starting April 28, 2017. The submission period for phase I will end on July 31, 2017. The Phase II (Prototype Implementation) submission period will begin September 4, 2017 and end December 31, 2017. The grand prize finalist is anticipated to be announced in February of 2018.

Information on the Behavioral Risk Factor Surveillance System can be found at *www.cdc.gov/brfss.*

Subject of Challenge Competition

The Healthy Behavior Data Challenge responds to the call for new ways to address the challenges and limitations of self-reported health surveillance information and tap into the potential of innovative data sources and alternative methodologies for public health surveillance.

The Healthy Behavior Data (HBD) Challenge will support the development and implementation of prototypes to use these novel methodologies and data sources (*e.g.,* wearable devices, mobile applications, and/or social media) to enhance traditional healthy behaviors surveillance systems in the areas of nutrition, physical activity, sedentary behaviors, and/or sleep among the adult population aged 18 years and older in the U.S. and U.S. territories.

Ideation Period

The Challenge will launch as an ideation/open submission period in which eligible participants (outlined in Eligibility Rules) may register and submit an entry onto the Challenge Web site (*https://www.challenge.gov/challenge/the-healthy-behavior-data-challenge/*). Information about the Challenge and a link to the Challenge Web site can also be found at *Challenge.gov*. The 13-week ideation period will be followed by a 16-week resubmission period held for those who were chosen by the judges as semifinalists to further refine their idea. The Challenge Web site serves as the destination and submission portal. Participants may find the Challenge rules, eligibility criteria, evaluation criteria, additional resources, and the Challenge timeline on the Challenge Web site or at *Challenge.gov.*

Submission Requirements

Entries not in compliance with the submission requirements outlined below will be ineligible for further review and prize award. During the open submission period, eligible participants may register and submit an entry onto the Challenge Web site, to include:

Phase I (Prototype Development)

1. A completed HBD Challenge Submission Template describing the proposed project, project personnel and data sources.
2. A PowerPoint or other visual presentation of the proposed project including purpose, methods and anticipated outcomes of the proposed approach, which could be used to present the proposal to a judging panel.
3. A description of data that are anticipated to be captured by the proposed approach, comparability to the Behavioral Risk Factor Surveillance System (BRFSS), and, if applicable, descriptions of online app(s), web-based tools or communication devices used to recruit or track subjects' healthy behavior information.
4. Proposal of a viable data source(s) from a currently available or a feasible future source (such as a proposed app or online tool). HBD Challenge participants may propose the use of public and/or private data sources, as long as respondent agrees to participate and the respondent confidentiality and privacy are maintained.
5. A demonstration of how CDC would be able to access the data.
6. A detailed outline of the information that will be obtained.
7. A demonstration of how data will be extracted and collected: Present the format in which it will be stored.
8. A description of how the new data source(s) could be linked with other data sources, in a statistically robust manner that could result in useful public health insights, citing statistical approaches and evidence to support the proposal.
9. A focus on one or more behavioral factors including physical activity, sleep, sedentary behaviors, and/or nutrition.
10. Information about the population reached and generalizability of the approach.
11. A description of how data could be stratified by demographic characteristics (*e.g.* age, sex, education, geographic jurisdiction).
12. An indication of how information gathered addresses some or all of the following common metrics in one or more of the healthy behavior topics below:

a. Sleep:

i. Hours of sleep per night (sleep duration)
ii. Amount of time awake (sleep quality)
iii. Number of times awake (sleep quality)
iv. Number of adults reporting having trouble getting to and staying asleep
v. Time to fall asleep
vi. Amount of time in REM vs. non-REM sleep (duration of sleep stage)
vii. Heart rate
viii. Respiration
ix. Sleep behaviors such as snoring, sleep talking, and sleep movement

b. Sedentary Behaviors:

i. Average number of hours per day spent sedentary, excluding sleep time
ii. Average number of hours per week spent on a computer/screen including watching TV, videos, playing computer games, emailing or using the internet
iii. Sedentary data with additional information on location (work, school, community, etc.) broken down by weekday and weekend day

c. Nutrition:

i. Total calories consumed per day
ii. Consumption of fruit (not including juices) by day, week, or month
iii. Consumption of green leafy or lettuce salads, with or without other vegetables, by day, week, or month
iv. Consumption of vegetables (not including lettuce salads and potatoes) by day, week, or month
v. Number of sugar-sweetened beverages consumed by day, week, or month

vi. Number of caffeinated drinks consumed by day, week, or month

d. Physical activity:

i. Minutes of moderate-to-vigorous physical activity (MVPA) per day (ideally by location—work, school, in community)
ii. Daily number of steps
iii. Miles/km (Distance) on foot
iv. Number of days of physical activity/week or month (and established number of days in one month)
v. Minutes of moderate-to-vigorous physical activity (MVPA) per day (ideally by location—work, school, in community) broken down by week day and weekend day.
vi. Calories burned
vii. Type of activity (aerobic, strength, etc.)
viii. Active minutes
ix. Duration of exercise
x. Flights of stairs climbed
xi. Average and peak heart rate
xii. Occupational physical activity and active chores amount: (location of physical activity)
xiii. Number of hours of reported physical activities while at work, in or around household
xiv. Leisure time physical activity amount:
xv. # of hours per week adult participants spent in sports, fitness or recreational physical activities, organized or non-organized, that lasted a minimum of 10 continuous minutes
xvi. Number of adults reporting and time spent walking or cycling to work or school

Participants may also choose to suggest additional metrics in the areas of nutrition, physical activity, sedentary behaviors, and/or sleep. If additional metrics are included, the participant should include a short description of the data and how it might inform public health efforts (such information and data will be collected in accordance with any applicable laws and regulations).

Phase II (Prototype Implementation Phase)

During The Phase II Prototype Implementation Phase, the six submissions selected under Phase I will test their solutions, utilizing their previously collected data from 300 or more adults (aged 18 and above) residing in the U.S. or its territories. During this phase there will be an opportunity for HBD Challenge participants to incorporate data from existing surveys including the Behavioral Risk Factor Surveillance System (BRFSS).

Phase II (Prototype Implementation) allows applicants to test proposals developed in Phase I. The prototype is a demonstration of possible methods for supplementing data from existing surveillance systems (such as the BRFSS). This prototype is not meant to be merged with existing surveillance systems, but rather to complement data collected with current infrastructures. At the end of implementation HBD Challenge participants should be able to:

1. Compare data obtained by the prototype to data from the BRFSS in the areas of nutrition, physical activity, sedentary behaviors, and/or sleep.
2. Demonstrate how data from the included participants could be stratified by demographics (age, sex, education, etc.).
3. Demonstrate the ease of adding additional types of mobile applications and wearable devices to existing survey methodologies.
4. Report that describes the prototype/methodology and the prototype's anticipated strengths and limitations for surveillance.
5. Demonstrate the applicability of the non-traditional data source(s) for ongoing public health surveillance purposes.
6. Describe the prototype in detail, including purpose, method, outcomes and comparability to data obtained from the Behavioral Risk Factor Surveillance System (BRFSS).
7. Provide a working prototype including data (in Excel format) obtained using the prototype from 300 or more adult respondents residing in the U.S. or its territories. The data must include the age, gender, location, and at least one of the measures associated with the HBD Challenge in the areas of nutrition, physical activity, sedentary behaviors and/or sleep.
8. Provide a PowerPoint presentation to the judges and invited CDC personnel which includes information on the purpose, methods, outcomes and comparability to the BRFSS.

Submissions must be free of security threats and/or malware. Applicants/Contestants agree that CDC may conduct testing on the product/submission to determine whether malware or other security threats may be present. CDC may disqualify the product if, in CDC's judgment, the app may damage government or others' equipment or operating environment or if the app, in CDC's judgment, is inconsistent with CDC's public health mission, utilizes software or other technologies without appropriate licenses, or any other reason deemed necessary.

How To Enter

Participants may enter by visiting *healthdatachallenge.gov* and *challenge.gov* and following the instructions for submission. The U.S. and Canadian challenges are being run in parallel and U.S. entrants should submit to this contest via *challenge.gov* and Canadian citizens to the Canadian contest found at *healthdatachallenge.gov*.

Eligibility Rules for Participating in the Competition

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by the Centers for Disease Control and Prevention;

(2) Shall have complied with all the requirements under this section;

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

(4) May not be a Federal entity or Federal employee acting within the scope of their employment.

(5) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(6) Are an individual or team comprised of members each of who are 18 years of age or over.

(7) Are not on the Excluded Parties List System located at *www.sam.gov.*

Additionally:

(a) Federal grantees may not use Federal funds to develop challenge applications unless consistent with the purpose of their grant award. Federal contractors may not use Federal funds from a contract to develop challenge applications or to fund efforts in support of a challenge submission.

(b) Employees of CDC, and/or any other individual or entity associated with the development, evaluation, or administration of the Challenge as well as members of such persons' immediate families (spouses, children, siblings, parents), and persons living in the same household as such persons, whether or not related, are not eligible to participate in the Challenge.

(c) An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

(d) Applicants must agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from their participation in a competition, whether the injury, death, damage, or loss arises through negligence or otherwise.

(e) A solution may be disqualified if it fails to function as expressed in the description provided by the user, or if it provides inaccurate or incomplete information.

(f) CDC reserves the right to disqualify participants from the Challenge for inappropriate, derogatory, defamatory, or threatening comments or communication through the Challenge Web site or on the *Challenge.gov* Web site.

(g) Submissions must be free of security threats and/or malware. Applicants/Contestants agree that CDC may conduct testing on the product/submission to determine whether malware or other security threats may be present. CDC may disqualify the product if, in CDC's judgment, the product may damage government or others' equipment or operating environment.

(h) Applicants must obtain liability insurance or demonstrate financial responsibility in the amount of $0 for claims by: (1) A third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a competition, with the Federal Government named as an additional insured under the registered applicant's insurance policy and registered applicant's agreeing to indemnify the Federal Government against third party claims for damages arising from or related to competition activities; and (2) the Federal Government for damage or loss to Government property resulting from such an activity. Applicants who are a group must obtain insurance or demonstrate financial responsibility for all members of the group.

(i) By participating in the Challenge, each Applicant agrees to comply with and abide by these Official Rules, Terms & Conditions and the decisions of the Federal Agency sponsors and/or the individual judges, which shall be final and binding in all respects.

Registration Process for Participants

To register for this Challenge, participants can access *https://www.challenge.gov/challenge/the-healthy-behavior-data-challenge/* anytime during the proposal submission period stated above to register.

Amount of the Prize

In Phase I (Prototype Development), participants will compete for a $30,000 prize pot from which up to six teams or submissions will be selected to receive a $5000 prize each).

In phase II, up to 3 participants will compete for a $70,000 prize pot. The following prizes will be awarded:

One First Place winner of $40,000
One Second Place winner of $20,000
One Third Place winner of $10,000
Three (3) winners will be notified via email.

Payment of the Prize

Prizes awarded under this competition will be paid by electronic funds transfer and may be subject to Federal income taxes. HHS will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Basis Upon Which Winner Will Be Selected

A review panel composed of subject-matter experts will judge eligible HBD Challenge entries. A judging panel will make final winner selections based upon the criteria outlined below and in compliance with the HHS Competition Judging Guidelines.

Phase I Scoring Criteria

All Criteria are scaled 1–5, with 1 being the lowest score on each dimension and 5 being the highest score on each dimension. Scores are weighted by the proportion of each dimension and then aggregated to create a final score.

1. Efficacy of Prototype (20%)

1 = Prototype is likely to not work in a way that is statistically appropriate/5 = Prototype is likely to successfully collect, and harmonize data, in a statistically robust manner, across multiple data sources to address common metrics.

2. Promise of Comparability to BRFSS Findings (20%)

1 = Prototype does not consider stratification parameters, or applies to only a narrow population/5 = Prototype holds promise for capturing data that is valid, reliable, and representative of a large population.

3. Acceptability (15%)

1 = All parties expressed concerns with data being used in terms of respondent privacy, feasibility and utility/5 = All parties involved are comfortable with data being used in terms of respondent privacy, feasibility and utility. NOTE: This means that federal and state restrictions on data collection and assurance of confidentiality are being respected. Any proposals that appear to violate the Privacy Act, HIPAA, and FERPA will be unacceptable. (Mandatory criteria; if not scored 5, prototype may be disqualified).

4. Innovation (15%)

1 = Prototype duplicates existing approach/5 = Prototype presents a novel approach.

5. Feasibility of Prototype (15%)

1 = Prototype is not feasible due to factors like cost, availability of data, etc./5 = Prototype is feasible and addresses potential implementation challenges by offering solutions.

6. Generalizability (10%)

1 = Prototype is not generalizable to a range of data sources/5 = Prototype is generalizable to a range of data sources.

7. Breadth of Data Collected (Scope) (5%)

1 = Prototype does not address required metrics, across the identified content area(s)/5 = Prototype includes required metrics.

Phase II Scoring Criteria

All Criteria are scaled 1–5, with 1 being the lowest score on each dimension and 5 being the highest score on each dimension. Scores are weighted by the proportion of each dimension and then aggregated to create a final score. Judging criteria for Phase II include:

- Data quality (20%)

1 = Prototype does not provide data that are likely to be valid or reliable or representative of a population/5 = Prototype provides data that demonstrate validity, reliability, and representativeness.

- Ability to complement BRFSS Findings (20%)

1 = Prototype does not outline steps to complement BRFSS efforts/5 = Prototype is provides data which can complement and/or supplement measures collected by the BRFSS or other publically available traditional surveillance systems.

- Validation of or Enhancement of existing national public health surveillance data (20%)

1 = Prototype cannot be statistically aligned with currently available health data/5 = Prototype statistically aligns with available data across population sub-groups.

- Flexibility (10%)

1 = Prototype does not demonstrate the ability to include additional types of

data and data sources/5 = Prototype demonstrates flexibility in the ability to add different data types and data from additional sources.

- Simplicity (structure and ease of operation) (10%)

1 = Prototype's structure and operation is complex/5 = Prototype's structure is clear and easy to implement; it is not burdensome on current systems.

- Resources for system operation (10%)

1 = Prototype requires heavy resource burden in terms of cost, training, administration, infrastructure/5 = Prototype has low resource burden in terms of cost, training, administration, infrastructure.

- Timeliness (5%)

1 = there is a significant gap in time between data collection and analysis/5 = there is a real-time monitoring through the collected data.

- Stratification by Demographics (5%)

1 = Prototype is unable to stratify the data by key demographics/5 = Prototype is able to stratify the data by age, sex, education, and race/ethnicity.

Additional Information

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Participants must also agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Participants are required to obtain liability insurance or demonstrate financial responsibility in the amount of $0, for claims by a third party for death, bodily injury, or property damage, or loss resulting from an activity carried out in connection with participation in a challenge.

Participants must also agree to indemnify the Federal Government against third party claims for damages arising from or related to HBD Challenge activities.

CDC reserves the right to cancel, suspend, and/or modify the HBD Challenge, or any part of it, for any reason, at CDC's sole discretion.

Compliance With Rules and Contacting Contest Winners

Finalists and the Contest Winners must comply with all terms and conditions of these Official Rules, and winning is contingent upon fulfilling all requirements herein. The initial finalists will be notified by email, telephone, or mail after the date of the judging. Awards may be subject to Federal income taxes, and the Department of Health and Human Services will comply with the Internal Revenue Service withholding and reporting requirements, where applicable.

Intellectual Property (IP) Rights

- Applicants are free to discuss their submission and the ideas or technologies that it contains with other parties; encouraged to share ideas/technologies publicly; encouraged to collaborate or combine with other teams to strengthen their solutions; and are free to contract with any third parties. Applicants should be aware that any agreement signed or obligation undertaken in regards to their participation in this HBD Challenge that conflicts with the HBD Challenge rules, terms and conditions may result in disqualification of the Applicant's submission.
- Upon submission, each Applicant warrants that he or she is the sole author and owner of the work and any pertinent Intellectual Property (IP) rights, that the work is wholly original of the Applicant (or is an improved version of an existing work that the Applicant has sufficient rights to use—including the substantial improvement of existing open-source work), and that it does not infringe any copyright or any other rights of any third party of which Applicant is aware. Each Applicant also warrants that the work is free of security threats and/or malware.
- Applicants retain ownership of the data that they develop and deliver under the scope of the HBD Challenge, including any software, research product, or other intellectual property (''IP'') that they develop in connection therewith. Applicants agree to grant a license to the Federal Agency sponsor (CDC) for the use of the IP developed in connection with the HBD Challenge as set forth herein.
- Each Applicant must clearly delineate any Intellectual Property (IP) and/or confidential commercial information contained in a submission that is owned by the Applicant, and which the Applicant wishes to protect as proprietary data.
- Upon completion of the HDB Challenge period, applicants consent to grant CDC an unlimited, non-exclusive, royalty-free, worldwide license and the right to reproduce, publically perform, publically display, and use the Submission, including, without limitation, for promotional purposes relating to the HBD Challenge.
- All materials submitted to CDC as part of a submission become CDC agency records. Any confidential commercial or financial information contained in a submission must be clearly designated at the time of submission.
- If the Submission includes any third party works (such as third party content or open source code), Applicant must be able to provide, upon request, documentation of all appropriate licenses and releases for use of such third party works. If Applicant cannot provide documentation of all required licenses and releases, Federal Agency sponsors reserve the right, at their sole discretion, to disqualify the Submission. Conversely, they may seek to secure the licenses and releases and allow the applicable Submission to remain in the HBD Challenge, while reserving all applicable Federal agency rights with respect to such licenses and releases.

Privacy

If Contestants choose to provide the CDC with personal information by registering or filling out the submission form through the *Challenge.gov* Web site, that information is used to respond to Contestants in matters regarding their submission, announcements of entrants, finalists, and winners of the Contest. Information is not collected for commercial marketing. Winners are permitted to cite that they won this contest.

General Conditions

The CDC reserves the right to cancel, suspend, and/or modify the Contest, or any part of it, for any reason, at CDC's sole discretion.

Participation in this Contest constitutes a contestants' full and unconditional agreement to abide by the Contest's Official Rules found at *www.Challenge.gov.*

Authority: 15 U.S.C. 3719.

Dated: April 26, 2017.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2017–08778 Filed 4–27–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–304/CMS–304a, CMS–368/CMS–R–144, and CMS–R–308]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 30, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. Comments submitted in response to the 60-day FR Notice have been addressed in Appendix A of the ICR. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Reconciliation of State Invoice and Prior Quarter Adjustment Statement; *Use:* Form CMS–304 (Reconciliation of State Invoice) is used by manufacturers to respond to the state's rebate invoice for current quarter utilization. Form CMS–304a (Prior Quarter Adjustment Statement) is required only in those instances where a change to the original rebate data submittal is necessary. *Form Number:* CMS–304 and –304a (OMB control number: 0938–0676); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 1,037; *Total Annual Responses:* 4,148; *Total Annual Hours:* 187,880. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Forms; *Use:* We develop the rebate amount per drug unit from information supplied by the drug manufacturers and distributes these data to the states. States then must report quarterly to the drug manufacturers and report to us the total number of units of each dosage form/strength of their covered outpatient drugs reimbursed during a quarter and the rebate amount to be refunded. This report is due within 60 days of the end of each calendar quarter. The information in the report is based on claims paid by the state Medicaid agency during a calendar quarter. Form CMS–R–144 (Quarterly Report Data) is required from states quarterly to report utilization for any drugs paid for during that quarter. Form CMS–368 (Administrative Data) is required only in those instances where a change to the original data submittal is necessary. *Form Number:* CMS–368 and –R–144 (OMB control number: 0938–0582); *Frequency:* Quarterly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 12,101. (For policy questions regarding this collection contact Andrea Wellington at 410–786–3490.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Children's Health Insurance Program and Supporting Regulations; *Use:* States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. *Form Number:* CMS–R–308 (OMB control number: 0938–0841); *Frequency:* Yearly, Once, and Occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 28,294,596; *Total Annual Hours:* 1,473,885. (For policy questions regarding this collection contact Amy Lutzky at 410–786–0721).

Dated: April 25, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–08663 Filed 4–27–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10151, CMS–10199, CMS–R–13, CMS–10279]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by May 30, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR*, Email: *OIRA_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at Web site address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. Comments submitted in response to the 60-day **Federal Register** Notice have been addressed in Appendix A of the ICR. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; *Use:* We provide coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, we consider coverage for ICDs reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, we issued a ''Decision Memo for Implantable Defibrillators'' on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). *Form Number:* CMS–10151 (OMB control number: 0938–0967); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 1,600; *Total Annual Responses:* 80,000; *Total Annual Hours:* 20,000. (For policy questions regarding this collection contact JoAnna Baldwin at 410–786–7205.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy; *Use:* We provide coverage for carotid artery stenting (CAS) with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis between 50 percent and 70 percent or have asymptomatic carotid artery stenosis ≥80 percent in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1, or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7). Accordingly, we consider coverage for CAS reasonable and necessary (section 1862(A)(1)(a) of the Social Security Act). However, evidence for use of CAS with embolic protection for patients with high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis ≥70 percent who are not enrolled in a study or trial is less compelling. To encourage responsible and appropriate use of CAS with embolic protection, we issued a Decision Memo for Carotid Artery Stenting on March 17, 2005, indicating that CAS with embolic protection for symptomatic carotid artery stenosis ≥70 percent will be covered only if performed in facilities that have been determined to be competent in

performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. In accordance with this criteria, we consider coverage for CAS reasonable and necessary (section 1862(A)(1)(a) of the Social Security Act). *Form Number:* CMS–10199 (OMB control number: 0938–1011); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,370; *Total Annual Responses:* 4,110; *Total Annual Hours:* 28,998. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Conditions of Coverage for Organ Procurement Organizations and Supporting Regulations; Use: Section 1138(b) of the Social Security Act, as added by section 9318 of the Omnibus Budget Reconciliation Act of 1986 (Pub. L. 99–509), sets forth the statutory qualifications and requirements that organ procurement organizations (OPOs) must meet in order for the costs of their services in procuring organs for transplant centers to be reimbursable under the Medicare and Medicaid programs. An OPO must be certified and designated by the Secretary as an OPO and must meet performance-related standards prescribed by the Secretary. The corresponding regulations are found at 42 CFR part 486 (Conditions for Coverage of Specialized Services Furnished by Suppliers) under subpart G (Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations).

Since each OPO has a monopoly on organ procurement within its designated service area (DSA), we must hold OPOs to high standards. Collection of this information is necessary for us to assess the effectiveness of each OPO and determine whether it should continue to be certified as an OPO and designated for a particular donation service area by the Secretary or replaced by an OPO that can more effectively procure organs within that DSA. *Form Number:* CMS–R–13 (OMB control number: 0938–0688); *Frequency:* Occasionally; *Affected Public:* Not-for-profit institutions; *Number of Respondents:* 58; *Total Annual Responses:* 58; *Total Annual Hours:* 13,546. (For policy questions regarding this collection contact Diane Corning at 410–786–8486.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Ambulatory Surgical Center Conditions for Coverage; *Use:* The Ambulatory Surgical Center (ASC) Conditions for Coverage (CfCs) focus on a patient-centered, outcome-oriented, and transparent processes that promote quality patient care. The CfCs are designed to ensure that each facility has properly trained staff to provide the appropriate type and level of care for that facility and provide a safe physical environment for patients. The CfCs are used by Federal or state surveyors as a basis for determining whether an ASC qualifies for approval or re-approval under Medicare. We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records, which this regulation specifies, is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS–10279 (OMB control number: 0938–1071); *Frequency:* Annual; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 5,500; *Total Annual Responses:* 5,500; *Total Annual Hours:* 209,000. (For policy questions regarding this collection contact Jacqueline Leach at 410–786–4282.)

Dated: April 26, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2017–08738 Filed 4–27–17; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1551]

Determination That DEMEROL (Meperidine Hydrochloride) Injectable and Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements. Through this notice, FDA is hoping to stimulate the economy and increase the regulatory certainty with respect to generic versions of these drug products by confirming that generic versions of the subject drug products may continue to be marketed.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or

effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 005010	DEMEROL	Meperidine Hydrochloride	50 milligrams (mg)/5 milliliter (mL).	Syrup; Oral	U.S. Pharmaceutical Holdings II, LLC.
NDA 006035	METHERGINE	Methylergonovine Maleate	0.2 mg	Tablet; Oral	Edison Therapeutics LLC.
NDA 007337	PERCODAN and PERCODAN–DEMI.	Aspirin, Oxycodone Hydrochloride, Oxycodone Terephthalate.	325 mg, 4.5 mg, 0.38 mg; and 325 mg, 2.25 mg, 0.19 mg.	Tablet; Oral	Endo Pharmaceuticals Inc.
NDA 008720	LEVO–DROMORAN	Levorphanol Tartrate	2 mg	Tablet; Oral	Valeant Pharmaceuticals North America LLC.
NDA 008848	PAMINE and PAMINE FORTE.	Methscopolamine Bromide.	2.5 mg and 5 mg	Tablet; Oral	Fougera Pharmaceuticals Inc.
NDA 009470	XYLOCAINE VISCOUS	Lidocaine Hydrochloride	2%	Solution; Oral	Fresenius Kabi USA, LLC.
NDA 010485	ATARAX	Hydroxyzine Hydrochloride.	10 mg/5 mL	Syrup; Oral	Pfizer Inc.
NDA 010742	COMPAZINE	Prochlorperazine Edisylate.	Equivalent to (EQ) 5 mg Base/mL.	Injectable; Injection	GlaxoSmithKline.
NDA 012111	MYDRIACYL	Tropicamide	0.5%; 1%	Solution/Drops; Ophthalmic.	Alcon Laboratories Inc.
NDA 012248	PLEGINE	Phendimetrazine Tartrate	35 mg	Tablet; Oral	Wyeth Ayerst Laboratories.
NDA 012365	SOMA COMPOUND	Aspirin; Carisoprodol	325 mg; 200 mg	Tablet; Oral	Meda Pharmaceuticals Inc.
NDA 012366	SOMA COMPOUND W/ CODEINE.	Aspirin; Carisoprodol; Codeine Phosphate.	325 mg; 200 mg; 16 mg	Tablet; Oral	Ditto.
NDA 016012	VIVACTIL	Protriptyline Hydrochloride	5 mg; 10 mg	Tablet; Oral	Teva Women's Health, Inc.
NDA 017352	FASTIN	Phentermine Hydrochloride.	30 mg	Capsule; Oral	GlaxoSmithKline.
NDA 017690	IMODIUM	Loperamide Hydrochloride	2 mg	Capsule; Oral	Johnson & Johnson Consumer Inc.
NDA 017694	IMODIUM	Loperamide Hydrochloride	2 mg	Capsule; Oral	Ditto.
NDA 017741	FLORONE	Diflorasone Diacetate	0.05%	Cream; Topical	Pharmacia and Upjohn Co.
NDA 017802	LO/OVRAL–28	Ethinyl Estradiol; Norgestrel.	0.03 mg; 0.3 mg	Tablet; Oral-28	Wyeth Pharmaceuticals Inc.
NDA 017857	STADOL	Butorphanol Tartrate	2 mg/mL	Injectable; Injection	Delcor Asset Corporation.
NDA 017857	STADOL PRESERVATIVE FREE.	Butorphanol Tartrate	1 mg/mL; 2 mg/mL	Injectable; Injection	Ditto.
NDA 018342	WELLCOVORIN	Leucovorin Calcium	EQ 5 mg Base; EQ 25 mg Base.	Tablet; Oral	GlaxoSmithKline.
NDA 018353	FLAGYL I.V.	Metronidazole Hydrochloride.	EQ 500 mg Base/Vial	Injectable; Injection	G.D. Searle LLC, a subsidiary of Pfizer Inc.
NDA 018733	TALWIN NX	Naloxone Hydrochloride; Pentazocine Hydrochloride.	EQ 0.5 mg Base; EQ 50 mg Base.	Tablet; Oral	Sanofi-Aventis U.S. LLC.
NDA 019488	CARDENE	Nicardipine Hydrochloride	20 mg; 30 mg	Capsule; Oral	Chiesi USA, Inc.
NDA 019578	MEFLOQUINE HYDROCHLORIDE.	Mefloquine Hydrochloride	250 mg	Tablet; Oral	U.S. Army Walter Reed Army Institute Research.
NDA 019591	LARIAM	Mefloquine Hydrochloride	250 mg	Tablet; Oral	Hoffmann-La Roche Inc.
NDA 019735	FLOXIN	Ofloxacin	200 mg; 300 mg; 400 mg	Tablet; Oral	Janssen Pharmaceuticals, Inc.
NDA 019890	STADOL	Butorphanol Tartrate	1 mg/Spray	Spray, Metered; Nasal	Bristol-Myers Squibb Co.
NDA 020142	CATAFLAM	Diclofenac Potassium	50 mg	Tablet; Oral	Novartis Pharmaceuticals Corp.
NDA 020254	VOLTAREN–XR	Diclofenac Sodium	100 mg	Extended-Release Tablet; Oral.	Ditto.
NDA 020312	UNIVASC	Moexipril Hydrochloride	7.5 mg; 15 mg	Tablet; Oral	UCB, Inc.
NDA 020346	ZYRTEC	Cetirizine Hydrochloride	5 mg/5 mL	Syrup; Oral	Johnson & Johnson Consumer Inc.
NDA 020584	LODINE XL	Etodolac	400 mg; 500 mg; 600 mg	Extended-Release Tablet; Oral.	Wyeth Pharmaceuticals Inc.
NDA 020625	ALLEGRA	Fexofenadine Hydrochloride.	60 mg	Capsule; Oral	Sanofi-Aventis U.S. LLC.
NDA 020729	UNIRETIC	Hydro chlorothiazide; Moexipril Hydrochloride.	12.5 mg/7.5 mg; 12.5 mg/15 mg; 25 mg/15 mg.	Tablet; Oral	UCB, Inc.
NDA 021066	ZADITOR	Ketotifen Fumarate	EQ 0.025% Base	Solution/Drops; Ophthalmic.	Alcon Pharmaceuticals, Ltd.
NDA 021224	RAZADYNE	Galantamine Hydrobromide.	4 mg/mL	Solution; Oral	Janssen Pharmaceuticals, Inc.
NDA 021378	COMBUNO$_X$	Ibuprofen; Oxycodone Hydrochloride.	400 mg; 5 mg	Tablet; Oral	Forest Laboratories, Inc.
NDA 021473	CIPRO XR	Ciprofloxacin; Ciprofloxacin Hydrochloride.	212.6 mg; EQ 287.5 mg Base; 425.2 mg; EQ 574.9 mg Base.	Extended-Release Tablet; Oral.	Bayer HealthCare Pharmaceuticals, Inc.
NDA 021606	ZEMPLAR	Paricalcitol	4 micrograms (mcg)	Capsule; Oral	AbbVie Inc.
NDA 021729	ABILIFY	Aripiprazole	10 mg and 15 mg	Tablet, Orally Disintegrating; Oral.	Otsuka Pharmaceutical Co., Ltd.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 050072	PENBRITIN–S	Ampicillin Sodium	EQ 125 mg Base/Vial; EQ 250 mg Base/Vial; EQ 500 mg Base/Vial; EQ 1 gram (g) Base/Vial; EQ 2 g Base/Vial; EQ 4 g Base/Vial.	Injectable; Injection	Wyeth Ayerst Laboratories.
NDA 050309	POLYCILLIN–N	Ampicillin Sodium	EQ 125 mg Base/Vial; EQ 250 mg Base/Vial; EQ 500 mg Base/Vial; EQ 1 g Base/Vial; EQ 2 g Base/Vial.	Injectable; Injection	Bristol Laboratories Inc.
NDA 050674	VANTIN	Cefpodoxime Proxetil	EQ 100 mg Base; EQ 200 mg Base.	Tablet; Oral	Pharmacia and Upjohn Co.
ANDA 064170	CEFAZOLIN SODIUM	Cefazolin Sodium	EQ 10 g Base/Vial; EQ 20 g Base/Vial.	Injectable; Injection	Fresenius Kabi USA, LLC.
ANDA 075406	OGESTREL 0.5/50–21	Ethinyl Estradiol; Norgestrel.	0.05 mg; 0.5 mg	Tablet; Oral-21	Watson Laboratories, Inc.
ANDA 085106	PERCOCET	Acetaminophen; Oxycodone Hydrochloride.	325 mg; 5 mg	Tablet; Oral	Vintage Pharmaceuticals LLC.
ANDA 089351	ROXICET	Acetaminophen; Oxycodone Hydrochloride.	325 mg/5 mL; 5 mg/5 mL	Solution; Oral	West-Ward Pharmaceuticals International Ltd.
ANDA 089456	PERPHENAZINE	Perphenazine	8 mg	Tablet; Oral	ANI Pharmaceuticals, Inc.
ANDA 089457	PERPHENAZINE	Perphenazine	16 mg	Tablet; Oral	Teva Pharmaceuticals USA.
ANDA 089707	PERPHENAZINE	Perphenazine	2 mg	Tablet; Oral	Ditto.
ANDA 089708	PERPHENAZINE	Perphenazine	4 mg	Tablet; Oral	Do.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs and ANDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs and ANDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

This is not a significant regulatory action subject to Executive Order 12866, and does not impose any additional burden on regulated entities.

Dated: April 24, 2017.

Anna K. Abram,

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

[FR Doc. 2017–08582 Filed 4–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1114]

Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period; request for information.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the Request for Information that appeared in the **Federal Register** of April 15, 2016. In the Request for Information, FDA requested comments regarding issues related to utilizing the product identifier for product tracing, improving the technical capabilities of the supply chain, and identifying system attributes that are necessary to implement the requirements established under the Drug Supply Chain Security Act (DSCSA). The information gathered from additional public comments will further inform the design and development of the pilot project(s) that FDA establishes under the DSCSA. FDA is reopening the comment period to receive updated comments and any new information.

DATES: FDA is reopening the comment period on the Request for Information published April 15, 2016 (81 FR 22279). Submit either electronic or written comments by April 30, 2018. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 30, 2018. The *https://www.regulations.gov/* electronic filing system will accept comments until midnight Eastern Time at the end of April 30, 2018. 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.

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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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–2016–N–1114 for '' Pharmaceutical Distribution Supply Chain Pilot Projects; Reopening of Comment Period; Request for Information.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov/* or at the Division of Dockets Management 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniel Bellingham, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3130, *DSCSAPilotProjects@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 15, 2016, FDA published a Request for Information with a 30-day comment period to request comments relating to FDA implementation of the DSCSA. To permit additional and update submissions, we are reopening this comment period and extending it for April 30, 2018. We are particularly interested in comments regarding past or present pilot projects related to enhancing the safety and security of the pharmaceutical distribution supply chain. Stakeholders that may be interested in responding to this request for information include manufacturers, repackagers, wholesale distributors, dispensers, State and Federal authorities, solution providers, and standards organizations, and other interested persons. FDA is particularly interested in learning about the practices, processes, and systems that supply chain stakeholders have used or considered using in such pilot projects. This includes, but is not limited to, information about the following:

• Utilizing the product identifier for tracing of a product, which may include verification of the product identifier of a product, including the use of aggregation and inference;

• Technical capabilities each sector of the supply chain to comply with systems and processes needed to utilize the product identifier to enhance the tracing of a product; or

• System attributes that are necessary to implement the requirements established under the DSCSA.

Interested persons are requested to provide any other relevant information that may inform FDA's development of a pilot project under the DSCSA.

FDA is reopening the comment period for the Request for Information for 1 year, until April 30, 2018. The Agency believes that an additional comment period of 1 year will allow time for interested persons to submit new, additional, or updated comments on these important issues.

Dated: April 19, 2017.

Anna K. Abram,

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

[FR Doc. 2017–08583 Filed 4–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–1393]

Government-Owned Inventions; Availability for Licensing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The invention listed in this document is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the patent applications listed in this document may be obtained by writing to the indicated licensing contact at the Food and Drug Administration (FDA) Technology Transfer Program, 10903 New Hampshire Ave., Bldg. 1, Rm. 4213, Silver Spring, MD 20993, telephone: 240–402–2561, FAX: 301–847–3539. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

Title of Abstract: Solid-Phase Purification of Synthetic DNA Sequences.

Description of Technology: Scientists at FDA have developed a high-throughput method for purifying full-length phosphorothioate and native DNA sequences. This method comprises a modified silica gel that enables capture of DNA sequences functionalized with a novel linker specifically designed for exclusive capture of full-length sequences. This

technology has been shown to generate DNA sequences of high purity without the need of expensive equipment and associated accessories. This discovery may improve the availability of pure DNA sequences for clinical and/or synthetic biology applications.

Potential Commercial Applications:

- A high-throughput purification technique for producing small and large quantities of highly pure DNA sequences.

Competitive Advantages:

- Cost effective.
- High-throughput capabilities.
- Time saving.
- High purity.

Development Stage:

- In vitro data available.

Inventors:

Serge L. Beaucage.

Andrzej Grajkowski.

Publication: Grajkowski, A., J. Cieslak, and S.L. Beaucage, ''Solid-Phase Purification of Synthetic DNA Sequences,'' *The Journal of Organic Chemistry,* 81 (15): pp. 6165–6175, 2016; DOI: 10.1021/acs.joc.6b01020.

Intellectual Property: U.S. Provisional Patent Application No. 62/356,214, filed June 29, 2016, FDA Reference No. E–2016–005.

Licensing and Collaborative Research Opportunity:

Parties interested in licensing this technology should contact Charlene Maddox at *Charlene.Maddox@fda.hhs.gov* or *FDAInventionlicensing@fda.hhs.gov.*

Dated: April 19, 2017.

Anna K. Abram,

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

[FR Doc. 2017–08596 Filed 4–27–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Health Workforce Connector, OMB No. 0906–xxxx—NEW

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

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than May 30, 2017.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Health Workforce Connector OMB No. 0906–xxxx—NEW

Abstract: The Health Workforce Connector is being developed to expand on the current National Health Service Corps (NHSC) Jobs Center, which includes positions approved for NHSC scholarship and loan repayment obligors. The new Health Workforce Connector will provide a central platform to connect participants in both the NHSC and NURSE Corps programs with facilities that are approved for performance of their NHSC or NURSE Corps service obligation. The Health Workforce Connector will become a resource that engages any health care professional or student interested in providing primary care services in underserved communities (whether or not those individuals are obligated to the NHSC or NURSE Corps) with facilities in need of health care providers. The Health Workforce Connector will also allow users to create a profile, search for NHSC and NURSE Corps sites, find job opportunities, and will be searchable by Site Points of Contact. Like the current NHSC Jobs Center, individuals will be able to use the Health Workforce Connector's search capability with Google Maps.

Need and Proposed Use of the Information: Information will be collected from users in the following two ways:

(1) *Account Creation:* Creating an account is optional, but to create an account, the user will be required to enter their first name, last name, and email address. Those are the only mandatory fields in the profile account creation process and will be used to send an automated email allowing the user to validate their login credentials. This information will also be used to validate any users who already exist within the Bureau of Health Workforce Management Information Systems Solution (BMISS) database and allow an initial import of existing data at the request of the user.

(2) *Profile Completion:* Users may fill out a profile, but this function will be completely optional and will include fields such as location, discipline, specialty, and languages spoken. The information collected, if 'published' by the user, will allow internal BMISS Site Points of Contact the ability to search on anyone who may be a potential candidate for job opportunities at the site. All information collected will be stored within existing secure BMISS databases and will be used internally for report generation on an as-needed basis.

Likely Respondents: Potential users will include individuals searching for a health care job opportunity or an NHSC or NURSE Corps health care facility, and health care facilities searching for potential candidates to fill open health care job opportunities at their sites.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Account Creation	15,600	1	15,600	.08	1,248
Complete Profile	9,400	1	9,400	1	9,400
Total	*15,600	—	15,600	—	10,648

*The 9,400 respondents who complete their profiles are a subset of the 15,600 respondents who create accounts.

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2017–08584 Filed 4–27–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier 0990–0421–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0421, which expires on July 31, 2017. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before June 27, 2017.

ADDRESSES: Submit your comments to *Information.CollectionClearance @hhs.gov* or by calling (202) 795–7714.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990–0421–60D for reference.

Information Collection Request Title: ASPE Generic Clearance for the Collection of Qualitative Research and Assessment.

OMB No.: 0990–0421.

Abstract: The Office of the Assistant Secretary for Planning and Evaluation (ASPE) is requesting an extension for their generic clearance for purposes of conducting qualitative research. ASPE conducts qualitative research to gain a better understanding of emerging health policy issues, develop future intramural and extramural research projects, and to ensure HHS leadership, agencies and offices have recent data and information to inform program and policy decision-making. ASPE is requesting approval for at least four types of qualitative research: (a) Interviews, (b) focus groups, (c) questionnaires, and (d) other qualitative methods. ASPE's mission is to advise the Secretary of the Department of Health and Human Services on policy development in health, disability, human services, data, and science, and provides advice and analysis on economic policy. ASPE leads special initiatives, coordinates the Department's evaluation, research and demonstration activities, and manages cross-Department planning activities such as strategic planning, legislative planning, and review of regulations. Integral to this role, ASPE will use this mechanism to conduct qualitative research, evaluation, or assessment, conduct analyses, and understand needs, barriers, or facilitators for HHS-related programs.

ASPE is requesting comment on the burden for qualitative research aimed at understanding emerging health and human services policy issues. The goal of developing these activities is to identify emerging issues and research gaps to ensure the successful implementation of HHS programs. The participants may include health and human services experts; national, state, and local health or human services representatives; public health, human services, or healthcare providers; and representatives of other health or human services organizations. The increase in burden from 747 in 2014 to 1,300 respondents in 2017 reflects an increase in the number of research projects conducted over the estimate in 2014.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Health Policy Stakeholder	Qualitative Research	1,300	1	1	1,300

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2017–08599 Filed 4–27–17; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation of Nominations for Three Organizations To Serve as Non-Voting Liaison Representatives to the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Chronic Fatigue Syndrome Advisory Committee (CFSAC) is one of the federal advisory committees for which the Department of Health and Human Services (HHS) provides management support. The Office of the Assistant Secretary for Health (OASH), a staff division in the Office of the Secretary, HHS, is assigned responsibility to provide management support for CFSAC activities. The CFSAC is authorized to have three non-voting liaison representative positions. The organizations designated to fill these positions will be selected from those concerned with myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). The Designated Federal Officer (DFO) for CFSAC will select the organizations from which the representative will be selected to fill these vacant positions. The representatives selected to fill these positions will serve a two-year term as a non-voting liaison representative. Details of nomination requirements are provided below.

DATES: Nominations must be received no later than 5 p.m. ET on May 30, 2017, at the address listed below.

ADDRESSES: All nominations should be sent to Commander Gustavo Ceinos, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 728F.6, Washington, DC 20201. Nomination materials, including attachments, may be submitted electronically to *cfsac@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Commander Gustavo Ceinos, Designated Federal Officer, Chronic Fatigue Syndrome Advisory Committee, Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 728F.6, Washington, DC 20201. The telephone number is: 202–401–9545. Inquiries can be sent to *cfsac@hhs.gov.*

SUPPLEMENTARY INFORMATION: CFSAC was established on September 5, 2002. The purpose of the CFSAC is to provide advice and recommendations to the Secretary of HHS, through the Assistant Secretary for Health, on issues related to ME/CFS. CFSAC advises and makes recommendations on a broad range of topics including: (1) Opportunities to improve knowledge and research about the epidemiology, etiologies, biomarkers and risk factors for ME/CFS; (2) research on the diagnosis, treatment, and management of ME/CFS and potential impact of treatment options; (3) strategies to inform the public, health care professionals, and the biomedical academic and research communities about ME/CFS advances; (4) partnerships to improve the quality of life of ME/CFS patients; and (5) strategies to insure that input from ME/CFS patients and caregivers is incorporated into HHS policy and research. Management and support services for Committee activities are provided by staff from the HHS Office on Women's Health, within the OASH. The CFSAC charter is available at *https://www.hhs.gov/ash/advisory-committees/cfsac/about-cfsac/charter/index.html.*

CFSAC meetings are held not less than two times per year. The CFSAC membership consists of 13 voting members, including the Chair. The voting members are composed of seven biomedical research scientists with demonstrated expertise in biomedical research applicable to ME/CFS; three individuals with expertise in health care delivery, private health care services or insurers, or voluntary organizations concerned with the problems of individuals with ME/CFS, and three are either patients or caregivers affected by ME/CFS.

CFSAC also includes eight non-voting *ex-officio* representatives from the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, National Institutes of Health, Social Security Administration, U.S. Department of Veteran Affairs, and the Department of Defense.

In 2012, the CFSAC structure was expanded to include three non-voting liaison representative positions. These positions are occupied by representatives from organizations that are concerned with ME/CFS. The terms of the current non-voting liaison representative positions expire in May. The selected organizations will occupy the position for a two-year term.

Nominations: The OASH is requesting nominations of organizations to fill the three non-voting liaison representative positions for the CFSAC. The organizations will be selected by the DFO or designee.

Selection of the three organizations which will serve as non-voting liaison representatives will be based on the organizations' qualifications to contribute to the accomplishment of the CFSAC mission, as described in the Committee charter. In selecting the organizations to be considered for these positions, the OASH will give close attention to equitable geographic distribution and give priority to U.S.-chartered 501(c)(3) organizations that operate within the United States and have membership with demonstrated expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues concerning ME/CFS.

The individuals designated by the selected organizations to serve as the official liaison representative will perform the associated duties without compensation, and will not receive per diem or reimbursement for travel expenses. The organizations selected will cover expenses for their designated representative to attend, at a minimum, one in-person CFSAC meeting per year during the designated term of appointment.

To qualify for consideration of selection to the Committee, an organization should submit the following items:

(1) A statement of the organization's history, mission, and focus, including information that demonstrates the organization's experience and expertise in ME/CFS and related research, clinical services, or advocacy and outreach on issues of ME/CFS, as well as expert knowledge of the broad issues and topics pertinent to ME/CFS. This information should demonstrate the organization's proven ability to work and communicate with the ME/CFS patient and advocacy community, and other public/private organizations concerned with ME/CFS, including public health agencies at the federal, state, and local levels.

(2) two to four letters of recommendation that clearly state why the organization is qualified to serve on CFSAC in a liaison representative position. These letters should be from individuals who are not part of the organization.

(3) A statement that the organization is willing to serve as a non-voting liaison representative of the Committee and will cover expenses for their representative to attend in-person, at a minimum, one CFSAC meeting per year in Washington, DC, during the designated term of appointment.

(4) A current financial disclosure statement (or annual report) demonstrating the organization's ability to cover expenses for its representative to attend in-person, at a minimum, one CFSAC meeting per year in Washington, DC, during the term of appointment.

Submitted nominations must include these critical elements in order for the organization to be considered for one of the liaison representative positions.

Nomination materials should be typewritten, using a 12-point font and

double-spaced. All nomination materials should be submitted (postmarked or received) by May 30, 2017.

Electronic submissions: Nomination materials, including attachments, may be submitted electronically to *cfsac@hhs.gov. An email from the CFSAC Support Team will be sent to the nominating organization and/or nominator to confirm receipt of the nomination. If the email confirmation is not received within two working days, please call 202–690–7650.* Telephone and facsimile submissions cannot be accepted.

Regular, Express, or Overnight Mail: Written documents may be submitted to the following addressee only: Commander Gustavo Ceinos, Designated Federal Officer, CFSAC, Office on Women's Health, Department of Health and Human Services, 200 Independence Avenue SW., Room 728F.6, Washington, DC 20201.

HHS makes every effort to ensure that the membership of federal advisory committees is fairly balanced in terms of points of view represented. Every effort is made to ensure that a broad representation of geographic areas, sex, ethnic and minority groups, and people with disabilities are given consideration for membership on federal advisory committees. Selection of the represented organizations shall be made without discrimination against the composition of an organization's membership on the basis of age, sex, race, ethnicity, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Authority: 42 U.S.C. 217a, section 222 of the Public Health Service (PHS) Act, as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. App 2), which sets forth standards for the formation and use of advisory committees.

Dated: April 18, 2017.

Nicole Greene,

Acting Director, Office on Women's Health.

[FR Doc. 2017–08383 Filed 4–27–17; 8:45 am]

BILLING CODE 4150–42–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Peer-Review of (SCORE) Advancement Award.

Date: June 23, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Cambria Suites Rockville, I Helen Heneghan Way, Rockville, MD 20850.

Contact Person: Manas Chattopadhyay, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Building 45, Room 3An12N, 45 Center Drive, Bethesda, MD 20892, 301–827–5320, *manasc@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Centers of Biomedical Research Excellence (COBRE) (P20).

Date: June 29, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Cambria Suites Rockville, 1 Helen Heneghan Way, Rockville, MD 20850.

Contact Person: Shinako Takada, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892–6200, 301–402–9448, *shinako.takada@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 25, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08629 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Interventions and Biomarkers Special Emphasis Panel.

Date: May 24, 2017.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892–9606, 301–443–9699, *bursteinme@mail.nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Confirmatory Efficacy Clinical Trials of Non-Pharmacological Interventions for Mental Disorders.

Date: May 24, 2017.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Marcy Ellen Burstein, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6143, MSC 9606, Bethesda, MD 20892–9606, 301–443–9699, *bursteinme@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: April 25, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08630 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: May 31–June 1, 2017.

Time: 8:00 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: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 25, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08625 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; Peer-Review of (SCORE) Advancement Award.

Date: June 28, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Cambria Suites Rockville, I Helen Heneghan Way, Rockville, MD 20850.

Contact Person: Manas Chattopadhyay, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, Building 45, Room 3An18, 45 Center Drive, Bethesda, MD 20892, 301–827–5320, *manasc@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS SCORE Review.

Date: June 29, 2017.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Brian R. Pike, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikebr@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel; NIGMS Program Project Review.

Date: June 30, 2017.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, RM 3AN12P, 45 Center Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikebr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 25, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08628 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel Review of NIGMS Institutional Postdoctoral T32 Applications.

Date: July 12, 2017.

Time: 8:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Brian R. Pike, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikebr@mail.nih.gov.*

Name of Committee: National Institute of General Medical Sciences Special Emphasis Panel Review of the Centers for Biomedical Research Excellence Applications.

Date: July 13, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn Bethesda, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: Nina Sidorova, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3An.22, Bethesda, MD 20892–6200, 301–594–3663, *sidorova@nigms.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88,

Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 25, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08627 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: NIGMS Initial Review GroupTraining and Workforce Development Subcommittee—C To review R25 Research Training Grant applications.

Date: June 22–23, 2017.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree By Hilton Bethesda, 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lee Warren Slice, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 1 Democracy Plaza, 6701 Democracy Blvd. Room 1068, Bethesda, MD 20892, 301–435–0807, *slicelw@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 25, 2017.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08626 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorder and Stroke Special Emphasis Panel; P30 and R24 Review.

Date: May 23, 2017.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Capital View, 2850 South Potomac Avenue, Arlington, VA 22202.

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH/DHHS, Neuroscience Center, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892–9529, (301) 496–9223, *JimokKim@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 25, 2017.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08631 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR17–033: Integrative Research to Understand the Impact of Sex Differences on the Molecular Determinants of AD Risk and Responsiveness to Treatment.

Date: May 24, 2017.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexei Kondratyev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5200, MSC 7846, Bethesda, MD 20892, 301–435–1785, *kondratyevad@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 25, 2017.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2017–08624 Filed 4–27–17; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under

OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Mandatory Guidelines for Federal Workplace Drug Testing Programs (OMB No. 0930–0158)—Revision

SAMHSA will request OMB approval for the Federal Drug Testing Custody and Control Form (CCF) for federal agency and federally regulated drug testing programs which must comply with the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (82 FR 7920) dated January 23, 2017, and OMB approval for information provided by test facilities (laboratories and Instrumented Initial Test Facilities, IITFs) for the National Laboratory Certification Program (NLCP).

The CCF is used by all federal agencies and employers regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) to document the collection and chain of custody of urine specimens at the collection site, for HHS-certified test facilities to report results, and for Medical Review Officers (MROs) to document and report a verified result. SAMHSA allows the use of the CCF as a paper or electronic form.

The current OMB-approved CCF has a May 31, 2017 expiration date. SAMHSA has resubmitted the CCF with minor content revisions to the form for OMB approval. These revisions are:

- Remove the checkbox, the letters ''DOT'', and hash line in front of Specify DOT Agency in Step 1: Completed by collector or employer Representative; Line D: Specify Testing Authority.
- Addition of four new analytes (oxycodone, oxymorphone, hydrocodone, and hydromorphone) in Step 5A: Primary Specimen Report—Completed by Test Facility.
- Removal of the analyte methylenedioxyethylamphetamine (MDEA) in Step 5A: Primary Specimen Report—Completed by Test Facility.

Based upon information from federal agencies and from DOT concerning their regulated industries, the number of respondents has been reduced from a total of 6.1 million in 2013 to 5.4 million, which reduces the total burden hours by 188,766.

Laboratories and IITFs seeking HHS certification under the NLCP must complete and submit the NLCP application form. The NLCP application form has not been revised compared to the previous form.

Prior to an inspection, an HHS-certified laboratory or IITF is required to submit specific information regarding its procedures. Collecting this information prior to an inspection allows the inspectors to thoroughly review and understand the testing procedures before arriving for the onsite inspection. The NLCP information checklist has not been revised compared to the previous form.

The annual total burden estimates for the CCF, the NLCP application, the NLCP information checklist, and the NLCP recordkeeping requirements are shown in the following table.

Form/respondent	Number of respondents	Responses per respondent	Total number of responses	Burden per response (hours)	Annual burden (hours)
Custody and Control Form:					
Donor	5,400,000	1	5,400,000	0.08	450,000
Collector	5,400,000	1	5,400,000	0.07	360,000
Laboratory	5,400,000	1	5,400,000	0.05	270,000
IITF	0	0	0	0	0
Medical Review Officer	5,400,000	1	5,400,000	0.05	270,000
NLCP Application Form:					
Laboratory	1	1	1	3	3
IITF	0	0	0	0	0
Sections B and C—NLCP Inspection Checklist:					
Laboratory	30	1	30	1	30
IITF	0	0	0	0	0
Recordkeeping:					
Laboratory	30	1	30	250	7,500
IITF	0	0	0	0	0
Total	5,400,061		5,400,061		1,357,533

Written comments and recommendations concerning the proposed information collection should be sent by May 30, 2017 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2017–08588 Filed 4–27–17; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2008–0010]

Board of Visitors for the National Fire Academy

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Committee Management; Notice of Open Federal Advisory Committee Meeting.

SUMMARY: The Board of Visitors for the National Fire Academy (Board) will

meet via teleconference on May 24 and June 21, 2017. The meetings will be open to the public.

DATES: The meetings will take place on Wednesday, May 24 and June 21, 2017, from 1:00 to 3:00 p.m. Eastern Daylight Time. Please note that the meetings may close early if the Board has completed its business.

ADDRESSES: Members of the public who wish to participate in the teleconference should contact Ruth MacPhail as listed in the **FOR FURTHER INFORMATION CONTACT** section by close of business May 22nd to obtain the call-in number and access code for the May 24th meeting, and by close of business June 19th for the June 21st meeting. For information on services for individuals with disabilities or to request special assistance, contact Ruth MacPhail as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Board as listed in the **SUPPLEMENTARY INFORMATION** section. Participants seeking to have their comments considered during the meeting should submit them in advance or during the public comment segment. Comments submitted up to 30 days after the meeting will be included in the public record and may be considered at the next meeting. Comments submitted in advance must be identified by Docket ID FEMA–2008–0010 and may be submitted by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: FEMA–RULES@fema.dhs.gov.* Include the docket number in the subject line of the message.
- *Mail/Hand Delivery:* Ruth MacPhail, 16825 South Seton Avenue, Emmitsburg, Maryland 21727.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the Docket ID for this action. Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received by the Board, go to *http://www.regulations.gov,* click on ''Advanced Search,'' then enter ''FEMA–2008–0010'' in the ''By Docket ID'' box, then select ''FEMA'' under ''By Agency,'' and then click ''Search.''

FOR FURTHER INFORMATION CONTACT: *Alternate Designated Federal Officer:* Kirby E. Kiefer, telephone (301) 447–1117, email *Kirby.Kiefer@fema.dhs.gov.*

Logistical Information: Ruth MacPhail, telephone (301) 447–1333 and email *Ruth.Macphail@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. Appendix.

Purpose of the Board

The purpose of the Board is to review annually the programs of the National Fire Academy (Academy) and advise the Federal Emergency Management Agency (FEMA) Administrator, through the United States Fire Administrator, on the operation of the Academy and any improvements therein that the Board deems appropriate. In carrying out its responsibilities, the Board examines Academy programs to determine whether these programs further the basic missions that are approved by the FEMA Administrator, examines the physical plant of the Academy to determine the adequacy of the Academy's facilities, and examines the funding levels for Academy programs. The Board submits a written annual report to the FEMA Administrator, through the United States Fire Administrator. The report provides detailed comments and recommendations regarding the operation of the Academy.

Agenda

The Board will discuss the direction of the Executive Fire Officer Program to include curriculum, projects, and other requirements.

There will be a public comment period after the Board has concluded their discussions of the agenda item; each speaker will be given no more than 5 minutes to speak. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact Ruth MacPhail to register as a speaker. Meeting materials will be posted at *https://www.usfa.fema.gov/training/nfa/about/bov.html* by May 10th for the May 24th meeting and by June 7th for the June 21st meeting.

Dated: April 20, 2017.

Kirby E. Kiefer,

Acting Superintendent, National Fire Academy, United States Fire Administration, Federal Emergency Management Agency.

[FR Doc. 2017–08561 Filed 4–27–17; 8:45 am]

BILLING CODE 9111–145–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2017–0017]

National Infrastructure Advisory Council

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee Management; Notice of an Open Federal Advisory Committee Meeting.

SUMMARY: The National Infrastructure Advisory Council (NIAC) will meet Monday, May 8, 2017, at 1331 F Street NW., Suite 800, Washington, DC 20004. This meeting will be open to the public.

DATES: The NIAC will meet on May 8, 2017 from 1:30 p.m.–4:30 p.m. ET. The meeting may close early if the committee has completed its business. For additional information, please consult the NIAC Web site, *www.dhs.gov/NIAC,* or contact the NIAC Secretariat by phone at (703) 235–2888 or by email at *NIAC@hq.dhs.gov.*

ADDRESSES: 1331 F Street NW., Suite 800, Washington, DC 20004. Members of the public will register at the registration table prior to entering the meeting room. For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, contact the person listed under **FOR FURTHER INFORMATION CONTACT** below as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Council as listed in the ''Summary'' section below. Comments must be submitted in writing no later than 12:00 p.m. on May 8, 2017, in order to be considered by the Council in its meeting. The comments must be identified by ''DHS–2016–0005,'' and may be submitted by any *one* of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting written comments.
- *Email: NIAC@hq.dhs.gov.* Include the docket number in the subject line of the message.
- *Fax:* (703)235–9707.
- *Mail:* Ginger Norris, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane SW., Mail Stop 0612, Washington, DC 20598–0607.

Instructions: All written submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Written comments received will be posted without alteration at

www.regulations.gov, including any personal information provided.

Docket: For access to the docket or to read background documents or comments received by the NIAC, go to *www.regulations.gov.* Enter ''NIAC'' in the search line and the Web site will list all relevant documents for your review.

Members of the public will have an opportunity to provide oral comments on the topics on the meeting agenda below, and on any previous studies issued by the NIAC. We request that comments be limited to the issues and studies listed in the meeting agenda and previous NIAC studies. All previous NIAC studies can be located at *www.dhs.gov/NIAC.* Public comments may be submitted in writing or presented in person for the Council to consider. Comments received by Ginger Norris on or after 1:00 p.m. on May 8, 2017 will still be accepted and reviewed by the Members, but not necessarily at the time of the meeting. In-person presentations will be limited to three minutes per speaker, with no more than 15 minutes for all speakers. Parties interested in making in-person comments should register on the Public Comment Registration list available at the entrance to the meeting location prior to the beginning of the meeting.

FOR FURTHER INFORMATION CONTACT: Ginger Norris, NIAC, Designated Federal Officer, Department of Homeland Security, 202–441–5885.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. appendix. The NIAC shall provide the President, through the Secretary of Homeland Security, with advice on the security and resilience of the Nation's critical infrastructure sectors. The NIAC will meet to discuss issues relevant to critical infrastructure security and resilience, as directed by the President.

The meeting will commence at 1:30 p.m. EST. At this meeting, the Council will discuss its newest tasking and receive briefings. All presentations will be posted prior to the meeting on the Council's public Web page—*www.dhs.gov/NIAC.*

Public Meeting Agenda

I. Opening of Meeting
II. Roll Call of Members
III. Opening Remarks and Introductions
IV. Approval of February 2017 Meeting Minutes
V. Presentations on Future Focus Study
VI. Public Comment
VII. Discussion of New NIAC Business
VIII. Closing Remarks
IX. Adjournment

The FACA requires that notices of meetings of advisory committees be announced in the **Federal Register** 15 days prior to the meeting date. However, this notice of the NIAC meeting is being published in the **Federal Register** notice on April 27, 2017 10 days prior to the meeting due to the immediate need for the NIAC members to meet to discuss cyber threats to critical infrastructure. Notwithstanding the difficulties that delayed publication, this NIAC meeting must occur. Although the meeting notice was published in the **Federal Register** late, the meeting date was announced during the public meeting on February 16, 2017 and the agenda will be published on the NIAC Web site listed in this **Federal Register** Notice.

Dated: April 17, 2017.

Ginger Norris,

Designated Federal Officer for the National Infrastructure Advisory Council.

[FR Doc. 2017–08637 Filed 4–27–17; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[OMB Control No. 1653–0021]

Agency Information Collection Activities: Extension, Without Changes, of an Existing Information Collection; Comment Request

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: 30-Day Notice of information collection for review; Form No. I–246; Application for Stay of Removal or Deportation; OMB Control No. 1653–0021.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE) is submitting the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies. This information collection was previously published in the **Federal Register** on February 13, 2017, Vol. 82 No. 10497 allowing for a 60-day comment period. USICE did not receive a comment in connection with the 60-day notice. The purpose of this notice is to allow an additional 30 days for public comments

Written comments and suggestions regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for U.S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information 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 agencies 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:* Extension, without change, of a currently approved information collection.

(2) *Title of the Form/Collection:* Application for a Stay of Deportation or Removal.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* ICE Form I–246; U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individual or Households, Business or other non-profit. The information collected is necessary for USICE to make a determination that the eligibility requirements for a request for a stay of deportation or removal are met by the applicant.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 10,000 responses at 30 minutes (.5 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 5,000 annual burden hours.

Dated: April 25, 2017.

Scott Elmore,

PRA Clearance Officer, Office of the Chief Information Officer, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2017–08580 Filed 4–27–17; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0044]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Application for Action on an Approved Application or Petition

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until June 27, 2017.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0044 in the body of the letter, the agency name and Docket ID USCIS–2007–0012. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2007–0012;

(2) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0012 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies 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:* Extension, without change, of a currently approved collection.

(2) *Title of the Form/Collection:* Application for action on an approved application or petition.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–824; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–824 is used to request a duplicate approval notice, or to notify the U.S. Consulate that a petition has been approved or that a person has been adjusted to permanent resident status.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection is 10,888 and the estimated hour burden per response is .42 hours (25 minutes).

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 4,572 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $1,333,780.

Dated: April 24, 2017.

Samantha Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2017–08548 Filed 4–27–17; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRSS–22699; PPWONRADD1, PPMRSNR1Y.NM0000 (177)]

Agency Information Collection Activities: OMB Control Number 1024–0236; Research Permit and Reporting System Applications and Reports

AGENCY: National Park Service, Interior.

ACTION: Notice; request for comments.

SUMMARY: We (National Park Service, NPS) will ask the Office of Management and Budget (OMB) to approve the

information collection (IC) described below. As required by the Paperwork Reduction Act of 1995 and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This IC is scheduled to expire on April 30, 2017. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: You must submit comments on or before May 30, 2017.

ADDRESSES: Send your comments and suggestions on this information collection to the Desk Officer for the Department of the Interior at OMB–OIRA at (202) 395–5806 (fax) or *OIRA_Submission@omb.eop.gov* (email). Please provide a copy of your comments to the Information Collection Clearance Officer, National Park Service, 12201 Sunrise Valley Drive (MS–242 ADIR–PMSP), Reston, VA 20192 (mail); or *tim_goddard@nps.gov* (email). Please reference OMB Control Number 1024–0236 in the subject line of your comments. You may review the ICR online at *http://www.reginfo.gov.* Follow the instructions to review Department of the Interior collections under review by OMB.

FOR FURTHER INFORMATION CONTACT: To request additional information about this IC, contact Bill Commins, Natural Resource Stewardship and Science, National Park Service, 1201 I St. NW. (Floor 8, Room 46), Washington, DC 20005 (mail); 202–513–7166 (telephone); 202–371–1944 (fax); or *bill_commins@nps.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Abstract

Regulations at 36 CFR 2.1 and 2.5 provide for taking of scientific research specimens in parks. We use a permit system to manage scientific research and collecting. National Park Service Forms 10–741a (Application for a Scientific Research and Collecting Permit) and 10–741b (Application for a Science Education Permit) collect information from persons seeking a permit to conduct natural or social science research and collection activities in individual units of the National Park System. The information we collect includes, but is not limited to:

- Names and business contact information.
- Project title, purpose of study, summary of proposed field methods and activities, and study and field schedules.
- Location where scientific activities are proposed to take place, including method of access.
- Whether or not specimens are proposed to be collected or handled, and if yes, scientific descriptions and proposed disposition of specimens.
- If specimens are to be permanently retained, the proposed repositories for those specimens.

Persons who receive a permit must report annually on the activities conducted under the permit. Form 10–226 (Investigator's Annual Report) collects the following information:

- Reporting year, park, and type of permit.
- Names and business contact information and names of additional investigators.
- Project title, park-assigned study or activity number, park-assigned permit number, permit start and expiration dates, and scientific study start and ending dates.
- Activity type, subject discipline, purpose of study/activity during the reporting year, and finding and status of study or accomplishments of education activity during the reporting year.

We use the above information to manage the use and preservation of park resources and for reporting to the public via the Internet about the status of permitted research and collecting activities. We encourage respondents to use the Internet-based, automated Research Permit and Reporting System (RPRS) to complete and submit applications and reports. For those who use RPRS, much of the information needed for the annual report is generated automatically through information supplied in the application or contained in the permit.

You may obtain additional information about the application and reporting forms and existing guidance and explanatory material by clicking on ''Help'' at the RPRS Web site (*https://irma.nps.gov/RPRS/*).

II. Data

OMB Control Number: 1024–0236.

Title: Research Permit and Reporting System Applications and Reports, 36 CFR 2.1 and 2.5.

Service Form Number(s): NPS Forms 10–226, 10–741a, and 10–741b.

Type of Request: Extension of a currently approved collection.

Description of Respondents: Individuals; businesses; academic and research institutions; and Federal, State, local, and tribal governments.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion for applications; annually for reports.

Activity	Number of respondents	Number of annual responses	Completion time per response	Total annual burden hours
Form 10–226, ''Investigator's Annual Report''				
Individuals	217	217	15 minutes	54
Private Sector	1,700	1,700	15 minutes	425
Government	1,300	1,300	15 minutes	325
Subtotal	3,217	3,217		804
Form 10–741a, ''Application for a Scientific Research and Collecting Permit''				
Individuals	272	272	1.38 hours	375
Private Sector	1,600	1,600	1.38 hours	2,208
Government	1,400	1,400	1.38 hours	1,932
Subtotal	3,272	3,272		4,515
Form 10–741b, ''Application for a Science Education Permit''				
Individuals	30	30	1 hour	30
Private Sector	50	50	1 hour	50
Government	50	50	1 hour	50

Activity	Number of respondents	Number of annual responses	Completion time per response	Total annual burden hours
Subtotal	130	130		130
Totals	6,619	6,619		5,449

*Total annual burden hours rounded.

Estimated Annual Non-hour Cost Burden: There is no non-hour burden cost associated with this collection.

III. Comments

On September 9, 2016, we published in the **Federal Register** (81 FR 44147) a Notice of our intent to request that OMB renew approval for this information collection. In that Notice, we solicited comments for 60 days, ending November 7, 2016. We received no comments in response to that Notice.

We again invite comments concerning this information collection on:

- Whether or not the collection of information is necessary, including whether or not the information will have practical utility;
- The accuracy of our estimate of the burden for this collection of information;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the collection of information on respondents.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask OMB in your comment to withhold your personal identifying information from public review, we cannot guarantee that it will be done.

Timothy Goddard,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2017–08697 Filed 4–27–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–23215; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting comments on the significance of properties nominated before April 1, 2017, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by May 15, 2017.

ADDRESSES: Comments may be sent via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C St. NW., MS 7228, Washington, DC 20240.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before April 1, 2017. Pursuant to section 60.13 of 36 CFR part 60, written comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State Historic Preservation Officers:

NEW YORK

Albany County

Tilley, John S., Ladders Company, 122 2nd St., Watervliet, SG100000993

Bronx County

Reformed Church of Melrose, 746 Elton Ave., Bronx, SG100000994

Dutchess County

Winans-Huntting House, 51 Bethel Cross Rd., Pine Plains, SG100000995

Essex County

Henry's Garage, 14 Church St., Port Henry, SG100000996

New York County

P.S. 186, 521 W. 145th St., New York, SG100000997

Suffolk County

Southold Milestone 7, (Southold Town Milestones MPS), 450 Franklinville Rd., Laurel, MP100000999

Nominations submitted by Federal Preservation Officers:

FLORIDA

Escambia County

Pensacola Harbor Defense Project, W. end of Santa Rosa Island, Pensacola, SG100000992

The State Historic Preservation Officer reviewed the nomination and responded to the Federal Preservation Officer within 45 days of receipt of the nomination and supports listing the property in the National Register of Historic Places.

Authority: 60.13 of 36 CFR part 60.

Dated: April 4, 2017.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

[FR Doc. 2017–08557 Filed 4–27–17; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

[MMAA104000]

Notice on Outer Continental Shelf Oil and Gas Lease Sales

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: List of Restricted Joint Bidders.

Pursuant to the joint bidding provisions of 30 CFR 556.511–556.515, the Bureau of Ocean Energy Management is publishing a List of Restricted Joint Bidders. Each entity within one of the following groups is restricted from bidding with any entity in any of the other following groups at Outer Continental Shelf oil and gas lease sales to be held during the bidding period May 1, 2017, through October 31, 2017. This List of Restricted Joint Bidders will cover the period May 1, 2017, through October 31, 2017, and replace the prior list published on November 4, 2016, which covered the period of November 1, 2016, through April 30, 2017.

Group I

BP America Production Company
BP Exploration & Production Inc.
BP Exploration (Alaska) Inc.

Group II

Chevron Corporation
Chevron U.S.A. Inc.
Chevron Midcontinent, L.P.
Unocal Corporation
Union Oil Company of California
Pure Partners, L.P.

Group III

Eni Petroleum Co. Inc.
Eni Petroleum US LLC
Eni Oil US LLC
Eni Marketing Inc.
Eni BB Petroleum Inc.
Eni US Operating Co. Inc.
Eni BB Pipeline LLC

Group IV

Exxon Mobil Corporation
ExxonMobil Exploration Company

Group V

Petroleo Brasileiro S.A.
Petrobras America Inc.

Group VI

Shell Oil Company
Shell Offshore Inc.
SWEPI LP
Shell Frontier Oil & Gas Inc.
SOI Finance Inc.
Shell Gulf of Mexico Inc.

Group VII

Statoil ASA
Statoil Gulf of Mexico LLC
Statoil USA E&P Inc.
Statoil Gulf Properties Inc.

Group VIII

Total E&P USA, Inc.

Dated: April 21, 2017.

Walter D. Cruickshank,

Acting Director, Bureau of Ocean Energy Management.

[FR Doc. 2017–08659 Filed 4–27–17; 8:45 am]

BILLING CODE 4310–MR–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–570 and 731–TA–1346 (Preliminary)]

Aluminum Foil From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of aluminum foil from China, provided for in subheadings 7607.11.30, 7607.11.60, 7607.11.90, and 7607.19.60 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'') and to be subsidized by the government of China.

Commencement of Final Phase Investigations

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (''Commerce'') of affirmative preliminary determinations in the investigations under sections 703(b) or 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) or 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On March 9, 2017, The Aluminum Association Trade Enforcement Working Group (Arlington, Virginia), on behalf of JW Aluminum Company (Goose Creek, South Carolina), Novelis North America (Atlanta, Georgia), and Reynolds Consumer Products (Lake Forest, Illinois) filed a petition with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV and subsidized imports of aluminum foil from China. Accordingly, effective March 9, 2017, the Commission, pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)), instituted countervailing duty investigation No. 701–TA–570 and antidumping duty investigation No. 731–TA–1346 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of March 15, 2017 (82 FR 13853). The conference was held in Washington, DC, on March 30, 2017, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 703(a) and 733(a) of the Act (19 U.S.C. 1671b(a) and 1673b(a)). It completed and filed its determinations in these investigations on April 24, 2017. The views of the Commission are contained in USITC Publication 4684 (May 2017), entitled *Aluminum Foil from China: Investigation Nos. 701–TA–570 and 731–TA–1346 (Preliminary).*

By order of the Commission.

Issued: April 24, 2017.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2017–08560 Filed 4–27–17; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0099]

Agency Information Collection Activities; Proposed eCollection eComments Requested; ATF Adjunct Instructor Data Form—ATF Form 6140.3

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit 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 February 24, 2017, allowing for a 60-day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until May 30, 2017.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, particularly with respect to the estimated public burden or associated response time, have suggestions, need a copy of the proposed information collection instrument with instructions, or desire any other additional information, please contact J. Wade Brashier, Professional/Technical Training & Development Branch, either by mail at 99 New York Avenue NE., Washington, DC 20226 or by email at *jerry.brashier@atf.gov.* Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.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. Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; 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:* Extension, without change, of a currently approved collection.
2. *The Title of the Form/Collection:* ATF Adjunct Instructor Data Form.
3. *The agency form number, if any, and the applicable component of the Department*
4. *sponsoring the collection:*
5. *Form number:* ATF Form 6140.3.
6. *Component:* Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.
7. *Affected public who will be asked or required to respond, as well as a brief abstract:*
8. *Primary:* State, Local, or Tribal Government.
9. *Other:* None.
10. *Abstract:* The information collected on ATF F 6140.3 will provide ATF with sufficient data to uniquely identify individual instructors, validate instructor topical expertise prior to training, and defend an instructor's qualifications in court regarding topical expertise.
11. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 20 respondents will utilize the form, and it will take each respondent approximately 30 minutes to complete the form.
12. *An estimate of the total public burden (in hours) associated with the collection:* An estimated 20 respondents will utilize the form, and it will take each respondent approximately 30 minutes to complete the form.

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: April 24, 2017.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2017–08550 Filed 4–27–17; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Resource Conservation and Recovery Act

On April 25, 2017, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Northern District of New York in the lawsuit entitled *United States* v. *Falcon Petroleum, LLC, RGLL, Inc., and GRJH, Inc.,* Civil Action No. 1:16–cv–1522.

This settlement resolves the United States' allegations that Falcon Petroleum, LLC, RGLL, Inc., and GRJH, Inc. (''Defendants'') violated the Resource Conservation and Recovery (''Act'') and its implementing regulations set forth at 40 CFR part 280 at eight gas stations in New York, all of which contain underground storage tanks (''tanks'') owned and operated, or owned and leased, by Defendants. The United States' claims against Defendants stem from the company's alleged failure to install overfill protection equipment; perform release detection on tanks and associated piping; equip piping with automatic line leak detectors; perform annual testing of an automatic line leak detector on piping; and maintain adequate records of release detection monitoring.

The proposed Consent Decree resolves these allegations by requiring that Defendants implement injunctive relief valued at approximately $218,000, undertake a Supplemental Environmental Project (''SEP'') valued at approximately $220,000, and pay a $60,000 civil penalty. As part of the injunctive relief, Defendants will install, or upgrade to, fully automated electronic release detection monitoring equipment at seven gas stations in New York. As part of the SEP, Defendants will install a centralized monitoring system in twenty-six stations that span three states: Twenty-three in New York, two in Connecticut and one in New Hampshire. The centralized monitoring system will transmit to and collect at one central location the information gathered at each gas station equipped with the electronic release detection monitoring equipment. This technology will therefore assist Defendants to respond to potential releases and other alarm events.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Falcon Petroleum, LLC, RGLL, Inc., and GRJH, Inc.,* D.O.J. Ref. No. 90–7–1–09896. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of

reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $10.25 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy without the exhibits and signature pages, the cost is $6.75.

Robert E. Maher, Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2017–08651 Filed 4–27–17; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of the Assistant Secretary for Administration and Management

Agency Information Collection Activities; Comment Request; Application for Use of Public Space by Non-DOL Agencies in the Frances Perkins Building

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning an Information Collection Request (ICR) proposing to extend Paperwork Reduction Act of 1995 (PRA), authority to conduct the information collection titled, ''Application for Use of Public Space by Non-DOL Agencies in the Frances Perkins Building.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden.

DATES: Submit written comments on or before June 27, 2017.

ADDRESSES: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) to request a free copy of this ICR that includes applicable supporting documentation providing a description of the likely respondents, proposed frequency of response, and estimated total burden. Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Information Policy and Assessment Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The DOL headquarters building, the Frances Perkins Building (FPB), has conference and meeting capabilities located in its public space areas that non-DOL entities may request to use. The Administrator of the General Services Administration set forth terms and conditions delegating FPB operation to the DOL, Office of the Assistant Secretary for Administration and Management (OASAM). The delegation sets forth conditions authorizing the DOL to issue occasional use permits for FPB public space. The delegation is also subject to applicable standard operating procedures for Government-owned real properties. More specifically, the DOL may only issue occasional use permits to organizations engaging in cultural, educational, or recreational activities. These permits are generally not available for commercial purposes. Any person or organization wishing to use a FPB public area must file a permit application with the DOL Conference Rooms and Services Center. Applicants must submit the following information: (a) Applicant's full name, mailing address, and telephone number; (b) organization sponsoring the proposed activity; (c) individual(s) responsible for supervising the activity; (d) documentation showing the applicant is authorized to represent the sponsoring organization; and (e) a description of the proposed activity, including dates and times during which it is to be conducted and the number of persons to be involved. OASAM policies and procedures concerning FPB public space are set forth in DOL Manual Series section 2–510 and an application—Form DL–1–6062B, Application for Use of Public Space by Non-DOL Agencies in the Frances Perkins Building.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the Office of Management and Budget (OMB) under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information if the collection of information does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1225–0087. The DOL intends to seek continued approval for this collection of information for an additional three years.

The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed. Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the ICR. Submitted comments will also be a matter of public record for this ICR and posted on the Internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OASAM.

Type of Review: Extension without change of a currently approved collection.

Title of Collection: Application for Use of Public Space by Non-DOL Agencies in the Frances Perkins Building.

Form: Application for Use of Public Space by Non-DOL Agencies in the Frances Perkins Building (Form DL–1–6062B).

OMB Control Number: 1225–0087.

Affected Public: Private Sector—not for-profit institutions.

Estimated Number of Respondents: 5.

Frequency: On occasion.

Total Estimated Annual Responses: 5.

Estimated Average Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 1 hour.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Dated: April 24, 2017.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2017–08612 Filed 4–27–17; 8:45 am]

BILLING CODE 4510–23–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–027 and 52–028; NRC–2008–0441]

South Carolina Electric & Gas Company, South Carolina Public Service Authority; Virgil C. Summer Nuclear Station, Units 2 and 3; Design Reliability Assurance Program (D–RAP) Changes

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and is issuing License Amendment No. 70 to Combined Licenses (COLs), NPF–93 and NPF–94. The COLs were issued to South Carolina Electric & Gas Company and the South Carolina Public Service Authority, (together referred to as the licensee); for construction and operation of the Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, located in Fairfield County, South Carolina.

The granting of the exemption allows the changes to Tier 1 information asked for in the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: The exemption and amendment were issued on April 11, 2017.

ADDRESSES: Please refer to Docket ID NRC–2008–0441 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–2008–0441. 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. The request for the amendment and exemption was submitted by letter dated September 22, 2016 and is available in ADAMS under Accession No. ML16270A582.
- *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: Billy Gleaves, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5848; email: *Bill.Gleaves@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting an exemption from Paragraph B of Section III, ''Scope and Contents,'' of Appendix D, ''Design Certification Rule for the AP1000,'' to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), and issuing License Amendment No. 70 to COLs, NPF–93 and NPF–94, to the licensee. The exemption is required by Paragraph A.4 of Section VIII, ''Processes for Changes and Departures,'' Appendix D, to 10 CFR part 52 to allow the licensee to depart from Tier 1 information. With the requested amendment, the licensee sought proposed changes that would revise the Updated Final Safety Analysis Report (UFSAR) in the form of departures from the incorporated plant-specific DCD Tier 2 information. The proposed amendment also involves related changes to plant-specific Tier 1 information, with corresponding changes to the associated COL Appendix C information. Specifically, the LAR revises the Design Reliability Assurance Program (D–RAP) to identify the covers for the in-containment refueling water storage tank (IRWST) vents and overflow weirs as the risk-significant components included in the D–RAP and to identify that the field control relays of each rod drive motor-generator (MG) sets are a part of the rod drive power supply control cabinets in which the relays are located.

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in §§ 50.12, 52.7, and Section VIII.A.4 of Appendix D to 10 CFR part 52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML17048A143.

Similar exemption documents were issued to the licensee for VCSNS Units 2 and 3 (COLs NPF–93 and NPF–94). The exemption documents for VCSNS Units 2 and 3 can be found in ADAMS under Accession Nos. ML17048A144 and ML17048A147, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The similar amendment documents for COLs NPF–93 and NPF–94 are available in ADAMS under Accession Nos. ML17048A145 and ML17048A148, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption document issued to VCSNS Units 2 and Unit 3. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In an application dated September 22, 2016, the licensee requested from the Commission an exemption to allow departures from Tier 1 information in the certified DCD incorporated by reference in 10 CFR part 52, Appendix

D, as part of license amendment request 16–14, ''Design Reliability Assurance Program (D–RAP) Changes.''

For the reasons set forth in Section 3.1 of the NRC staff's Safety Evaluation, which can be found in ADAMS under Accession No. ML17048A143, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, the licensee is granted an exemption from the certified DCD Tier 1 information related to the in-containment refueling water storage tank vents and overflow weirs, the rod drive motor-generator sets field control relays, and the rod drive power supply control cabinets, as described in the licensee's request dated September 22, 2016. This exemption is related to, and necessary for the granting of License Amendment No. 70, which is being issued concurrently with this exemption.

3. As explained in Section 5.0 of the NRC staff's Safety Evaluation (ADAMS Accession No. ML17048A143), this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated September 22, 2016 (ADAMS Accession No. ML16270A582), the licensee requested that the NRC amend the COLs for VCSNS, Units 2 and 3, COLs NPF–93 and NPF–94. The proposed amendment is described in Section I of this **Federal Register** Notice.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on November 8, 2016 (81 FR 78652). No comments were received during the 30-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that the licensee requested on September 22, 2016.

The exemption and amendment were issued on April 11, 2017, as part of a combined package to the licensee (ADAMS Accession No. ML17048A142).

Dated at Rockville, Maryland, this 14th day of April 2017.

For the Nuclear Regulatory Commission.

Brian Hughes,

Acting Branch Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2017–08633 Filed 4–27–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–027 and 52–028; NRC–2008–0441]

Virgil C. Summer Nuclear Station, Units 2 and 3; South Carolina Electric & Gas Company; South Carolina Public Service Authority Debris Screen Related Dimensions

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption and combined license amendment; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is granting an exemption to allow a departure from the certification information of Tier 1 of the generic design control document (DCD) and is issuing License Amendment No. 66 to Combined Licenses (COL), NPF–93 and NPF–94. The COLs were issued to South Carolina Electric & Gas Company and the South Carolina Public Service Authority, (both collectively referred to as the licensee) for construction and operation of the Virgil C. Summer Nuclear Station (VCSNS) Units 2 and 3, located in Fairfield County, South Carolina.

The granting of the exemption allows the changes to Tier 1 information asked for in the amendment. Because the acceptability of the exemption was determined in part by the acceptability of the amendment, the exemption and amendment are being issued concurrently.

DATES: The exemption and amendment were issued on March 27, 2017.

ADDRESSES: Please refer to Docket ID NRC–2008–0441 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–2008–0252. 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. The request for the amendment and exemption was submitted by letter dated August 12, 2016 (ADAMS Accession No. ML16225A437).
- *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: Ruth Reyes, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3249; email: *Ruth.Reyes@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is granting an exemption from Paragraph B of Section III, ''Scope and Contents,'' of appendix D, ''Design Certification Rule for the AP1000,'' to part 52 of title 10 of the *Code of Federal Regulations* (10 CFR), and issuing License Amendment No. 66 to COLs, NP–93 and NPF–94, to the licensee. The exemption is required by Paragraph A.4 of Section VIII, ''Processes for Changes and Departures,'' appendix D, to 10 CFR part 52 to allow the licensee to depart from Tier 1 information. With the requested amendment, the licensee sought proposed changes that would revise the Updated Final Safety Analysis Report in the form of departures from the incorporated plant-specific DCD Tier 2 information. The proposed amendment also involves related changes to plant-specific Tier 1 information, with corresponding changes to the associated COL Appendix C information. The proposed changes are to information identifying the frontal face area and screen surface area for the In-Containment Refueling Water Storage Tank (IRWST) screens, the location and dimensions of the protective plate located above the containment recirculation (CR) screens, and increasing the maximum Normal Residual Heat Removal System flowrate through the IRWST and CR screens.

Part of the justification for granting the exemption was provided by the review of the amendment. Because the exemption is necessary in order to issue the requested license amendment, the NRC granted the exemption and issued the amendment concurrently, rather than in sequence. This included issuing a combined safety evaluation containing the NRC staff's review of both the exemption request and the license amendment. The exemption met all applicable regulatory criteria set forth in 10 CFR 50.12, 10 CFR 52.7, and Section VIII.A.4 of appendix D to 10 CFR part 52. The license amendment was found to be acceptable as well. The combined safety evaluation is available in ADAMS under Accession No. ML17040A590.

Identical exemption documents (except for referenced unit numbers and license numbers) were issued to the licensee for VCSNS Units 2 and 3 (COLs NPF–93 and NPF–94). The exemption documents for VCSNS Units 2 and 3 can be found in ADAMS under Accession Nos. ML17040A547 and ML17040A553, respectively. The exemption is reproduced (with the exception of abbreviated titles and additional citations) in Section II of this document. The amendment documents for COLs NPF–93 and NPF–94 are available in ADAMS under Accession Nos. ML17040A543 and ML17040A545, respectively. A summary of the amendment documents is provided in Section III of this document.

II. Exemption

Reproduced below is the exemption document issued to V. C. Summer Units 2 and 3. It makes reference to the combined safety evaluation that provides the reasoning for the findings made by the NRC (and listed under Item 1) in order to grant the exemption:

1. In an application dated August 12, 2016, the licensee requested from the Commission an exemption to allow departures from Tier 1 information in the certified DCD incorporated by reference in 10 CFR part 52, appendix D, as part of License Amendment Request 14–11, ''Debris Screen Related Dimensions.''

For the reasons set forth in Section 3.1 of the NRC staff's Safety Evaluation, which can be found at ADAMS Accession No. ML17040A590, the Commission finds that:

A. The exemption is authorized by law;

B. the exemption presents no undue risk to public health and safety;

C. the exemption is consistent with the common defense and security;

D. special circumstances are present in that the application of the rule in this circumstance is not necessary to serve the underlying purpose of the rule;

E. the special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption; and

F. the exemption will not result in a significant decrease in the level of safety otherwise provided by the design.

2. Accordingly, the licensee is granted an exemption from the certified DCD Tier 1 information, with corresponding changes to Appendix C of the Facility COLs as described in the licensee's request dated August 12, 2016. This exemption is related to, and necessary for, the granting of License Amendment No. 66, which is being issued concurrently with this exemption.

3. As explained in Section 5.0 of the NRC staff's Safety Evaluation this exemption meets the eligibility criteria for categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment needs to be prepared in connection with the issuance of the exemption.

4. This exemption is effective as of the date of its issuance.

III. License Amendment Request

By letter dated August 12, 2016, the licensee requested that the NRC amend the COLs for VCSNS, Units 2 and 3, COLs NPF–93 and NPF–94. The proposed amendment is described in Section I of this **Federal Register** notice.

The Commission has determined for these amendments that the application complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the license amendment.

A notice of consideration of issuance of amendment to facility operating license or combined license, as applicable, proposed no significant hazards consideration determination, and opportunity for a hearing in connection with these actions, was published in the **Federal Register** on October 11, 2016 (81 FR 70182). No comments were received during the 30-day comment period.

The Commission has determined that these amendments satisfy the criteria for categorical exclusion in accordance with 10 CFR 51.22. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared for these amendments.

IV. Conclusion

Using the reasons set forth in the combined safety evaluation, the staff granted the exemption and issued the amendment that the licensee requested on August 12, 2016.

The exemption and amendment were issued on March 27, 2017, as part of a combined package to the licensee (ADAMS Accession No. ML17040A530).

Dated at Rockville, Maryland, this 17th day of April 2017.

For the Nuclear Regulatory Commission.

Jennifer Dixon-Herrity,

Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2017–08615 Filed 4–27–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–027 and 52–028; NRC–2008–0441]

South Carolina Electric & Gas Company, South Carolina Public Service Authority, Virgil C. Summer Nuclear Station, Units 2 and 3, Inspections, Tests, Analyses, and Acceptance Criteria

AGENCY: Nuclear Regulatory Commission.

ACTION: Determination of the successful completion of inspections, tests, and analyses.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) staff has determined that the inspections, tests, and analyses have been successfully completed, and that the specified acceptance criteria are met for multiple inspections, tests, analyses, and acceptance criteria (ITAAC) for the Virgil C. Summer Nuclear Station (VCSNS), Units 2 and 3.

DATES: The determination of the successful completion of inspections, tests, and analyses for these ITAAC for VCSNS, Units 2 and 3 is effective April 28, 2017.

ADDRESSES: Please refer to Docket ID NRC–2008–0441 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–2008–0441. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov*. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html*. To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search*.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov*. The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Billy Gleaves, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5848; email: *Bill.Gleaves@nrc.gov*.

SUPPLEMENTARY INFORMATION:

I. Licensee Notification of Completion of ITAAC

South Carolina Electric & Gas (SCE&G), on behalf of itself and the South Carolina Public Service Authority, (both hereafter called the licensee) has submitted ITAAC closure notifications (ICNs) under title 10 of the *Code of Federal Regulations* (10 CFR) 52.99(c)(1), informing the NRC that the licensee has successfully performed the required inspections, tests, and analyses, and that the acceptance criteria are met for:

VCSNS Unit 2 ITAAC
2.1.01.06.ii (7), 2.1.03.09a.i (81), 2.5.01.03c (513), and C.3.8.01.02.03 (845)

VCSNS Unit 3 ITAAC
2.1.01.06.ii (7), 2.1.03.09a.i (81), 2.5.01.03c (513), 3.3.00.09 (814), and C.3.8.01.02.03 (845)

The ITAAC for VCSNS Unit 2 are in Appendix C of the VCSNS Unit 2 combined license (ADAMS Accession No. ML14100A092). The ITAAC for VCSNS Unit 3 are in Appendix C of VCSNS Unit 3 combined license (ADAMS Accession No. ML14100A101).

II. NRC Staff Determination of Completion of ITAAC

The NRC staff has determined that the specified inspections, tests, and analyses have been successfully completed, and that the specified acceptance criteria are met. The documentation of the NRC staff's determination is in the ITAAC Closure Verification Evaluation Form (VEF) for each ITAAC. The VEF is a form that represents the NRC staff's structured process for reviewing ICNs. Each ICN presents a narrative description of how the ITAAC was completed. The NRC's ICN review process involves a determination on whether, among other things: (1) Each ICN provides sufficient information, including a summary of the methodology used to perform the ITAAC, to demonstrate that the inspections, tests, and analyses have been successfully completed; (2) each ICN provides sufficient information to demonstrate that the acceptance criteria of the ITAAC are met; and (3) any NRC inspections for the ITAAC have been completed and any ITAAC findings associated with that ITAAC have been closed.

The NRC staff's determination of the successful completion of these ITAAC is based on information available at this time and is subject to the licensee's ability to maintain the condition that the acceptance criteria are met. If the staff receives new information that suggests the staff's determination on any of these ITAAC is incorrect, then the staff will determine whether to reopen that ITAAC (including withdrawing the staff's determination on that ITAAC). The NRC staff's determination will be used to support a subsequent finding, pursuant to 10 CFR 52.103(g), at the end of construction that all acceptance criteria in the combined license are met. The ITAAC closure process is not finalized for these ITAAC until the NRC makes an affirmative finding under 10 CFR 52.103(g). Any future updates to the status of these ITAAC will be reflected on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/oversight/itaac.html*.

This notice fulfills the staff's obligations under 10 CFR 52.99(e)(1) to publish a notice in the **Federal Register** of the NRC staff's determination of the successful completion of inspections, tests, and analyses.

Virgil C. Summer Nuclear Station Unit 2, Docket No. 5200027

A complete list of the review status for VCSNS Unit 2 ITAAC, including the submission date and ADAMS Accession Number for each ICN received, the ADAMS Accession Number for each VEF, and the ADAMS Accession Numbers for the inspection reports associated with these specific ITAAC, can be found on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/new-licensing-files/sum2-icnsr.pdf*.

Virgil C. Summer Nuclear Station Unit 3, Docket No. 5200028

A complete list of the review status for VCSNS Unit 3 ITAAC, including the submission date and ADAMS Accession Number for each ICN received, the ADAMS Accession Number for each VEF, and the ADAMS Accession Numbers for the inspection reports associated with these specific ITAAC, can be found on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/new-licensing-files/sum3-icnsr.pdf*.

Dated at Rockville, Maryland, this 17th day of April 2017.

For the Nuclear Regulatory Commission.

Jennifer Dixon-Herrity,

Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2017–08618 Filed 4–27–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2017–0001]

Sunshine Act Meeting Notice

DATE: Weeks of May 1, 8, 15, 22, 29, June 5, 2017.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and Closed.

Week of May 1, 2017

There are no meetings scheduled for the week of May 1, 2017.

Week of May 8, 2017—Tentative

Tuesday, May 9, 2017

10:00 a.m. Briefing on Security Issues (Closed Ex. 1).

2:00 p.m. Briefing on Security Issues (Closed Ex. 1).

Thursday, May 11, 2017

9:00 a.m. Briefing on Risk-Informed Regulation (Public Meeting); (Contact: Steve Ruffin: 301–415–1985).

This meeting will be webcast live at the Web address—*http://www.nrc.gov/.*

Week of May 15, 2017—Tentative

There are no meetings scheduled for the week of May 15, 2017.

Week of May 22, 2017—Tentative

There are no meetings scheduled for the week of May 22, 2017.

Week of May 29, 2017—Tentative

There are no meetings scheduled for the week of May 29, 2017.

Week of June 5, 2017—Tentative

There are no meetings scheduled for the week of June 5, 2017.

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The schedule for Commission meetings is subject to change on short notice. For more information or to verify the status of meetings, contact Denise McGovern at 301–415–0681 or via email at *Denise.McGovern@nrc.gov.*

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/public-involve/public-meetings/schedule.html.*

* * * * *

The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Kimberly Meyer, NRC Disability Program Manager, at 301–287–0739, by videophone at 240–428–3217, or by email at *Kimberly.Meyer-Chambers@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

* * * * *

Members of the public may request to receive this information electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC 20555 (301–415–1969), or email *Brenda.Akstulewicz@nrc.gov* or *Patricia.Jimenez@nrc.gov.*

Dated: April 26, 2017.

Denise L. McGovern,

Policy Coordinator, Office of the Secretary.

[FR Doc. 2017–08793 Filed 4–26–17; 4:15 pm]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 52–025 and 52–026; NRC–2008–0252]

Southern Nuclear Operating Company, Inc. Vogtle Electric Generating Plant, Units 3 and 4 Inspections, Tests, Analyses, and Acceptance Criteria

AGENCY: Nuclear Regulatory Commission.

ACTION: Determination of the successful completion of inspections, tests, and analyses.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) staff has determined that the inspections, tests, and analyses have been successfully completed, and that the specified acceptance criteria are met for multiple inspections, tests, analyses, and acceptance criteria (ITAAC) for the Vogtle Electric Generating Plant (VEGP), Units 3 and 4.

DATES: The determination of the successful completion of inspections, tests, and analyses for these ITAAC for VEGP, Units 3 and 4 is effective April 28, 2017.

ADDRESSES: Please refer to Docket ID NRC–2008–0252 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–2008–0252. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this document (if that document is available in ADAMS) is provided the first time that a document is referenced.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Chandu Patel, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3025; email: *Chandu.Patel@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Licensee Notification of Completion of ITAAC

Southern Nuclear Operating Company, Inc. (SNC), Georgia Power Company, Oglethorpe Power Corporation, MEAG Power SPVM, LLC., MEAG Power SPVJ, LLC., MEAG Power SPVP, LLC., and the City of Dalton, Georgia, (hereafter called the licensee) has submitted ITAAC closure notifications (ICNs) under title 10 of the *Code of Federal Regulations* (10 CFR) 52.99(c)(1), informing the NRC that the licensee has successfully performed the required inspections, tests, and analyses, and that the acceptance criteria are met for:

VEGP Unit 3 ITAAC

2.1.01.07.iii (10), 2.1.02.08d.iv (35), 2.1.03.02c (71), and 2.2.03.08c.xi (196)

VEGP Unit 4 ITAAC

2.1.01.07.iii (10), 2.1.02.08d.iv (35), and 2.2.03.08c.xi (196)

The ITAAC for VEGP Unit 3 are in Appendix C of the VEGP Unit 3 combined license (ADAMS Accession No. ML14100A106). The ITAAC for VEGP Unit 4 are in Appendix C of VEGP Unit 4 combined license (ADAMS Accession No. ML14100A135).

II. NRC Staff Determination of Completion of ITAAC

The NRC staff has determined that the specified inspections, tests, and analyses have been successfully completed, and that the specified acceptance criteria are met. The documentation of the NRC staff's determination is in the ITAAC Closure Verification Evaluation Form (VEF) for each ITAAC. The VEF is a form that represents the NRC staff's structured process for reviewing ICNs. Each ICN presents a narrative description of how the ITAAC was completed. The NRC's ICN review process involves a determination on whether, among other things: (1) Each ICN provides sufficient information, including a summary of the methodology used to perform the ITAAC, to demonstrate that the inspections, tests, and analyses have been successfully completed; (2) each ICN provides sufficient information to demonstrate that the acceptance criteria of the ITAAC are met; and (3) any NRC inspections for the ITAAC have been completed and any ITAAC findings associated with that ITAAC have been closed.

The NRC staff's determination of the successful completion of these ITAAC is based on information available at this time and is subject to the licensee's ability to maintain the condition that the acceptance criteria are met. If the staff receives new information that suggests the staff's determination on any of these ITAAC is incorrect, then the staff will determine whether to reopen that ITAAC (including withdrawing the staff's determination on that ITAAC). The NRC staff's determination will be used to support a subsequent finding, pursuant to 10 CFR 52.103(g), at the end of construction that all acceptance criteria in the combined license are met. The ITAAC closure process is not finalized for these ITAAC until the NRC makes an affirmative finding under 10 CFR 52.103(g). Any future updates to the status of these ITAAC will be reflected on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/oversight/itaac.html.*

This notice fulfills the staff's obligations under 10 CFR 52.99(e)(1) to publish a notice in the **Federal Register** of the NRC staff's determination of the successful completion of inspections, tests and analyses.

Vogtle Electric Generating Plant Unit 3, Docket No. 5200025

A complete list of the review status for VEGP Unit 3 ITAAC, including the submission date and ADAMS Accession Number for each ICN received, the ADAMS Accession Number for each VEF, and the ADAMS Accession Numbers for the inspection reports associated with these specific ITAAC, can be found on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/new-licensing-files/vog3-icnsr.pdf*

Vogtle Electric Generating Plant Unit 4, Docket No. 5200026

A complete list of the review status for VEGP Unit 4 ITAAC, including the submission date and ADAMS Accession Number for each ICN received, the ADAMS Accession Number for each VEF, and the ADAMS Accession Numbers for the inspection reports associated with these specific ITAAC, can be found on the NRC's Web site at *http://www.nrc.gov/reactors/new-reactors/new-licensing-files/vog4-icnsr.pdf.*

Dated at Rockville, Maryland, this 17th day of April 2017.

For the Nuclear Regulatory Commission.

Jennifer Dixon-Herrity,

Chief, Licensing Branch 4, Division of New Reactor Licensing, Office of New Reactors.

[FR Doc. 2017–08616 Filed 4–27–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–275 and 50–323; NRC–2016–0080]

Pacific Gas and Electric Company

AGENCY: Nuclear Regulatory Commission.

ACTION: Director's decision under 10 CFR 2.206; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued a director's decision with regard to a Petition to Intervene and Request for Hearing concerning Diablo Canyon Power Plant (DCPP) dated August 26, 2014, filed by Friends of the Earth (FOE or petitioner), asserting, in part, its concerns about DCPP's operational safety and ability to safely shut down in the event of a nearby earthquake. The petitioner's requests and the director's decision are included in the **SUPPLEMENTARY INFORMATION** section of this document.

ADDRESSES: Please refer to Docket ID NRC–2016–0080 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–2016–0080. 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.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the ''Availability of Documents'' section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Margaret Watford, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1233, email: *Margaret.Watford@nrc.gov.*

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has issued a director's decision on a Petition to Intervene and Request for Hearing, filed by the FOE on August 26, 2014, which the Commission referred to the NRC's EDO for consideration under the regulations of section 2.206 of title 10 of the *Code of Federal Regulations* (10 CFR) in Commission Memorandum and Order (CLl–15–14) dated May 21, 2015. The EDO then referred these concerns to the NRC's Office of Nuclear Reactor Regulation for consideration under 10 CFR 2.206. The petition was supplemented by letters dated September 30, 2015, and February 8, 2016.

The petitioner requested that the NRC take enforcement actions to ensure that DCPP can operate safely and demonstrate its ability to safely shut down in the event of an earthquake

caused by nearby faults. As the basis of the request, the petitioner states that the ''NRC staff's determination that the new seismic information, including the Shoreline earthquake and its effect on the San Luis Bay and Los Osos faults, is a lesser-included case within the Hosgri earthquake is insufficient to insure that Diablo Canyon is operating safely with an adequate margin of safety.''

On two occasions, the NRC offered FOE opportunities to address the Petition Review Board (PRB), which was established to review FOE's enforcement concerns. In response, on September 30, 2015, and February 8, 2016, FOE provided written submissions to the PRB in lieu of addressing the PRB in person or by telephone. The NRC staff considered these submittals during its evaluation.

The NRC sent a copy of the proposed director's decision to the petitioner and the Pacific Gas and Electric Company (the licensee) for comment on February 28, 2017. The petitioner and the licensee were asked to provide comments by March 16, 2017, on any part of the proposed director's decision that was considered to be erroneous or any issues in the petition that were not addressed. The NRC staff did not receive any comments on the proposed director's decision.

The Director of the Office of Nuclear Reactor Regulation has determined that the request to take enforcement actions to ensure that DCPP can operate safely and demonstrate its ability to safely shut down in the event of an earthquake caused by nearby faults be denied. The reasons for this decision are explained in the director's decision DD–17–02 pursuant to section 2.206 of 10 CFR of the Commission's regulations.

The NRC will file a copy of the director's decision with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206. As provided by this regulation, the director's decision will constitute the final action of the Commission 25 days after the date of the decision unless the Commission, on its own motion, institutes a review of the director's decision in that time.

Availability of Documents

The documents identified in the following table are available for public inspection through the NRC's ADAMS.

Title	Date	ADAMS Accession No.
SRM–M150521A–2—Final Director's Decision Re: Friends of the Earth 2.206 Petition Based on Commission Memorandum and Order CLI–15–14 (CAC Nos. MF6443 and MF6444).	4/21/2017	ML17090A182
Petition to Intervene and Request for Hearing By Friends of the Earth	8/26/2014	ML14254A231
Commission Memorandum and Order CLI–15–14	5/21/2015	ML15141A084
SRM–M150521A–2/CLI–15–14—E-mail and Letter to 2.206 Panel, Request Pursuant to 10 CFR 2.206 for Suspension of Operations and Enforcement of Nuclear Regulatory Commission Regulations to Ensure Seismic Safety of Diablo Canyon Power Plant.	9/30/2015	ML15274A054
Friends of the Earth, E-mail, Supplemental Information Regarding Request Pursuant to 10 CFR 2.206 for Suspension of Operations and Enforcement of Nuclear Regulatory Commission Regulations to Ensure Seismic Safety of Diablo Canyon Power Plant.	2/8/2016	ML16040A221
SRM–M150521A–2, Petitioner Letter Re: Friends of the Earth 2.206 Petition Based on Commission Memorandum and Order CLI–15–14 (CAC Nos. MF6443 and MF6444).	2/28/2017	ML17011A205
SRM–M150521A–2—Licensee Letter Re: Friends of the Earth 2.206 Petition Based on Commission Memorandum and Order CLI–15–14 (CAC Nos. MF6443 and MF6444).	2/28/2017	ML17011A206

Dated at Rockville, Maryland, this 21st day of April 2017.

For the Nuclear Regulatory Commission.

William M. Dean,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 2017–08609 Filed 4–27–17; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on NuScale; Notice of Meeting

The ACRS Subcommittee on NuScale will hold a meeting on May 3, 2017, at 11545 Rockville Pike, Room T–2B3, Rockville, Maryland 20852.

The meeting will be open to public attendance with the exception of portions that may be closed to protect information that is proprietary pursuant to 5 U.S.C. 552b(c)(4). The agenda for the subject meeting shall be as follows:

Wednesday, May 3, 2017—2:00 p.m. Until 5:00 p.m.

The Subcommittee will hear a briefing on the NRC staff's NuScale Safety Focused Review approach. The Subcommittee will hear presentations by and hold discussions with the NRC staff and other interested persons regarding this matter. The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Michael Snodderly (Telephone 301–415–2241 or Email: *Michael.Snodderly@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 17, 2016, (81 FR 71543).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs*. Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in a major inconvenience.

If attending this meeting, please enter through the One White Flint North Building, 11555 Rockville Pike, Rockville, Maryland. After registering with Security, please contact Mr. Theron Brown (Telephone 240–888–9835) to be escorted to the meeting room.

Dated: April 4, 2017.

Mark L. Banks,

Chief, Technical Support Branch, Advisory Committee on Reactor Safeguards.

[FR Doc. 2017–08607 Filed 4–27–17; 8:45 am]

BILLING CODE 7590–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before May 30, 2017.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB approval number and should be sent via email to: *oira_submission@omb.eop.gov* or fax to: 202–395–3086. Attention: Desk Officer for Peace Corps.

FOR FURTHER INFORMATION CONTACT: Denora Miller, FOIA/Privacy Act Officer, Peace Corps, 1111 20th Street NW., Washington, DC 20526, (202) 692–1236, or email at *pcfr@peacecorps.gov.*

SUPPLEMENTARY INFORMATION:

Title: Global Health Service Peace Corps Staff Reference form.

OMB Control Number: 0420–0548.

Type of Request: New.

Affected Public: Individuals.

Respondents Obligation to Reply: Voluntary.

Burden to the Public:

Estimated burden (hours) of the collection of information:

a. *Number of interviewed applicants:* 120.

b. *Number of references required per interviwed applicant:* ** 2.

c. *Estimated number of reference forms received:* 240.

d. *Frequency of response:* One time.

e. *Completion time:* 10 minutes.

f. *Annual burden hours:* 40.

** Reference information is collected only if an applicant is contacted for an interview. The estimated number of applicants interviewed is 120 based on the first three years of the GHSP program.

General Description of Collection: Peace Corps Response uses the staff, personal and professional reference forms to learn from someone who knows the applicant and his or her background whether the applicant possesses the necessary characteristics and skills to serve as a Global Health Service Partnership Volunteer.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on April 25, 2017.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2017–08636 Filed 4–27–17; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request; Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

DATES: Submit comments on or before May 30, 2017.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB approval number and should be sent via email to: *oira_submission@omb.eop.gov* or fax to: 202–395–3086. Attention: Desk Officer for Peace Corps.

FOR FURTHER INFORMATION CONTACT: Denora Miller, FOIA/Privacy Act Officer, Peace Corps, 1111 20th Street NW., Washington, DC 20526, (202) 692–1236, or email at *pcfr@peacecorps.gov.*

ADDRESSES: Comments should be addressed to Denora Miller, FOIA/Privacy Act Officer. Denora Miller can be contacted by telephone at 202–692–1236 or email at *pcfr@peacecorps.gov.* Email comments must be made in text and not in attachments.

FOR FURTHER INFORMATION CONTACT: Denora Miller at Peace Corps address above.

SUPPLEMENTARY INFORMATION:

Title: Global Health Service Application.

OMB Control Number: 0420–0547.

Type of Request: New.

Affected Public: Individuals.

Respondents Obligation to Reply: Voluntary.

Respondents: Potential Volunteers.

Burden to the Public:

Estimated burden (hours) of the collection of information:

a. *Number of respondents:* 200.

b. *Frequency of response:* One time.

c. *Completion time:* 60 minutes.

d. *Annual burden hours:* 200 hours.

General Description of Collection: The Global Health Service Partnership Application (''the Application'') is necessary to recruit qualified volunteers to serve in Peace Corps Response, as Global Health Service Partnership Volunteers to build institutional capacity and help strengthen the quality of medical and nursing education. Applicants are selected based on their qualifications for a specific Volunteer assignment.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on April 25, 2017.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2017–08635 Filed 4–27–17; 8:45 am]

BILLING CODE 6051–01–P

PEACE CORPS

Information Collection Request Submission for OMB Review

AGENCY: Peace Corps.

ACTION: 30-Day notice and request for comments.

SUMMARY: The Peace Corps will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval. The purpose of this notice is to allow 30 days for public comment in the **Federal Register** preceding submission to OMB. We are conducting this process in accordance with the Paperwork Reduction Act of 1995.

DATES: Submit comments on or before May 30, 2017.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB approval number and should be sent via email to: *oira_submission@omb.eop.gov* or fax to: 202–395–3086. Attention: Desk Officer for Peace Corps.

FOR FURTHER INFORMATION CONTACT: Denora Miller, FOIA/Privacy Act Officer, Peace Corps, 1111 20th Street NW., Washington, DC 20526, (202) 692–1236, or email at *pcfr@peacecorps.gov.*

SUPPLEMENTARY INFORMATION:

Title: Onboarding.

OMB Control Number: 0420–xxxx.

Type of Request: New.

Affected Public: Individuals.

Respondents Obligation to Reply: Voluntary.

Respondents: Peace Corps Volunteers.

Burden to the Public:

Estimated burden (hours) of the collection of information:

a. *Number of respondents:* 5,000.

b. *Frequency of response:* One time.

c. *Completion time:* 60 minutes.

d. *Annual burden hours:* 5,000 hours.

General Description of Collection: The Peace Corps uses the Onboarding Portal to collect essential administrative information from invitees for use during volunteer service, including information such as emergency contacts, legal history updates, direct deposit instructions, and life insurance designations. The information is used by the Peace Corps to establish specific services for invitees for the purposes of supporting the volunteer during service.

Request for Comment: Peace Corps invites comments on whether the proposed collections of information are necessary for proper performance of the functions of the Peace Corps, including whether the information will have practical use; the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the information to be collected; and, ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This notice is issued in Washington, DC, on April 25, 2017.

Denora Miller,

FOIA/Privacy Act Officer, Management.

[FR Doc. 2017–08634 Filed 4–27–17; 8:45 am]

BILLING CODE 6051–01–P

PENSION BENEFIT GUARANTY CORPORATION

Proposed Submission of Information Collection for OMB Review; Comment Request; Mergers and Transfers Between Multiemployer Plans

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of intent to request extension of OMB approval of information collection.

SUMMARY: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Mergers and Transfers Between Multiemployer Plans. This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

DATES: Comments must be submitted on or before June 27, 2017.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Email: paperwork.comments@pbgc.gov.*
- *Mail or Hand Delivery:* Regulatory Affairs Group, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026.

Comments received, including personal information provided, will be posted to *www.pbgc.gov.*

Copies of the collection of information may also be obtained without charge by writing to Disclosure Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005–4026, or calling 202–326–4040 during normal business hours. (TTY and TDD users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4040.)

FOR FURTHER INFORMATION CONTACT: Hilary Duke (*duke.hilary@pbgc.gov*), Attorney, Regulatory Affairs Group, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington DC 20005–4026; 202–326–4400, extension 3839. (TTY and TDD users may call the Federal relay service toll-free at 800–877–8339 and ask to be connected to 202–326–4400, extension 3839.)

SUPPLEMENTARY INFORMATION: The Pension Benefit Guaranty Corporation (PBGC) intends to request that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of a collection of information contained in its regulation on Mergers and Transfers Between Multiemployer Plans (29 CFR part 4231) (OMB control number 1212–0022; expires July 31, 2017). This notice informs the public of PBGC's intent and solicits public comment on the collection of information.

Section 4231(a) and (b) of the Employee Retirement Income Security Act of 1974 (ERISA) requires plans that are involved in a merger or transfer to give PBGC 120 days' notice of the transaction and provides that if PBGC determines that specified requirements are satisfied, the transaction will be deemed not to be in violation of ERISA section 406(a) or (b)(2) (dealing with prohibited transactions).

PBGC's regulation on Mergers and Transfers Between Multiemployer Plans (29 CFR part 4231) sets forth the procedures for giving notice of a merger or transfer under section 4231 and for requesting a determination that a transaction complies with section 4231.

PBGC uses information submitted by plan sponsors under the regulation to determine whether mergers and transfers conform to the requirements of ERISA section 4231 and the regulation.

The collection of information under the regulation has been approved by OMB under control number 1212–0022 (expires July 31, 2017). PBGC intends to request that OMB extend its approval for another three years. An agency may

not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

PBGC estimates that there are 14 transactions each year for which plan sponsors submit notices and approval requests under this regulation. The estimated annual burden of the collection of information is 9.50 hours and $42,800.

PBGC is soliciting public comments to—

- 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 methodologies and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Issued in Washington, DC.

Deborah Chase Murphy,

Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2017–08514 Filed 4–27–17; 8:45 am]

BILLING CODE P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–80514; File No. SR–IEX–2017–11]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing of Proposed Rule Change To Modify the Manner in Which the Exchange Opens Trading for Non-IEX-Listed Securities

April 24, 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 April 13, 2017, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the 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''), and Rule 19b–4 thereunder, Investors Exchange LLC (''IEX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (''Commission'') proposed rule changes to (i) amend Rule 11.231 to modify the manner in which the Exchange opens trading for non-IEX-listed securities beginning at the start of Regular Market Hours and retitle it ''Regular Market Session Opening Process for Non-IEX-Listed Securities''; and (ii) amend Rules 11.190 and 11.220 to specify the order types eligible to participate in the proposed Regular Market Session Opening Process for non-IEX listed securities (''Opening Process'') described in proposed Rule 11.231 and priority thereof.

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 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The purpose of the proposed rule change is to (i) amend Rule 11.231 to modify the manner in which the Exchange opens trading for non-IEX-listed securities beginning at the start of Regular Market Hours and retitle it ''Regular Market Session Opening Process for Non-IEX-Listed Securities''; (ii) amend Rule 11.190(a)(2)(E) to allow market orders with a time-in-force of DAY to be entered in the Pre-Market Session for queuing and participation in the Regular Market Session Opening Process for non-IEX-listed securities (''Opening Process'') described in proposed Rule 11.231; (iii) amend Rule 11.220(a)(2) regarding the priority of orders eligible to execute in the proposed Opening Process; and (iv) amend Rule 11.190(b)(11) to clarify that orders with a Minimum Quantity as defined in Rule 11.190(b)(11) (''Minimum Quantity orders'') are not eligible to participate in the Opening Process pursuant to proposed Rule 11.231.

Currently, the Exchange begins accepting limit orders with a time-in-force of IOC, FOK, SYS, and GTT [3] for non-IEX-listed securities for trading at the beginning of the Pre-Market Session and any such orders received by the Exchange are immediately eligible for execution in the Pre-Market Session. In addition, limit orders with a time-in-force of DAY or GTX [4] and pegged orders with a time-in-force of DAY that are entered during the Pre-Market Session are queued in the time sequence of their receipt by the System pursuant to Rule 11.220(a)(2), until the start of the Regular Market Session, or until the order is canceled by the User. Any such queued orders that are in the System at the beginning of Regular Market Hours are released to the Order Book as incoming orders in their relative time priority pursuant to Rule 11.220(a)(2) and are immediately eligible for trading in the Regular Market Session, subject to the User's instructions and market conditions. Pursuant to IEX Rule 11.190(a)(2)(E), market orders may only be submitted in the Regular Market Session, and are rejected by the System in the Pre-Market Session and Post-Market Session. Furthermore, under paragraph (iii) of IEX Rule 11.190(a)(2)(E), market orders marked DAY, by default, are rejected. When elected by the User, market orders marked DAY submitted by that User are accepted and eligible to trade or route during the Regular Market Session. Market orders marked DAY are treated by the System as having a TIF of IOC.[5]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] See Rules 11.190(c)(1), 11.190(c)(2), 11.190(c)(5), and 11.190(c)(6), defining the time-in-force of IOC, FOK, SYS, and GTT, respectively.

[4] See Rules 11.190(c)(3), 11.190(c)(4), defining a time-in-force of DAY and GTX, respectively.

[5] Members that would like to enter market orders with time-in-force of DAY and have the Exchange accept such orders are required to have authorized

Continued

Description of Proposed Rule Change

The Exchange proposes to amend Rule 11.231 to offer an enhanced opening process for non-IEX-listed securities. Specifically, as proposed, the Exchange will attempt to perform the Opening Process in each non-IEX-listed security pursuant to which all eligible interest resting on the Order Book in the Pre-Market Session available for continuous trading (*i.e.,* orders on the ''Continuous Book'') or orders queued for execution in the Regular Market Session (*i.e.,* orders on the ''Cross Book'') will be executed at a single price. As proposed, the Opening Process offers Users an opportunity to participate in an electronic price discovery mechanism that efficiently matches all eligible buy and sell orders in each non-IEX-listed security queued for the Opening Process along with all eligible orders resting on the Continuous Book from the Pre-Market Session at a single price. The Opening Process is designed to efficiently maximize the number of shares executed at a single price that is reflective of the broader market for the security, as described more fully below.

As proposed, prior to the beginning of Regular Market Hours, Users who wish to participate in the Opening Process may enter limit, market, and pegged orders designated with a time-in-force of DAY and limit orders designated with a time-in-force of GTX, which shall queue in the System and are eligible for execution in the Opening Process (orders on the Cross Book); interest resting on the Order Book in the Pre-Market Session available for continuous trading (*i.e.,* orders on the Continuous Book) are also eligible for execution in the Opening Process (collectively, ''Cross Eligible Orders''). Minimum Quantity orders are not eligible for execution in the Opening Process, and are therefore not Cross Eligible Orders. Accordingly, the Exchange is proposing to amend Rule 11.190(a)(2)(E) to extend the queuing functionality to market orders with a time-in-force of DAY that are entered during the Pre-Market Session and are not designated to route pursuant to Rule 11.230(c), allowing such orders to queue in the System for participation in the Opening Process.[6] Orders with a time-in-force of IOC or FOK do not rest on the Order Book and are therefore ineligible to participate in the Opening Process. In addition, the Exchange is proposing to make a minor conforming change to the language used in reference to LULD Price Bands in Rule 11.190(a)(1)(2) [sic] in order to conform the reference to the language used throughout the Exchange's rules.

As proposed, orders on the Continuous Book and orders on the Cross Book (collectively, the Order Book) shall be ranked and maintained for the Opening Process pursuant to Rule 11.220(a)(2), as follows:

- Midpoint peg orders, as defined in IEX Rule 11.190(b)(9), on the Cross Book are ranked and eligible for execution in the Opening Process at the less aggressive of the Midpoint Price or the order's limit price, if any.
- Primary peg orders, as defined in IEX Rule 11.190(b)(8), on the Cross Book are ranked and eligible for execution in the Opening Process at the less aggressive of one (1) MPV below (above) the NBB (NBO) for buy (sell) orders or the order's limit price, if any, but may exercise price discretion up (down) to the Opening Match Price, subject to the less aggressive of the NBB (NBO) or the order's limit price, if any, except during periods of quote instability, as defined in IEX Rule 11.190(g). When exercising price discretion, primary peg orders are ranked behind any non-displayed interest at the Opening Match Price for the duration of the Opening Process. If multiple primary peg orders are exercising price discretion during the Opening Process, they maintain their relative time priority at the Opening Match Price.
- Discretionary Peg orders, as defined in IEX Rule 11.190(b)(10), on the Cross Book are ranked and eligible for execution in the Opening Process at the less aggressive of the NBB (NBO) for buy (sell) orders or the order's limit price, if any, but may exercise price discretion up (down) to the Opening Match Price, subject to the less aggressive of the Midpoint Price or the order's limit price, if any, except during periods of quote instability, as defined in IEX Rule 11.190(g). When exercising price discretion, Discretionary Peg orders are ranked behind any non-displayed interest at the Opening Match Price for the duration of the Opening Process. If multiple Discretionary Peg orders are exercising price discretion during the Opening Process, they maintain their relative time priority at the Opening Match Price.
- Limit orders on the Cross Book are ranked and eligible for execution in the Opening Process at their limit price.
- Non-displayed limit orders and non-displayed portions of reserve orders on the Continuous Book are ranked and eligible for execution in the Opening Process at the less aggressive of the Midpoint Price or the order's limit price.
- Displayed limit orders on the Continuous Book are ranked and eligible for execution in the Opening Process at their resting price.

As noted above, orders shall be ranked and prioritized for the Opening Process in price—display—time priority pursuant to proposed Rule 11.220(a)(2). Specifically, the best priced Cross Eligible Order (the highest priced resting order to buy or the lowest priced resting order to sell) has priority over all other orders to buy (or orders to sell) in all cases. Market orders have precedence over limit orders. Cross Eligible Orders resting on the Continuous Book are ranked by the price at which they are resting on the Continuous Book and Cross Eligible Orders resting on the Cross Book are ranked by the limit price defined by the User, if any, except in the case of pegged orders, which are ranked by their current book price (in each case, the order's ''resting price''). Equally priced Cross Eligible Orders are ranked by display priority, *i.e.,* displayed orders and displayed portions of Cross Eligible Orders will have precedence over non-displayed orders and non-displayed portions of Cross Eligible Orders at a given price. Equally priced Cross Eligible Orders with the same display priority are ranked in time priority, *i.e.,* where Cross Eligible Orders to buy (or sell) are ranked at the same price with the same display priority, the oldest order at such price and display shall have precedence at that price and display. Orders are ranked by the time at which they are posted to the Order Book at a given price, the first to be posted at a given price being the oldest. Cross Eligible Orders maintain their time priority once booked until:

- In the case of an order on the Cross Book, the order is: (i) Incremented by the User, (ii) re-priced by the User, (iii) the Minimum Quantity instruction is removed from an order by the User, and therefore becomes a Cross Eligible Order, or (iv) a pegged order is re-priced by the System in response to changes in the NBBO, at which time the order will receive a new timestamp. Pursuant to IEX Rule 11.231(a)(1)(ii) and (iii), respectively, when exercising price discretion, primary peg and Discretionary Peg orders maintain time priority at their resting price, however they are prioritized behind any non-displayed interest at the Opening Match

personnel contact IEX Market Operation (*marketops@iextrading.com*) in writing requesting such port setting changes, and must specifically identify the order entry sessions to which such port setting will apply.

[6] Orders canceled before the Opening Process will not participate in the Opening Process. Market orders with a time-in-force of DAY that are entered during the Pre-Market Session and *are* designated to route pursuant to Rule 11.230(c) will be rejected upon entry.

Price for the duration of the Opening Process.

• In the case of an order on the Continuous Book, any one of the events specified in IEX Rule 11.220(a)(1)(C) occurs to an order, at which time the order will receive a new timestamp.

Under proposed Rule 11.231(b), beginning at the start of Regular Market Hours, Cross Eligible Orders that are eligible to trade at the Opening Match Price (as described below) will be processed in accordance with price—display—time priority pursuant to proposed Rule 11.220(a)(2). First, to the extent there is contra side interest eligible to trade at the Opening Match Price, market orders will be executed at the Opening Match Price in time priority. After the execution of all market orders, the remaining Cross Eligible Orders priced more aggressively than the Opening Match Price will be executed in price—display—time priority at the Opening Match Price. All remaining Cross Eligible Orders priced equal to the Opening Match Price will execute in display—time priority at the Opening Match Price. Executions will occur until there is no remaining volume or there is an imbalance of orders (*i.e.,* there are no remaining eligible shares to buy (sell), while eligible shares to sell (buy) remain unexecuted) (the process described above, collectively, being the ''Opening Match''). AGID modifiers, as defined in Rule 11.190(e), will not be supported for executions in the Opening Match, but will be enforced on all unexecuted shares released to the Order Book following the Opening Match.

An imbalance of Cross Eligible Orders on the buy side or sell side may result in orders that are not executed in whole or in part. Unexecuted Cross Eligible Orders to buy (sell) that are priced at or above (below) the Cross Price Constraint (but remained unexecuted due to an imbalance of Cross Eligible Orders) will price slide pursuant to IEX Rule 11.190(h) and all remaining unexecuted Cross Eligible Orders, along with any orders that were either ineligible to participate in the Opening Process or too passive to be executed in the Opening Process, will be released to the Order Book for continuous trading or canceled in accordance with the terms of the order. Routable orders that are released to the Order Book will be routed in accordance with IEX Rule 11.230(c)(3) (Re-Sweep Behavior), subject to the order's instructions.

Proposed Rule 11.231(c)(1) sets forth proposed definitions applicable to the Opening Process. As proposed:

• The term ''Away Protected NBB'' or ''Away Protected NBO'' shall mean the national best bid or offer, respectively, that is a Protected Quotation and not a quotation of the Exchange.

• The term ''Away Protected Bid'' or ''Away Protected Offer'' shall mean a Protected Bid or Protected Offer, respectively, that is not a quotation of the Exchange.

• The term ''Cross Price Constraint'' shall mean, collectively, the upper and lower threshold prices within which the Opening Match must occur, inclusive of the boundaries. During a crossed market, if the upper threshold price is below the lower threshold price when performing the Opening Process, no Opening Match will occur and orders eligible to post on the Order Book will price slide in accordance with the price sliding process, pursuant to IEX Rule 11.190(h), and the security will open for trading on IEX in accordance with prevailing market session rules.

○ The upper threshold price of the Cross Price Constraint is equal to the price of the Away Protected NBO, except in the event that an Away Protected Bid is crossing an Away Protected Offer, the upper threshold price is equal to the greater of five cents ($0.05) or one half of a percent (0.5%) higher than the lowest Away Protected Offer.

○ The lower threshold price of the Cross Price Constraint is equal to the price of the Away Protected NBB, except in the event that an Away Protected Bid is crossing an Away Protected Offer, the lower threshold price is equal to the greater of five cents ($0.05) or one half of a percent (0.5%) lower than the highest Away Protected Bid.

• The term ''Cross Tie Breaker'' shall mean the price of the most current Order Collar Reference Price pursuant to IEX Rule 11.190(f).[7]

Under proposed Rule 11.231(c)(2), if both an Away Protected Bid and Away Protected Offer exists (*i.e.,* a two-sided market) the price of the Opening Match (''Opening Match Price'') will be the price that maximizes the number of shares of Cross Eligible Orders to be executed. If more than one price exists that maximizes the number of shares of Cross Eligible Orders to be executed, the Opening Match shall occur at the entered price at which shares will remain unexecuted in the match (*i.e.,* the price of the most aggressive unexecuted order). If Cross Eligible Order shares are maximized and left unexecuted at more than one price, the Opening Match shall occur at the price that minimizes the distance from the Cross Tie Breaker (*i.e.,* the price at or higher than the most aggressive unexecuted buy order and at or lower than the most aggressive unexecuted sell order that is closest or equal to the Cross Tie Breaker). Lastly, if the Opening Match Price established pursuant to the procedures above is below (above) the lower (upper) threshold price of the Cross Price Constraint, the Opening Match shall occur at the lower (upper) threshold price of the Cross Price Constraint.

The following examples are designed to illustrate the process for determining the Opening Match Price in a two-sided market, as described above. Each example below assumes the Away Protected NBB is $10.09, the Away Protected NBO is $10.11, and the last trade price that qualified as an Order Collar Reference Price was $10.10:

• *Example 1*

○ The Cross Book includes the following orders:

▪ Limit order to buy 1,500 shares with a limit price of $10.10; and

▪ Limit order to sell 1,000 shares with a limit price of $10.10.

○ Shares are maximized at $10.10; therefore

▪ 1,000 shares would execute at the Opening Match Price of $10.10.

• *Example 2*

○ The Cross Book contains the following orders:

▪ Limit order to buy 1,500 shares with a limit price of $10.10; and

▪ Market order to sell 1,000 shares.

○ Shares are maximized at each price at and between the lower threshold of the Cross Price Constraint (*i.e.,* $10.09) and $10.10;

○ The price at which shares will remain unexecuted in the auction is $10.10;[8] therefore

[7] Rule 11.190(f)(1)(A) defines the Order Collar Reference Price as the most current of: (i) The consolidated last sale price disseminated during the Regular Market Session on the current trade date, (ii) the last trade price disseminated outside of the Regular Market Session by the SIP (Form T, as communicated by the relevant SIP) on the current trade date, which but for the Form T designation would have been considered a valid last sale price, or, (iii) if no such trades exist, the previous official closing price. If no Pre-Market Session trades have occurred that qualify to update the Order Collar Reference Price and the previous official closing price for the security is not available, in the interest of maintaining a fair and orderly market, the Exchange will prevent trading in a security pursuant to Rule 11.190(f)(1)(B) by rejecting orders beginning at the start of the Pre-Market Session, and will not conduct an Opening Match in such security. Accordingly, in such cases, the Opening Process will conclude with IEX opening the Regular Market Session without an Opening Match, and trading will begin upon receipt of the first Order Collar Reference Price for the security.

[8] Note, while shares are maximized at and between the lower threshold of the Cross Price Constraint ($10.09) and $10.10, the *entered* price at which shares will remain unexecuted in the auction

Continued

▪ 1,000 shares would execute at the Opening Match Price of $10.10.

• *Example 3*

○ The Cross Book contains the following orders:

▪ Limit order to buy 2,000 shares with a limit price of $10.11;

▪ Limit order to sell 2,000 shares with a limit price of $10.09.

○ The Continuous Book contains the following orders:

▪ Displayed limit order to buy 500 shares with a limit price of $10.09;

▪ Displayed limit order to sell 600 shares with a limit price of $10.11.

○ Shares are maximized at each price at or between $10.09 and $10.11;

○ The range of prices at or between the prices at which shares will remain unexecuted in the auction is $10.09 and $10.11;

○ Because a range of prices exist after evaluating the prior two conditions (*i.e.,* an auction price range), the price closest to the Cross Tie Breaker (*i.e.,* the last trade price that qualified as an Order Collar Reference Price) within the auction price range is $10.10; therefore

▪ 2,000 shares would execute at the Opening Match Price of $10.10.

• *Example 4*

○ The Cross Book contains the following orders:

▪ Limit order to buy 2,000 shares with a limit price of $10.08;

▪ Limit order to sell 2,000 shares with a limit price of $10.08.

○ The Continuous Book contains the following orders:

▪ Displayed limit order to buy 500 shares with a limit price of $10.09;

▪ Displayed limit order to sell 600 shares with a limit price of $10.11.

○ Shares are maximized at $10.08, however $10.08 is below the lower threshold of the Cross Price Constraint (*i.e.,* $10.09); therefore

▪ 500 shares would execute at the Opening Match Price of $10.09.

The following examples are designed to illustrate the process for determining the Opening Match Price and the proposed execution priority including non-displayed orders on the Cross Book in two-sided market, as described above. Each example below assumes the Away Protected NBB is $20.19, the Away Protected NBO is $20.21, and the last trade price that qualified as an Order Collar Reference Price was $20.20:

• *Example 1*

○ The Cross Book includes the following orders:

▪ Midpoint Peg order to buy 2,500 shares with a resting price of $20.20.

▪ Limit order to buy 500 shares with a limit price of $20.18; and

▪ Limit order to sell 2,000 shares with a limit price of $20.18.

○ For purposes of determining the Opening Match Price, the Midpoint Peg order is priced at its resting price ($20.20);

○ Accordingly, shares are maximized between $20.18 and $20.20, and the price at which shares are left unexecuted within such range, is $20.20; therefore

▪ 2,000 shares would execute at the Opening Match Price of $20.20;

• The Midpoint Peg buy order would receive an execution of 2,000 shares and the remaining 500 shares remain booked at the midpoint of the NBBO;

• The limit sell order would receive an execution of 2,000 shares, and thus be fully filled; and

• The limit buy order would not receive an execution, because the limit sell order is fully filled after matching with the Midpoint Peg buy order with superior priority. The entire limit buy order is booked at the $20.18.

• *Example 2*

○ The Cross Book includes the following orders:

▪ Primary Peg order to buy 2,500 shares with a resting price of $20.18, and limit price of $20.20;

▪ Limit order to buy 500 shares with a limit price of $20.19; and

▪ Displayed limit order to sell 2,000 shares with a limit price of 20.19.

○ For purposes of determining the Opening Match Price, the Primary Peg order is priced at its resting price ($20.18); the Primary Peg order is eligible exercise price discretion up to the Opening Match Price, so long as the match price is at or below the less aggressive of the NBB or the order's limit price;

○ Accordingly, shares are maximized at $20.19; therefore

▪ 2,000 shares would execute at the Opening Match Price of $20.19;

• The limit buy order would receive an execution of 500 shares;

• Assuming IEX has determined the quote to be stable pursuant to IEX Rule 11.190(g), the Primary Peg buy order would exercise discretion up to the Opening Match Price and receive an execution of 1,500 shares; the remaining 1,000 shares remain booked at $20.18; and

• Assuming IEX has determined the quote to be stable pursuant to IEX Rule 11.190(g), the limit sell order would receive an execution of 2,000 shares. If IEX has determined the quote to be unstable pursuant to IEX Rule 11.190(g), the limit sell order would receive an execution of 500 shares and the remaining 1,500 shares would post, in accordance with the display-price sliding behavior, 1 MPV above the NBB at $20.20.

• *Example 3*

○ The Cross Book includes the following orders:

▪ Midpoint Peg order to buy 2,500 shares with a resting price of $20.20.

▪ Displayed limit order to buy 500 shares with a limit price of $20.20; and

▪ Limit order to sell 2,000 shares with a limit price of $20.20.

○ For purposes of determining the Opening Match Price, the Midpoint Peg order is priced at its resting price ($20.20);

○ Accordingly, shares are maximized at $20.20; therefore

▪ 2,000 shares would execute at the Opening Match Price of $20.20;

• The limit buy order would receive an execution of 500 shares;

• The Midpoint Peg buy order would receive an execution of 1,500 shares; and

• The limit sell order would receive an execution of 2,000 shares.

• *Example 4*

○ The Cross Book includes the following orders:

▪ Discretionary Peg order to buy 2,500 shares with a resting price of $20.19, and limit price of $20.21;

▪ Limit order to buy 500 shares with a limit price of $20.20; and

▪ Limit order to sell 2,000 shares with a limit price of $20.20.

○ For purposes of determining the Opening Match Price, the Discretionary Peg order is priced at its resting price ($20.19); the Discretionary Peg order is eligible exercise price discretion up to the Opening Match Price, so long as the match price is at or below the less aggressive of the midpoint of the NBBO or the order's limit price.

○ Accordingly, shares are maximized at $20.20; therefore

▪ 2,000 shares would execute at the Opening Match Price of $20.20;

• The limit buy order would receive an execution of 500 shares;

• Assuming IEX has determined the quote to be stable pursuant to IEX Rule 11.190(g), the Discretionary Peg buy order would exercise discretion up to the Opening Match Price and receive an execution of 1,500 shares; and

• Assuming IEX has determined the quote to be stable pursuant to IEX Rule 11.190(g), the limit sell order would receive an execution of 2,000 shares. If IEX has determined the quote to be unstable pursuant to IEX Rule 11.190(g), the limit sell order would receive an execution of 500 shares and the

is $10.10, as $10.10 is the resting price of the most aggressive order where shares remain unexecuted.

remaining 1,500 shares would post at $20.20.

Under proposed Rule 11.231(c)(3), if there is a lack of an Away Protected Bid and/or Away Protected Offer (*i.e.,* a one-sided, or zero-sided market) the Opening Match Price will be the price of the Cross Tie Breaker. If the price of the Cross Tie Breaker is below (above) the lower (upper) threshold price of the Cross Price Constraint, the Opening Match shall occur at the lower (upper) threshold price of the Cross Price Constraint.[9]

The following examples are designed to illustrate the process for determining the Opening Match Price in a one-sided or zero-sided market as described above. Each example below assumes the last trade price that qualified as an Order Collar Reference Price was $10.10:

- *Example 1*
  - ○ Away Protected NBB is $10.09;
  - ○ The Cross Book includes the following orders:
    - ▪ Limit order to buy 1,500 shares with a limit price of $10.11; and
    - ▪ Limit order to sell 1,000 shares with a limit price of $10.09.
  - ○ The Cross Tie Breaker is $10.10 and such price is above the lower threshold of the Cross Price Constraint (*i.e.,* $10.09);[10] therefore
    - ▪ 1,000 shares would execute at the Opening Match Price of $10.10.
- *Example 2*
  - ○ Away Protected NBB is $10.11;
  - ○ The Cross Book includes the following orders:
    - ▪ Limit order to buy 1,500 shares with a limit price of $10.11; and
    - ▪ Limit order to sell 1,000 shares with a limit price of $10.09.
  - ○ The Cross Tie Breaker is $10.10 however such price is below the lower threshold of the Cross Price Constraint (*i.e.,* $10.11); therefore
    - ▪ 1,000 shares would execute at the Opening Match Price of $10.11.
- *Example 3*
  - ○ There is neither an Away Protected NBB nor an Away Protected NBO;
  - ○ The Cross Book includes the following orders:
    - ▪ Limit order to buy 1,500 shares with a limit price of $10.11; and
    - ▪ Limit order to sell 1,000 shares with a limit price of $10.09.
  - ○ The Cross Tie Breaker is $10.10;[11] therefore
    - ▪ 1,000 shares would execute at the Opening Match Price of $10.10.

Proposed Rule 11.231(e) provides that if a security is subject to a halt, suspension, or pause in trading during the Pre-Market Session, the Exchange will not accept orders in the security for continuous trading, or for queuing and participation in the Opening Process. Pursuant to IEX Rule 11.271, any order submitted during a halt will be rejected by the System. Any orders resting on the Order Book at the time of a trading halt will not be canceled by the System, and will be unavailable for trading or re-sweep during the trading halt, but will be available for cancelation by the submitting User. Orders that were submitted prior to the halt, suspension, or pause in trading that joined the Cross Book or the Continuous Book will remain on the Cross Book or the Continuous Book unless canceled by the User. If the halt, suspension, or pause remains in effect at the start of the Regular Market Hours, the Opening Process will not occur at the normally scheduled time. Instead, once the security resumes trading, the Exchange will conduct the Opening Process, as described in proposed Rule 11.231(b) and (c), including all Cross Eligible Orders that remain on the Cross Book and the Continuous Book. Following the conclusion of the Opening Process, the Exchange will accept and execute orders as usual in accordance with prevailing market session rules.

In the event of a disruption that prevents the execution of the Opening Process, Rule 11.231(d) provides for Opening Process Contingency Procedures designed to allow for timely and orderly opening of non-IEX-listed securities. As proposed, rather than matching orders at the Opening Match Price as described in Rule 11.231(c), IEX will publicly announce that no Opening Process will occur.[12] All orders on the Order Book will be canceled, and IEX will open the security for trading without an Opening Match.

Lastly, proposed Rule 11.231(f) states that for purposes of Rule 611(b)(3) of Regulation NMS, and section VI(D)(6) of the Plan to Implement a Tick Size Pilot Program, orders executed in the Opening Process shall constitute a single-priced opening transaction by the Exchange and may trade-through or trade-at the price of any other Trading Center's Manual or Protected Quotations. Each of the orders executed in the Opening Process are by definition a single priced opening or re-opening transaction, and therefore meet the letter and spirit of Rule 611(B)(3) of Regulation NMS and section VI(D)(6) of the plan to Implement a Tick Size Pilot Program, consistent with the protection of investors and the public interest.

Implementation

The Exchange plans to implement the proposed changes during the second quarter of 2017 pending completion of necessary technology changes and subject to Commission approval. The Exchange will announce the implementation date of the proposed changes by Trader Alert at least 10 business days in advance of such implementation date and within 90 days of approval of this proposed rule change.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with Section 6(b) of the Act[13] in general, and furthers the objectives of Section 6(b)(5) of the Act,[14] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest. Specifically, the Exchange believes that the proposal is consistent with the protection of investors and the public interest in that the price discovery mechanism utilized to determine the Opening Match Price under proposed Rule 11.231(c) will provide the greatest opportunity to match buy and sell orders at a price that is reflective of market conditions for the security, while also providing for orderly and timely openings of non-IEX-listed securities.

Specifically, the Exchange believes that constraining the Opening Match Price to prices at or between the Away Protected NBB and Away Protected NBO is designed to respect the fact that

[9] In a one-sided market where there is no Away Protected NBB or no Away Protected NBO, the Cross Tie Breaker is compared to the available threshold price of the Cross Price Constraint (*i.e.,* the Opening Match Price will be at or above the lower threshold price, or at or below the upper threshold price of the Cross Price Constraint, as applicable). In a zero-sided market, the Opening Match Price will be the Cross Tie Breaker.

[10] Note, there is no upper threshold price of the Cross Price Constraint because there is no Away Protected NBO, and therefore the Cross Tie Breaker of $10.10 is compared to the available lower threshold price of the Cross Price Constraint ($10.09).

[11] Note, there is neither an upper threshold price nor a lower threshold price of the Cross Price Constraint because there are no away protected quotations.

[12] Note, the Exchange intends to disseminate a System Status Alert to publicly announce that no Opening Process will occur, which automatically publishes an email alert, twitter update, and text message to all persons registered to receive such alerts, as well as publishing to the IEX public Web site. To register for System Status Alerts, visit *https://www.iextrading.com/status/#/.*

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(5).

much of the liquidity seeking execution at the start of Regular Market Hours is aggregated at the primary market center. Therefore, including the quotations of the primary market (along with those of all other protected markets) for purposes of pricing the Opening Match is designed to provide the greatest opportunity to match buy and sell orders at a price that is reflective of the market for the security, in furtherance of the perfection of a free and open market and a national market system, and consistent with the protection of investors and the public interest. The Exchange notes that as proposed, the Cross Price Constraint will not include IEX's protected quotations when determining the upper and lower threshold prices within which the Opening Match must occur, because the inclusion of such quotes may unnecessarily constrain the prices at which the Opening Match may occur, needlessly restricting price discovery in the Opening Process when the Opening Match would maximize shares traded at a price beyond the IEX best bid (offer) but within the Away Protected NBB (NBO). However, shares that comprise protected quotations on IEX would necessarily be included in the Opening Process pursuant to proposed Rule 11.220(a)(2) regarding priority. Accordingly, the Exchange believes that excluding IEX's protected quotations is consistent with the protection of investors and the public interest, in that it is designed to allow for robust price discovery to occur at or within the prices which best reflect the broader market for the security.

The Exchange believes that not supporting AGID modifiers in the Opening Process is consistent with the protection of investors and the public interest because within the context of the Opening Match process, counterparties are not considered; only the aggregate available volume for execution is considered. It is illogical to cancel an order that happens to be allocated an execution against an order entered using the same MPID, because both orders execute at the exact same price to the exact same effect where the orders happen to execute against orders of a different MPID. Furthermore, the Exchange believes that supporting AGID modifiers and including Minimum Quantity orders in the Opening Process would introduce additional technical complexities to the Opening Process, and the Exchange believes providing simplicity in this regard is in the interest of the protection of investors and the public interest.[15]

The Exchange notes that the proposed handling of Minimum Quantity orders in the Opening Process is distinct from the proposed handling of such orders in the Opening Auction for IEX-listed securities pursuant to proposed Rule 11.350(c).[16] Specifically, in the case of an Opening Auction for an IEX-listed security pursuant to proposed Rule 11.350(c)(2)(C), Minimum Quantity orders are eligible for execution in the auction, but the minimum quantity instructions will not be supported, although it will be enforced on all unexecuted shares released for continuous trading following the Opening Auction match. Conversely, for the Opening Process for non-IEX-listed securities, Minimum Quantity orders are not eligible for execution in the Opening Process. The Exchange believes the Opening Process will yield small execution sizes in comparison the size of an Opening Auction. Accordingly, the Exchange does not believe that including Minimum Quantity orders but not supporting the instruction is an effective approach for handling such orders because the Opening Match is likely to result in more executions that are smaller than an order's minimum quantity instruction. Accordingly, the Exchange believes that the proposed functionality regarding Minimum Quantity orders is consistent with the protection of investors and the public interest.

Furthermore, the Exchange believes that the proposed changes to Rule 11.220(a)(2) regarding the priority of orders eligible to execute in the proposed Opening Process is consistent with the protection of investors and the public interest because the proposed Opening Process priority is designed to create continuity between the priority rules applied during continuous trading and in the Opening Process. Specifically, identical to the Pre-Market, Regular Market, and Post Market Sessions, the Exchange is proposing to apply price—display—time priority for purpose of ranking and maintaining orders eligible to execute in the proposed Opening Process. Furthermore, the Exchange notes that the proposed priority for the Opening Process is substantially similar to the priority of the opening processes for non-listed securities on NYSE Arca, Inc. (''NYSE Arca'') and the Nasdaq Stock Market (''Nasdaq'').[17]

The Exchange believes that allowing primary peg, midpoint peg and Discretionary Peg orders to participate in the proposed Opening Process is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system, and protect investors and the public interest. Specifically, as proposed, primary peg, midpoint peg, and Discretionary Peg orders as set forth in Rules 11.190(b)(8), 11.190(b)(9), and 11.190(b)(10), respectively, would be ranked and eligible for execution in the Opening Process at their resting price. As proposed, primary peg and Discretionary Peg orders would have the ability to exercise price discretion to execute at the Opening Match Price. When primary peg and Discretionary Peg orders exercise discretion to execute at the Opening Match Price, such orders are prioritized behind all other non-displayed interest at the Opening Match Price; if multiple orders exercise discretion, they maintain their relative time priority at the Opening Match Price. Primary peg orders may exercise price discretion up (down) to the Opening Match Price, subject to the less aggressive of the NBB (NBO) or the order's limit price, if any, except during periods of quote instability, as defined in IEX Rule 11.190(g). Discretionary Peg orders may exercise price discretion up (down) to the Opening Match Price, subject to the less aggressive of the Midpoint Price or the order's limit price, if any, except during periods of quote instability, as defined in IEX Rule 11.190(g). The Exchange believes that inclusion of such orders is designed to maximize the liquidity available for execution in the Opening Process, thereby facilitating price discovery and a more orderly opening.

As proposed, primary peg, midpoint peg, and Discretionary Peg orders participate in the Opening Process in a manner that is fundamentally substantially similar to the behavior of such orders during continuous trading. Specifically, the manner in which such orders are eligible for execution in the Opening Process are functionally identical to their eligibility for execution during continuous trading. For example, a resting Discretionary Peg

[15] The Exchange notes that Bats BZX Exchange, Inc (''Bats'') does not support broker self-match restrictions in their opening process for non-listed securities. See Bats Rule 11.24(b), which states that all MTP modifiers, as defined in Bats Rule 11.9(f), will be ignored as it relates to executions occurring as part of the Bats opening match process.

[16] *See* proposed Rule 11.350(c)(2)(C) in SR–IEX–2017–10 available at *https://www.iextrading.com/regulation/rule-filings/.*

[17] *See, e.g.,* Nasdaq Rule 4752(d)(3)(A)–(D), and NYSE Arca Rule 7.35(a)(6) and 7.35(c)(4), describing priority for the opening auction.

order would exercise discretion up (down) to the less aggressive of the Midpoint Price or the order's limit price to interact with an incoming spread crossing order. Similarly, in the Opening Process, a Discretionary Peg order would exercise discretion up (down) to the Opening Match Price, subject to the less aggressive of the Midpoint Price, or the order's limit price to interact contra-side liquidity in the Opening Process. Accordingly, inclusion of such orders would be in accord with existing functionality already approved by the Commission in connection with its grant of IEX's application for registration as a national securities exchange under Sections 6 and 19 of the Act, wherein the Commission specifically found IEX's order type rules to be consistent with the Act and, in particular, the Section 6(b)(5) requirement that the Exchange's rules be designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system, and protect investors and the public interest.[18] Accordingly, the Exchange does not believe that allowing these orders to participate in the proposed Opening Process in accordance with their current functionality raises any new or novel issues that have not already been considered by the Commission, and is thus consistent with the protection of investors and the public interest.

The Exchange also believes that the proposal is designed 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, because proposed Rule 11.231(d) sets forth an opening process contingency procedure, which provides a clear and transparent process designed to provide a means for trading in a non-IEX-listed security to open in an orderly and timely manner even after a disruption has prevented the execution of the Opening Process. Furthermore, the Exchange believes that proposed Rule 11.231(e) is designed 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 that the Exchange would conduct the Opening Process for non-IEX-listed securities that were subject to and remained in a halt, suspension, or pause in trading at the commencement of the Opening Process, while still allowing Users to cancel any queued interest prior to the commencement of the Opening Process. Applying the proposed Opening Process for securities that open after the start of Regular Market Hours as a result of a halt, suspension, or pause in trading provides the greatest opportunity to match buy and sell orders at a price that is reflective of market conditions for the security, while also providing for orderly and timely openings of non-IEX-listed securities, and creating uniformity among all non-IEX-listed securities by applying a consistent approach to open trading on IEX in such securities.

In addition, the Exchange believes that allowing market orders with a time-in-force of DAY to be entered into the System for queueing in the Pre-Market session while also allowing such orders to participate in the Opening Process provides Users with greater control and flexibility with respect to entering orders, and may simplify the order entry process for Users. In this regard, Users are able to enter orders that will either queue on the Cross Book for participation in the Opening Process, or are eligible for execution in the Pre-Market Session prior to participating in the Opening Process, which removes impediments to a free and open market and benefits all Users of the Exchange. In addition, the Exchange believes that its proposal to make a minor conforming change to the language used in reference to the LULD Price Bands in Rule 11.190(a)(1)(2) [sic] in order to conform the reference to the language used throughout the Exchange's rules is consistent with the protection of investors and the public interest because it is designed to provide consistency and clarity in the Exchange's rules, which benefits all market participants.

The Exchange is not proposing to disseminate indicative pricing or imbalance information relating to the Opening Process. The Exchange is not proposing to disseminate indicative pricing or imbalance information prior to the Opening Process because the Exchange is not trying to establish equilibrium in order to determine the official opening price of the security. Rather, the Opening Process is designed to efficiently resolve the queue of orders awaiting the Regular Market Session at a fair price, that reflects the broader market for the security. Accordingly, the Exchange believes that not providing indicative pricing or imbalance information related to the Opening Process is consistent with the protection of investors and the public interest.[19]

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. To the contrary, the Exchange believes that the proposed Opening Process is designed to promote fair competition among brokers and dealers and among exchange markets by offering an Opening Process that competes with existing opening processes for non-listed securities offered by IEX's competitors, thereby promoting intermarket competition between exchanges in furtherance of the principles of Section 11A(a)(1).[20]

With respect to intramarket competition, the proposed Opening Process will apply equally to all non-IEX-listed securities, and all Members and market participants that send orders to IEX through Members. Members are permitted to enter any type of Cross Eligible Order and there are no privileged participants who receive enhanced priority, or have access to special order types. Consequently, IEX does not believe that the proposal will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

[18] *See* Securities Exchange Act Release No. 34–78101 at 47 (June 17, 2016), 81 FR 41142 (June 23, 2016) (File No. 10–222).

[19] The Exchange notes that Bats does not provide indicative pricing or imbalance information for its process for opening non-listed securities pursuant to Bats Rule 11.24.

[20] 15 U.S.C. 78k–1(a)(1).

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–2017–11 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–2017–11. 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–IEX–2017–11, and should be submitted on or before May 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–08575 Filed 4–27–17; 8:45 am]

BILLING CODE 8011–01–P

[21] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–80511]

Order Granting Petition for Review and Scheduling Filing of Statements; in the Matter of Bats BZX Exchange, Inc.; Regarding an Order Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, To List and Trade Shares Issued by the Winklevoss Bitcoin Trust

April 24, 2017.

This matter comes before the Securities and Exchange Commission (''Commission'') on petition to review the disapproval, through delegated authority, of the Bats BZX Exchange, Inc. (''BZX'') proposed rule change to list and trade shares of the Winklevoss Bitcoin Trust as Commodity-Based Trust Shares under BZX Rule 14.11(e)(4).

On July 8, 2016, the Commission issued a notice of filing of the proposed rule change filed with the Commission pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'')[1] and Rule 19b–4[2] thereunder.[3] On August 23, 2016, the Commission designated a longer time period within which to act on the proposed rule change.[4] On October 12, 2016, the Commission instituted proceedings under Section 19(b)(2)(B) of the Exchange Act[5] to determine whether to approve or disapprove the proposed rule change.[6] On January 4, 2017, the Commission designated a longer period for Commission action on the proposed rule change.[7] After consideration of the record in the proposed rule change, the Division of Trading and Markets (''Division''), pursuant to delegated authority,[8] issued an order disapproving the proposed rule change (''Disapproval Order'') on March 10, 2017.[9]

On March 24, 2017, pursuant to Rule 430 of the Rules of Practice,[10] BZX filed a petition for review of the Disapproval Order. Pursuant to Rule 431 of the Rules of Practice,[11] BZX's petition for review of the Disapproval Order is granted. Further, the Commission hereby establishes that any party to the action or other person may file a written statement in support of or in opposition to the Disapproval Order on or before May 15, 2017.

For the reasons stated above, it is hereby:

Ordered that the petition of BZX for review of the Division's action to disapprove the proposed rule change by delegated authority be *granted;* and

It is further *ordered* that any party or other person may file a statement in support of or in opposition to the action made pursuant to delegated authority on or before May 15, 2017.

The order disapproving such proposed rule change shall remain in effect.

By the Commission.

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–08565 Filed 4–27–17; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *Notice of Filing of a Proposed Rule Change to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, to List and Trade Winklevoss Bitcoin Shares Issued by the Winklevoss Bitcoin Trust,* Securities Exchange Act of 1934, Release No. 78262 (July 8, 2016), 81 FR 45554 (July 14, 2016).

[4] *Notice of Designation of a Longer Period for Commission Action on Proposed Rule Change to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, to List and Trade Winklevoss Bitcoin Shares Issued by the Winklevoss Bitcoin Trust,* Securities Exchange Act of 1934, Release No. 78653 (August 23, 2016), 81 FR 59256 (August 29, 2016).

[5] 15 U.S.C. 78s(b)(2)(B).

[6] *Order Instituting Proceedings to Determine Whether to Approve or Disapprove a Proposed Rule Change to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, to List and Trade Winklevoss Bitcoin Shares Issued by the Winklevoss Bitcoin Trust,* Securities Exchange Act of 1934, Release No. 79084 (October 12, 2016), 81 FR 71778 (October 18, 2016). On October 20, 2016, BZX filed Amendment No. 1 to the proposed rule change, replacing the original filing in its entirety. *See* Exchange Act Release No. 79183 (October 28, 2016), 81 FR 76650 (November 3, 2016).

[7] *Notice of Designation of a Longer Period for Commission Action on Proceedings to Determine Whether to Approve or Disapprove a Proposed Rule Change, as Modified by Amendment No. 1, to BZX Rule 14.11(e)(4), Commodity-Based Trust Shares, to List and Trade Winklevoss Bitcoin Shares Issued by the Winklevoss Bitcoin Trust,* Securities Exchange Act of 1934, Release No. 79725 (January 4, 2017), 82 FR 2425 (January 9, 2017). On February 22, 2017, BZX filed Amendment No. 2 to the proposed rule change, which did not materially alter the substance of the proposed rule change. Amendment No. 2 is available on the Commission's Web site at *https://www.sec.gov/comments/sr-batsbzx-2016-30/batsbzx201630-1594698-132357.pdf.*

[8] 17 CFR 200.30–3(a)(12).

[9] *Order Disapproving a Proposed Rule Change, as Modified by Amendments No. 1 and 2, to BZX Rule 14.1(e)(4), Commodity-Based Trust Shares, to List and Trade Shares Issued by the Winklevoss Bitcoin Trust,* Securities Exchange Act of 1934, Release No. 80206 (March 10, 2017), 82 FR 14076 (March 16, 2017).

[10] 17 CFR 201.430.

[11] 17 CFR 201.431.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–80517; File No. SR–FICC–2017–010]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Notice of Filing of Proposed Rule Change To Amend the Mortgage-Backed Securities Division Rules Concerning Use of Clearing Fund for Losses, Liabilities or Temporary Needs for Funds Incident to the Clearance and Settlement Business and Make Other Related Changes

April 24, 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 April 11, 2017, Fixed Income Clearing Corporation (''FICC'') 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. 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 consists of modifications to the Mortgage-Backed Securities Division (''MBSD'') Clearing Rules (''MBSD Rules'') [3] of FICC. Specifically, FICC proposes to amend Section 5 of MBSD Rule 4 to (i) delete language that would potentially limit FICC's access to MBSD Clearing Fund cash and collateral to address losses, liabilities, or temporary needs for funds incident to its clearance and settlement business and (ii) make additional changes to correct grammar errors, delete superfluous words and otherwise align the text of Section 5 of MBSD Rule 4 to the text of Section 5 of Rule 4 of FICC's Government Securities Division (''GSD'') Rulebook (''GSD Rules'').[4]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the MBSD Rules, *available at www.dtcc.com/legal/rules-and-procedures.aspx*.

[4] *See* Rule 4 in the GSD Rules, *available at www.dtcc.com/legal/rules-and-procedures.aspx*. Capitalized terms used herein specifically with respect to GSD and not otherwise defined shall have the meaning assigned to such terms in the GSD Rules.

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

The proposed rule change would (i) delete language that would potentially limit FICC's access to MBSD Clearing Fund cash and collateral to address losses, liabilities or temporary needs for funds incident to its clearance and settlement business and (ii) make additional changes to correct grammar errors, delete superfluous words, and otherwise align the text of Section 5 of MBSD Rule 4 to the text of Section 5 of GSD Rule 4.

Section 5 of MBSD Rule 4 (the ''Rule'' or the ''MBSD Rule'' as used herein) describes the purposes for which FICC may use MBSD Clearing Fund deposits. The Rule is based on the parallel Section 5 of GSD Rule 4. The Rule describes the use of Clearing Fund deposits both to satisfy ''losses or liabilities of the Corporation'' and as collateral.[5] The first category is further divided between losses or liabilities ''arising from the failure of a Defaulting Member'' [6] and those ''otherwise incident to the clearance and settlement business of the Corporation *with respect to losses or liabilities to meet unexpected or unusual requirements for funds that represent a small percentage of the Clearing Fund*.'' [7] The second category refers to Clearing Fund deposits serving as collateral (i) to meet FICC's temporary financing needs, (ii) to ensure Members' satisfaction of settlement obligations, and (iii) ''*to meet unexpected or unusual requirements for funds that represent a small percentage of the Clearing Fund*.'' [8]

Section 5 of GSD Rule 4 reflects the same two-part construction but does not contain the limiting language relating to ''unexpected or unusual requirements for funds.'' [9] This limiting language was approved and became effective in 2012 when FICC introduced central counterparty and guaranteed settlement services for MBSD, at which time the entirety of the MBSD Rules were updated and replaced.[10] Neither FICC's proposal nor the Commission's approval order describes the purpose of the limiting language.[11]

The language appears to have been drawn from the Commission's publication in 1980 of standards for the Commission's Division of Market Regulation (the ''Division'') to employ in connection with the registration of clearing agencies.[12] In the 1980 Standards Release, the Division stated, in relevant part, that a clearing agency ''should have a clearing fund which . . . is limited in the purposes for which it may be used.'' [13] The Division further stated that ''the rules of the clearing agency should limit the purposes for which the clearing fund may be used to protecting participants and the clearing agency (i) from the defaults of participants and (ii) from clearing agency losses (*not including day-to-day operating expenses*) such as losses of securities not covered by insurance or other resources of the clearing agency.'' [14] The Division observed that some commenters opposed the limitation contained in clause (ii) on grounds that it could limit a clearing agency's access to its clearing fund in the event of a temporary need to cover an operating funds shortfall while a fee increase was being implemented or a temporary need to cover a delay in payment by a participant due to circumstances beyond the participant's control.[15] The Division noted that the commenter expressed concern that the clearing agency not be forced into insolvency in such circumstances.[16] The Division stated that it ''appreciate[ed] a clearing agency's possible need for temporary applications of a clearing fund in limited amounts to meet unexpected or

[5] MBSD Rule 4, Section 5.

[6] This category of losses or liabilities also includes those relating to failures relating to Cross-Guaranty Agreements, discussion of which is omitted herein for simplicity. *Id.*

[7] *Id.* (*Emphasis added.*)

[8] *Id.* (*Emphasis added.*)

[9] GSD Rule 4, Section 5.

[10] *See* Securities Exchange Act Release No. 66550 (March 9, 2012), 77 FR 15155 (March 14, 2012) (SR–FICC–2008–01) (the ''FICC CCP Approval Order'') at 15155.

[11] *See* Securities Exchange Act Release No. 65899 (Dec. 6, 2011), 76 FR 77287 (Dec. 12, 2011) (SR–FICC–2008–01) (proposed rule change) and FICC CCP Approval Order, *id.*

[12] *See* Securities Exchange Act Release No. 16900 (June 17, 1980), 45 FR 41920 (June 23, 1980) (the ''1980 Standards Release'').

[13] *Id.* at 41929.

[14] *Id.* (*Emphasis added.*)

[15] *See id.*

[16] *See id.*

unusual requirements for funds,'' but noted that ''regular or substantial use of a clearing fund for such purposes, however, would be inappropriate.'' [17]

At the time that the Commission published the 1980 Standards Release, clearing agencies operated in a very different manner from how FICC operates today. Clearing agencies were not, for example, subject to requirements with respect to maintaining any particular amount of operating capital.[18] Against this background, it is understandable that the Division could have deemed the temporary access by a clearing agency to a limited amount of its clearing fund to cover operating expense shortfalls to be acceptable.

FICC is now subject to substantially enhanced requirements. On September 28, 2016, the Commission adopted amendments to Rule 17Ad–22 under the Act, including the addition of new section 17Ad–22(e), which specifies enhanced standards for covered clearing agencies.[19] The new and enhanced standards specified in Rule 17Ad–22(e) require, among other things, that FICC ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by'' FICC, including ''plans for the recovery . . . of [FICC] necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.'' [20] Rule 17Ad–22(e) also requires FICC to maintain policies and procedures reasonably designed to ''[i]dentify, monitor, and manage [its] general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that [it] can continue operations and services as a going concern if those losses materialize.'' [21] The above requirement includes the requirement that FICC maintain ''a viable plan . . . for raising additional equity should its equity fall below the amount required [to satisfy its operating capital requirement].'' [22]

FICC proposes to delete the language in Section 5 of MBSD Rule 4 that limits certain uses by FICC of the MBSD Clearing Fund to ''unexpected or unusual'' requirements for funds that represent a ''small percentage'' of the MBSD Clearing Fund because (i) the first instance of the limiting language could impair FICC's access to the MBSD Clearing Fund as one tool (among many) that FICC could employ in order to manage non-default risks, so that it can withstand or recover from such risks and continue operations and services as a going concern while implementing its viable plan for raising additional capital, and (ii) the effect of the second instance of the limiting language is confusing and unclear.

Although, as noted above, FICC's original objective in including the limiting language when it revised the MBSD Rules is not clear, the comments described in the 1980 Standards Release suggests two examples for which such language could have been intended: (i) Limiting FICC's use of the MBSD Clearing Fund should an MBSD member experience an operational problem that caused a temporary delay in payment and (ii) limiting FICC's use of the MBSD Clearing Fund should FICC suffer an operating funds shortfall to the point that FICC's viability as a going concern became temporarily impaired.[23]

The first example, however, is inconsistent with FICC's broad and unlimited access to the MBSD Clearing Fund to satisfy ''losses or liabilities . . . arising from the failure of a Defaulting Member . . .'' and to use Clearing Fund deposits as collateral ''to meet its temporary financing needs'' with respect to securities settlement.[24] Additionally, FICC believes that both examples would represent a misreading of the objective of this discussion in the 1980 Standards Release, in which the Division stated that a clearing agency's rules should provide that it may access its clearing fund to cover clearing agency losses, in addition to losses caused by a participant default, in an unrestricted manner ''but not including day-to-day operating expenses.'' [25] In other words, it appears that the Division believed, at the time when the 1980 Standards Release was published, that a clearing agency *should* be permitted to access its clearing fund on a temporary basis to cover even short-term day-to-day operating losses if such use was necessary to avoid ''going out of business'' and such use was neither ''regular'' nor ''substantial.'' [26] FICC notes that it would be extraordinarily unlikely for it to access the MBSD Clearing Fund for such a purpose at the present time, because, as noted above, FICC is now subject to a requirement that it hold, at a minimum, capital equal to six months of operating expenses.[27] To summarize, the limiting language as currently included in the Rule would not be effective to limit FICC's use of the MBSD Clearing Fund to address a temporary operational issue that caused a delay in payment by a participant, nor does FICC believe such limitation would have been intended. While the language would be effective to limit to small amounts FICC's access to MBSD Clearing Fund deposits to cover temporary shortfalls in funds needed to meet day-to-day operating expenses, the utility of such a restriction has been eliminated by the new capital requirements to which FICC is subject.

FICC is concerned, however, that the limiting language could be interpreted to prevent FICC from accessing MBSD Clearing Fund deposits as a tool to address an unexpected short-term need for funds that would allow FICC to continue operations and services as a going concern while it implements other tools available to it, because such use may be deemed to be either ''satisfaction of losses or liabilities of FICC,'' even if the use of deposits is temporary, or the use of deposits as collateral is to meet ''temporary financing needs'' (see discussion below), both of which are impacted by the limiting language in the Rule. There are many tools that are available to FICC to address such a need for funds, which tools are described in the FICC Capital Plan PRC. The tools directly available to FICC include increasing fees or decreasing expenses, and FICC's parent company, The

[17] *Id.*

[18] The 1980 Standards Release does not include specific financial requirements for clearing agencies. The Division stated that clearing agencies should provide financial statements to their participants on a periodic basis and that clearing agencies should plan for contingencies including (in relevant part) loss of funds, with respect to which the Division advised that clearing agencies should maintain adequate insurance. *See id.* at 41926–27 and 41929.

[19] *See* Securities Exchange Act Release No. 78961 (September 28, 2016), 81 FR 70786 (October 13, 2016) (S7–03–14) (the ''Covered Clearing Agency Standards Release''). FICC is a ''covered clearing agency'' as defined in Rule 17Ad–22(a)(5) and must comply with the new section (e) of Rule 17Ad–22 by April 11, 2017.

[20] 17 CFR 240.17Ad–22(e)(3).

[21] 17 CFR 240.17Ad–22(e)(15). The capital requirement set forth in Rule 17Ad–22(e)(15) is equal to, at a minimum, six months of FICC's current operating expenses. 17 CFR 240.17Ad–22(e)(15)(ii).

[22] 17 CFR 240.17Ad–22(e)(15)(iii).

[23] *See* 1980 Standards Release, *supra* note 12, at 41929.

[24] MBSD Rule 4, Section 5.

[25] *See* 1980 Standards Release, *supra* note 12, at 41929.

[26] *Id.*

[27] On April 6, 2017, FICC submitted a proposed rule change to adopt a Clearing Agency Policy on Capital Requirements and a Clearing Agency Capital Replenishment Plan in connection with its compliance with Rule 17Ad–22(e)(15). *See* SR–FICC–2017–007 (the ''FICC Capital Plan PRC''), which was filed with the Commission but has not yet been published in the **Federal Register**. A copy of the proposed rule change is *available at http://www.dtcc.com/legal/sec-rule-filings.aspx.*

Depository Trust & Clearing Corporation (''DTCC''),[28] may also implement tools available to it to raise capital that may be contributed to FICC.[29] While the FICC Capital Plan PRC does not contemplate recourse to either the GSD Clearing Fund or the MBSD Clearing Fund as a formal tool for capital replenishment, FICC believes that it would be imprudent to limit FICC's ability to employ this tool, particularly on a temporary basis, and it is clear that this was not the Division's objective when it discussed the underlying concerns in the 1980 Standards Release. Finally, FICC notes that FICC's access to GSD Clearing Fund deposits is not so limited. While FICC believes that its use of either the MBSD Clearing Fund or the GSD Clearing Fund for such purposes would be extraordinarily unlikely, the distinction between the two rules creates an appearance of inequity between MBSD Members and GSD Netting Members.

FICC also proposes to delete the second instance of the limiting language and otherwise amend the ''collateral'' portion of Section 5 of MBSD Rule 4, for the reasons described above, to the extent that the second instance of the limiting language that appears in the Rule would limit FICC's ability to pledge MBSD Clearing Fund deposits that are in the form of securities in order to meet temporary financing needs for purposes otherwise permitted by the Rule as FICC proposes to amend it. Section 5 of MBSD Rule 4 states that the MBSD Clearing Fund also may be used to provide FICC

> a source of collateral both [*sic*] to meet its temporary financing needs (through an appropriate financing method determined by the Corporation in its sole discretion) for any financing that is obtained by the Corporation to hold securities pending settlement, to ensure the satisfaction of Members' settlement obligations and to meet unexpected or unusual requirements for funds that represent a small percentage of the Clearing Fund.[30]

This section of the Rule identifies that the MBSD Clearing Fund is a source of collateral for FICC to meet ''temporary financing needs'' (*i.e.,* where FICC may pledge the assets as collateral to a lender to FICC) and to ensure that Members perform to FICC (*i.e.,* where Members have pledged collateral to FICC as surety against their own default). This understanding of the construction of the Rule is clear from comparison to Section 5 of GSD Rule 4, which also uses the word ''both,'' but where only the temporary financing example and the member surety example follow.[31] It is reasonable to believe that the second instance of the limiting language in the MBSD Rule was simply intended to make clear that, to the extent FICC was permitted to use the MBSD Clearing Fund to address a particular loss or liability ''otherwise incident to the clearance and settlement business,'' FICC was also permitted to use MBSD Clearing Fund deposits as collateral to address ''temporary financing needs'' for the same purpose. If so, the same rationale for deleting the limiting language that is described above would apply.

Finally, with respect to both instances of the limiting language in the Rule, FICC is concerned that scenarios that previously may have been fairly described as generating ''unexpected or unusual requirements for funds'' may no longer be fairly described as ''unexpected'' or ''unusual'' given the expectations described in the Covered Clearing Agency Standards Release that covered clearing agencies contemplate and plan for such scenarios.[32]

Consequently, FICC proposes to delete the limiting language in both places where it appears in MBSD Rule 4, Section 5, because the original purpose of the language is unclear, and potential applications of the limiting language may not have been intended or would not be, as a prudential matter, appropriate today. FICC also believes that, because of the uncertain intent of the language and the inherent ambiguity of terms such as ''unexpected or unusual,'' FICC's use of MBSD Clearing Fund deposits to address needs that are ''otherwise incident to [its] clearance and settlement business'' could be subject to legal challenges. FICC believes that the limiting language could impair FICC's compliance with Rule 17Ad–22(e)(3)(ii), pursuant to which FICC is preparing a recovery plan that provides for FICC's management of a broad range of risks such that it can continue to provide critical clearance and settlement operations and services even if such risks materialize.[33] FICC also believes that, because of its unclear purpose and the ambiguity of its terms, the limiting language could also impair FICC's compliance with Rule 17Ad–22(e)(1), pursuant to which FICC is required to ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . [p]rovide for a well-founded, clear, transparent and enforceable legal basis for each of its activities in all relevant jurisdictions.''[34]

FICC also proposes to amend Section 5 of MBSD Rule 4 to make additional changes that would align the Rule to Section 5 of GSD Rule 4 (where applicable), remove superfluous words and correct grammar errors and sentence construction ambiguities in the paragraph of the Rule that FICC proposes to amend in order to delete the limiting language discussed above. The first instance of the limiting language modifies the phrase ''otherwise incident to the clearance and settlement business'' with the phrase ''with respect to losses and liabilities to meet unexpected or unusual requirements for funds . . . .'' FICC proposes that, upon deleting this phrase, ''otherwise incident to the clearance and settlement business of the Corporation'' would be followed immediately by ''including losses and liabilities arising other than from such failure of such Member,'' which would align the amended MBSD Rule to Section 5 of GSD Rule 4 but would not otherwise change the extent of FICC's authority if the limiting language was deleted. FICC also proposes to replace the word ''provide'' with the word ''providing'' because ''providing'' would be grammatically correct where the sentence construction is that the use of MBSD Clearing Fund deposits ''shall be limited to . . . satisfaction of losses or liabilities . . . and to [providing] the Corporation with a source of collateral.'' Next, FICC proposes to add to the clause referring to temporary financing needs the modifier ''including, without limitation,'' and delete the parenthetical modifier ''(through an appropriate financing method determined by the Corporation in its sole discretion) for'' that currently precedes the reference to ''financing that is obtained by the Corporation to hold securities pending settlement.'' This change would delete a superfluous parenthetical clause and align the amended MBSD Rule to Section 5 of GSD Rule 4. Finally, FICC proposes to delete a comma and add the word ''and'' before the phrase ''to ensure the satisfaction of Members' settlement obligations,'' because these changes would be grammatically

[28] DTCC operates on a shared services model with respect to FICC and its other subsidiaries. Most corporate functions are established and managed on an enterprise-wide basis pursuant to intercompany agreements.

[29] *See* FICC Capital Plan PRC, *supra* note 27, at 8.

[30] MBSD Rule 4, Section 5.

[31] GSD Rule 4, Section 5.

[32] *See* Covered Clearing Agency Standards Release, *supra* note 19, at 70810 and 70836.

[33] The Commission issued a temporary exemption from compliance with the recovery and wind-down plan requirements of Rule 17Ad–22(e)(3) and (e)(15) until December 31, 2017. Securities Exchange Act Release No. 80378 (April 5, 2017) (File No. S7–03–14).

[34] 17 CFR 240.17Ad–22(e)(1).

necessary upon deletion of the second instance of the limiting language. FICC also believes it is reasonable and appropriate to align the language of Section 5 of MBSD Rule 4 to Section 5 of GSD Rule 4, because it would avoid any question whether Section 5 of MBSD Rule 4 should be interpreted differently from Section 5 of GSD Rule 4. FICC does not believe that these sections should be interpreted differently, except as necessary with respect to differences that are specific to the services and defined terminology of each division.

2. Statutory Basis

FICC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to FICC. In particular, FICC believes that the proposed rule change is consistent with Section 17A(b)(3)(F) [35] of the Act and Rule 17Ad–22(e) under the Act,[36] for the reasons described below.

Section 17A(b)(3)(F) of the Act requires, in part, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions.[37] The proposed rule change would enhance FICC's prompt and accurate clearance and settlement of securities transactions because it would enhance FICC's ability to ensure that it can continue its operations and services as a going concern in the unlikely event that it would be necessary or appropriate for FICC to access MBSD Clearing Fund deposits to address losses, liabilities or temporary financing needs incident to its clearance and settlement business. Additionally, the more technical aspects of the proposed rule change would promote the prompt and accurate clearance and settlement of securities transactions by removing potentially ambiguous language, correcting grammar errors, and deleting superfluous text in Section 5 of MBSD Rule 4, which changes would enhance the clarity of the Rule. The proposed rule change would also promote the prompt and accurate clearance and settlement of securities transactions by aligning Section 5 of MBSD Rule 4 to Section 5 of GSD Rule 4, which would reduce the risk of legal challenges to FICC's use of MBSD Clearing Fund deposits based upon the argument that differences between the two rules indicate that Section 5 of MBSD Rule 4 should be interpreted differently from Section 5 of GSD Rule 4.

FICC also believes that the proposed rule change is consistent Rule 17Ad–22(e)(1) and (3). Rule 17Ad–22(e)(1) requires FICC to ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . [p]rovide for a well-founded, clear, transparent and enforceable legal basis for each of its activities in all relevant jurisdictions.'' [38] As described above, FICC believes that the proposed rule change to eliminate the limiting language described above would reduce the risk of legal challenges to FICC's ability to access MBSD Clearing Fund deposits under scenarios in which FICC believes that such limitation was not intended or in which such limitation would not be appropriate, as a prudential matter, in light of the enhanced standards to which FICC is now subject. The more technical aspects of the proposed rule change would also reduce the risk of legal challenges to FICC's actions that could be based upon grammar errors or differences between Section 5 of MBSD Rule 4 and Section 5 of GSD Rule 4. Rule 17Ad–22(e)(3) requires FICC to ''establish, implement, maintain and enforce written policies and procedures reasonably designed to . . . maintain a sound risk management framework for comprehensively managing legal, credit, liquidity, operational, general business, investment, custody, and other risks that arise in or are borne by'' FICC, including ''plans for the recovery . . . of [FICC] necessitated by credit losses, liquidity shortfalls, losses from general business risk, or any other losses.'' [39] The proposed rule change would enhance FICC's compliance with Rule 17Ad–22(e)(3) by enhancing and clarifying FICC's ability to access MBSD Clearing Fund deposits as one tool that it may employ in order to address losses, liabilities or temporary needs for funds incident to its clearance and settlement business. In particular, FICC believes that enhancing and clarifying FICC's ability to access MBSD Clearing Fund deposits in this manner and making the related more technical changes to Section 5 of MBSD Rule 4 would enhance FICC's comprehensive management of legal and operational risks, consistent with Rule 17Ad–22(e)(3)(i).[40] FICC also believes that enhancing and clarifying FICC's ability to access MBSD Clearing Fund deposits to address such risks would enhance FICC's ability to establish and maintain appropriate recovery and orderly wind-down plans, as required by Rule 17Ad–22(e)(3)(ii),[41] by enhancing and clarifying one tool that FICC may employ in order to address such risks.

(B) Clearing Agency's Statement on Burden on Competition

FICC believes that the proposed rule change to delete the limiting language in Section 5 of MBSD Rule 4 could have an impact upon competition. Specifically, as a result of the proposed rule change FICC's ability to access MBSD Clearing Fund deposits with respect to certain non-default losses would be expanded and clarified. Although FICC believes it is extraordinarily unlikely that FICC would find it necessary or appropriate to employ this tool in lieu of other tools that are available to FICC, if FICC were to access MBSD Clearing Fund deposits for this purpose, and such use became a loss or liability that was allocated to MBSD Members pursuant to Section 5 and Section 7 of MBSD Rule 4, such allocation could have a different financial impact upon MBSD Members than would be imposed by use of another tool that FICC could employ to address the underlying loss, liability, or temporary needs for funds incident to its clearance and settlement business. Accordingly, FICC believes that the proposed rule change to delete the limiting language in Section 5 of MBSD Rule 4 could burden competition. However, FICC does not believe that this aspect of the proposed rule changes would impose a significant burden on competition, both because it is extraordinarily unlikely that FICC would employ this tool and because FICC's access to MBSD Clearing Fund deposits for these purposes would, if employed, likely replace (possibly temporarily) alternative tools such as fee increases or capital-raising tools available to DTCC that would also have a financial impact on MBSD Members.

FICC believes that the above described potential burden on competition would be necessary and appropriate in furtherance of the Act, specifically Section 17A(b)(3)(F) of the Act,[42] because, as described above, the proposed rule change would enhance FICC's prompt and accurate clearance and settlement of securities transactions by enhancing FICC's ability to ensure that it can continue its operations and services as a going concern, in the

[35] 15 U.S.C. 78q–1(b)(3)(F).

[36] 17 CFR 240.17Ad–22(e).

[37] 15 U.S.C. 78q–1(b)(3)(F).

[38] 17 CFR 240.17Ad–22(e)(1).

[39] 17 CFR 240.17Ad–22(e)(3).

[40] 17 CFR 240.17Ad–22(e)(3)(i). *See also* Covered Clearing Agency Standards Release, *supra* note 19, at 70810 (discussing guidelines that a covered clearing agency should consider with respect to its comprehensive risk management framework).

[41] 17 CFR 240.17Ad–22(e)(3)(ii).

[42] 15 U.S.C. 78q–1(b)(3)(F).

unlikely event that it would be necessary or appropriate for FICC to access MBSD Clearing Fund deposits to address losses, liabilities or temporary financing needs incident to its clearance and settlement business. FICC also believes that the proposed rule change to delete the limiting language in Section 5 of MBSD Rule 4 is necessary and appropriate in furtherance of the Act because it would (i) reduce the risk of legal challenges to FICC's ability to access MBSD Clearing Fund deposits under scenarios in which FICC believes that such limitation was not intended or in which, FICC believes, such limitation would not be appropriate, thereby supporting FICC's compliance with Rule 17Ad–22(e)(1),[43] (ii) enhance FICC's comprehensive management of legal and operational risks, thereby supporting FICC's compliance with Rule 17Ad–22(e)(3)(i),[44] and (iii) enhance FICC's ability to establish and maintain appropriate recovery and orderly wind-down plans, thereby supporting FICC's compliance with Rule 17Ad–22(e)(3)(ii).[45]

FICC does not believe the additional changes to correct grammar errors, delete superfluous words and otherwise align the text of Section 5 of MBSD Rule 4 to the text of Section 5 of GSD Rule 4 would have any impact upon competition, because these proposed rule changes would enhance the clarity and grammatical accuracy of the Rule and therefore would not have an impact on MBSD members or impose any other potential burden on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

FICC has not received or solicited any written comments relating to this proposal. FICC will notify the Commission of any written comments received by FICC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FICC–2017–010 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–FICC–2017–010. 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 FICC 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–FICC–2017–010 and should be submitted on or before May 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[46]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–08578 Filed 4–27–17; 8:45 am]

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[43] 17 CFR 240.17Ad–22(e)(1).

[44] 17 CFR 240.17Ad–22(e)(3)(i).

[45] 17 CFR 240.17Ad–22(e)(3)(ii).

[46] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–80516; File No. SR–NYSEArca–2017–43]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services

April 24, 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 April 20, 2017, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services (''Fee Schedule'') to add a new pricing tier, the Large Order Tier, and to change pricing in Tier 3. The Exchange proposes to implement the fee changes effective April 20, 2017.[4] 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

[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 to amend the Fee Schedule on March 31, 2017 (SR–NYSEArca–2017–34) and withdrew such filing on April 10, 2017. On April 10, 2017, the Exchange re-filed to amend the Fee Schedule (SR–NYSEArca–2017–39) and withdrew such filing on April 20, 2017.

statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule, as described below, to add a new pricing tier, the Large Order Tier, and change pricing in Tier 3. The proposed fee changes would be applicable to securities with a per share price of $1.00 or above. The Exchange proposes to implement the fee changes on April 20, 2017.

Large Order Tier

Currently, ETP Holders, including Market Makers, are charged a fee of $0.0010 per share for Market Orders,[5] Market-On-Close (''MOC'') Orders,[6] Limit-On-Close (''LOC'') Orders [7] and Auction-Only Orders [8] that are executed in the Closing Auction [9] if the ETP Holder meets the current Tier 1, Tier 2 or Tier 3 requirements. ETP Holders that do not meet the Tier 1, Tier 2 or Tier 3 requirements are charged a fee of $0.0012 per share for such orders, as provided in the Basic Rates section of the Fee Schedule. The Exchange is proposing a new pricing tier to incentivize large order flow to the Exchange. The proposed Large Order Tier fee of $0.0010 per share would be applicable to ETP Holders, including Market Makers, that execute an average daily volume (''ADV'') of 1,250,000 shares or greater of Market Orders, MOC Orders, LOC Orders and Auction-Only Orders executed in the Closing Auction from orders of 650,000 shares and greater (''Large Closing Orders'') and that have a ratio of Large Closing Order shares to total shares executed during the month of at least 35%.

For example, if, in a month, an ETP Holder has an ADV of 3,000,000 shares of Market, MOC, LOC, and Auction-Only orders that are executed in the Closing Auction, of which 2,000,000 shares are from Large Closing Orders, and a total ADV of 5,000,000 shares (all volume, including but not limited to orders that add liquidity, take liquidity, are routed to and executed at other markets, and are executed in the Core Open Auction [10] and Closing Auction), such ETP Holder will have a ratio of Large Closing Orders to total shares executed during the month of 40% (2,000,000/5,000,000). Such ETP Holder would therefore meet the proposed requirements of the Large Order Tier and the Exchange would charge this ETP Holder a fee of $0.0010 per share for the 2,000,000 shares from Large Closing Orders. The remaining 1,000,000 shares executed in the Closing Auction that are not from Large Closing Orders would be charged per the Exchange's current fees, *i.e.,* $0.0010 per share if the ETP Holder meets the Tier 1, Tier 2 or Tier 3 requirements, or $0.0012 per share under the Basic Rates section of the Fee Schedule.

The proposed fee for Large Closing Orders is the lowest fee applicable to ETP Holders, and would be equivalent to the fee charged for Market, MOC, LOC, and Auction-Only orders that are executed in the Closing Auction if an ETP Holder meets Tier 1, Tier 2 or Tier 3 requirements. For the ETP Holder in the example above, absent the proposed fee, the ETP Holder would be charged a fee of $0.0010 per share for Market, MOC, LOC, and Auction-Only orders that are executed in the Closing Auction if that ETP Holder met Tier 1, Tier 2 or Tier 3 requirements, or $0.0012 per share under the Basic Rates section of the Fee Schedule.

For ETP Holders that qualify for the proposed Large Order Tier, Tiered or Basic Rates would apply to all other fees and credits, based on the ETP Holder's qualifying levels, and if an ETP Holder qualifies for more than one tier in the Fee Schedule, the Exchange would apply the most favorable rate available under such tiers.

Tier 3

The Fee Schedule currently provides, in Tier 1 and Tier 2 sections, that a fee of $0.0010 per share is charged for Market, MOC, LOC and Auction-Only Orders executed in the Closing Auction. For Basic Rates customers, this fee is $0.0012 per share.[11] Per the current Fee Schedule, Tier 3 customers are subject to the fee provided in the Basic Rates section of the Fee Schedule, or $0.0012 per share. The Exchange proposes to modify the Tier 3 section of the Fee Schedule to include a $0.0010 per share fee for Market, MOC, LOC and Auction-Only Orders executed in the Closing Auction for Tapes A, B and C.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[12] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[13] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes the proposed Large Order Tier is reasonable and equitably allocated because it would apply to ETP Holders and Market Makers that execute large orders in the Exchange's Closing Auction and is designed to incentivize these market participants to increase the orders sent directly to the Exchange and therefore provide liquidity that supports the quality of price discovery and promotes market transparency. The Exchange believes the new Large Order Tier is equitable because it would be available to all similarly situated ETP Holders and Market Makers on an equal basis and provides a fee that is reasonably related to the value of an exchange's market quality associated with higher volumes. The Exchange believes that the Large Order Tier proposal is reasonable because it provides ETP Holders with an additional way to qualify for the same $0.0010 fee for Market, MOC, LOC, and Auction-Only orders that are charged to tiered customers.

The Exchange further believes that the proposed Large Order Tier is reasonable, equitable and not unfairly discriminatory because providing pricing tiers that favor a particular segment of securities or type of activity

[5] A Market Order is an unpriced order to buy or sell a stated amount of a security that is to be traded at the best price obtainable without trading through the NBBO. *See* Rule 7.31(a)(1).

[6] A MOC Order is a Market Order that is to be traded only during the Closing Auction. *See* Rule 7.31(c)(4).

[7] A LOC Order is a Limit Order that is to be traded only during the Closing Auction. *See* Rule 7.31(c)(3).

[8] An Auction-Only Order is a Limit or Market Order that is to be traded only within an auction pursuant to Rule 7.35 or routed pursuant to Rule 7.34. Any quantity of an Auction-Only Order that is not traded in the designated auction is cancelled. *See* Rule 7.31(c).

[9] The Closing Auction is conducted at the end of the Core Trading Session. *See* Rule 7.35(d).

[10] The Core Open Auction is conducted at the beginning of the Core Trading Session. *See* Rule 7.35(c).

[11] This fee for Basic Rates customers was increased to $0.0012 per share in June 2016. *See* Securities Exchange Act Release No. 77925 (May 26, 2016), 81 FR 35412 (June 2, 2016) (SR–NYSEArca–2016–78) (''June Fee Filing''). Prior to the June Fee Filing, the fee for Market, MOC, LOC and Auction-Only Orders executed in the Closing Auction was $0.0010 per share for all customers.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(4) and (5).

is not unusual. For example, NYSE MKT LLC provides a higher per share credit on a per transaction basis for displayed liquidity when adding liquidity in orders that originally display a minimum of 2,000 shares.[14]

The Exchange believes that the proposed new pricing tier would create an added incentive for ETP Holders and Market Makers to execute large orders on the Exchange. The Exchange believes that the proposed change is equitable and not unfairly discriminatory because providing a lower fee as an incentives for orders in exchange-listed securities that are executed on a registered national securities exchange (rather than relying on certain available off-exchange execution methods) would contribute to investors' confidence in the fairness of their transactions and would benefit all investors by deepening the Exchange's liquidity pool, supporting the quality of price discovery, promoting market transparency and improving investor protection.

Tier 3 customers have always been charged a fee of $0.0010 per share. The Exchange does not believe that there is any confusion among market participants with respect to the applicable Tier 3 fee for Market, MOC, LOC and Auction-Only Orders executed in the Closing Auction, but rather that the addition of the proposed language would serve to provide transparency in the Exchange's rules, and is an equitable allocation of reasonable fees. The Exchange believes that the addition of the proposed Tier 3 fee is consistent with Section 6(b)(5) of the Act in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by clarifying what fees apply for certain transactions and market participants.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

[14] *See* NYSE MKT Equities Price List, Transaction Fees and Credits For Non-ETP Securities Traded Pursuant to Unlisted Trading Privileges at *https://www.nyse.com/publicdocs/nyse/markets/nyse-mkt/NYSE_MKT_Equities_Price_List.pdf. See also* Securities Exchange Act Release No. 66599 (March 14, 2012), 77 FR 16302 (March 20, 2012) (SR–NYSEAmex–2012–17). The proposed Large Order Tier omits a reference to the originally displayed size like the NYSE MKT credit because auction orders on the Exchange are submitted to the auction once and do not decrement in size. While it could be possible for a market order to receive a fill and resize, the Exchange believes that this would be extremely unlikely.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[15] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the addition of the new Large Order Tier and the Tier 3 fee would encourage the submission of additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for ETP Holders and Market Makers. The Exchange believes that this could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed changes will impair the ability of ETP Holders or competing order execution venues to maintain their competitive standing in the financial markets.

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 foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[16] of the Act and subparagraph (f)(2) of Rule 19b–4[17] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[18] of the Act to determine whether the proposed rule change should be approved or disapproved.

[15] 15 U.S.C. 78f(b)(8).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2017–43 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–NYSEArca–2017–43. 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

[16] 15 U.S.C. 78s(b)(3)(A).

[17] 17 CFR 240.19b–4(f)(2).

[18] 15 U.S.C. 78s(b)(2)(B).

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–NYSEArca–2017–43, and should be submitted on or before May 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–08577 Filed 4–27–17; 8:45 am]

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[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–80515; File No. SR–NYSEArca–2017–45)

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Reflect a Change in the Index Methodology Applicable to the Virtus Enhanced U.S. Equity ETF Under NYSE Arca Equities Rule 5.2(j)(3)

April 24, 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 April 20, 2017, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I 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 the Substance of the Proposed Rule Change

The Exchange proposes to reflect a change in the index methodology applicable to the Virtus Enhanced U.S. Equity ETF (''Fund''). The Commission, pursuant to Section 19(b)(2) of the Act, has previously approved listing and trading of shares of the Fund on the Exchange under NYSE Arca Equities Rule 5.2(j)(3). The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Commission has approved the listing and trading on the Exchange of shares (''Shares'') of the Fund,[4] under NYSE Arca Equities Rule 5.2(j)(3), which governs the listing and trading of Investment Company Units. The Exchange proposes to reflect a change in the index methodology applicable to the Fund from the index description in the Prior Notice, as described below. Shares of the Fund have not commenced trading on the Exchange as of the date of filing of this proposed rule change.

Index Methodology

As stated in the Prior Notice, the Fund's investment objective will be to seek investment results that, before fees and expenses, closely correspond to the price and yield performance of the Rampart Enhanced U.S. Equity Index (the ''Index''). The Prior Notice stated that the Index is comprised of an equity portfolio enhanced by an ''Options Strategy Overlay''. The equity portfolio is comprised of the largest 400 U.S. exchange-listed stocks as measured by market capitalization. The portfolio is market capitalization-weighted and is reconstituted and rebalanced on a quarterly basis. The Options Strategy Overlay uses an objective, rules-based methodology to transact in options linked to the S&P 500 Index (SPX). SPX options are traded on the Chicago Board Options Exchange. Each week, out of the money SPX put options and out of the money SPX call options are sold. The proceeds are used to buy an SPX call option. The strike prices of the options are systematically selected according to the prevailing volatility environment. In general, in higher volatility environments the short options will be struck farther out of the money.

The Exchange proposes to delete the representation in the eighth sentence of the preceding paragraph that proceeds are used to buy an SPX call option. Instead, proceeds from weekly sales of out-of-the-money SPX put and call options by the Fund (to the extent there are profits from such sales), as it attempts to meet its investment objective, will be collected by the Fund, and distributed periodically to shareholders, instead of such proceeds being used to purchase additional SPX call options. Between such distributions, there would be no additional exposure to SPX options via reinvestment in such options. Virtus ETF Advisers LLC (the ''Adviser'') represents that the proposed change to the Index methodology would provide a simplified strategy that emphasizes enhanced income to investors rather than enhanced total return.

There will be no change to the Fund's investment objective. Except for the change noted above, all other representations made in the Prior Releases remain unchanged.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[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.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, and is designed to promote just and equitable principles of trade and to protect investors and the public interest. Proceeds from weekly sales of out-of-the-money SPX put and call options by the Fund, as it attempts

[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. 79402 (November 25, 2016), 81 FR 86760 (December 1, 2016) (SR–NYSEArca–2016–131) (''Prior Order''). *See also* Securities Exchange Act Release No. 79101 (October 14, 2016) (SR–NYSEArca–2016–131) (notice of filing of proposed rule change relating to listing on the Exchange of Shares of the Fund) (''Prior Notice'' and, together with the Prior Order, the ''Prior Releases'').

[5] 15 U.S.C. 78f(b)(5).

to meet its investment objective, will be distributed periodically to shareholders instead of such proceeds being used to purchase additional SPX call options.

The proposed rule change is designed to perfect the mechanism of a free and open market, and, in general, to promote just and equitable principles of trade and to protect investors and the public interest. The Adviser represents that, by not using proceeds of sales to add to exposure to SPX options in the Index, the proposed change to the Index methodology would provide a simplified strategy that emphasizes enhanced income to investors rather than enhanced total return. Except for the change noted above, all other representations in the Prior Releases remain unchanged.

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 Exchange believes the proposed rule change will enhance competition among issues of exchange-traded funds that invest in both U.S. exchange listed stocks and U.S. exchange-traded options to the benefit of investors and the marketplace.

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)(iii) of the Act [6] and subparagraph (f)(6) of Rule 19b–4 thereunder.[7]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative before 30 days from the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[8] the Commission may 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. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The proposed rule change does not raise any regulatory issues. Additionally, waiver of the operative delay will allow the Adviser to pursue the Fund's investment objective in a consistent manner should the Exchange wish to commence trading in the Shares without delay. For these reasons, the Commission hereby waives the 30-day operative delay and designates the proposed rule change to be operative upon filing with the Commission.[9]

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–NYSEArca–2017–45 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–NYSEArca–2017–45. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal offices of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2017–45, and should be submitted on or before May 19, 2017.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Eduardo A. Aleman,

Assistant Secretary.

[FR Doc. 2017–08576 Filed 4–27–17; 8:45 am]

BILLING CODE 8011–01–P

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 17 CFR 240.19b–4(f)(6).

[8] 17 CFR 240.19b–4(f)(6)(iii).

[9] For purposes only of waiving the operative delay for this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[10] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15121 and #15122]

Utah Disaster #UT–00049

AGENCY: U.S. Small Business Administration.

ACTION: Notice

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of UTAH (FEMA–4311–DR), dated 04/21/2017.

Incident: Severe Winter Storms and Flooding.

Incident Period: 02/07/2017 through 02/27/2017.

Effective Date: 04/21/2017.

Physical Loan Application Deadline Date: 06/20/2017.

Economic Injury (EIDL) Loan Application Deadline Date: 01/22/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and

Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 04/21/2017, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Box Elder, Cache

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.500
Non-Profit Organizations Without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 151216 and for economic injury is 151226.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–08595 Filed 4–27–17; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15115 and #15116]

Louisiana Disaster #LA–00075

AGENCY: U.S. Small Business Administration

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Louisiana dated 04/21/2017.

Incident: Severe Weather, Tornadoes and Flooding.

Incident Period: 04/01/2017 through 04/02/2017.

Effective Date: 04/21/2017.

Physical Loan Application Deadline Date: 06/20/2017.

Economic Injury (EIDL) Loan Application Deadline Date: 01/22/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Parishes: Rapides.

Contiguous Parishes:

LOUISIANA: ALLEN, AVOYELLES, EVANGELINE, GRANT, LA SALLE, NATCHITOCHES, VERNON.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	3.750
Homeowners Without Credit Available Elsewhere	1.875
Businesses With Credit Available Elsewhere	6.300
Businesses Without Credit Available Elsewhere	3.150
Non-Profit Organizations With Credit Available Elsewhere	2.500
Non-Profit Organizations Without Credit Available Elsewhere	2.500
For Economic Injury:	
Businesses & Small Agricultural Co-operatives Without Credit Available Elsewhere	3.150
Non-Profit Organizations Without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 15115 6 and for economic injury is 15116 0.

The State which received an EIDL Declaration # is Louisiana.

(Catalog of Federal Domestic Assistance Number 59008)

Dated: April 21, 2017.

Linda E. McMahon,

Administrator.

[FR Doc. 2017–08640 Filed 4–27–17; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15117 and #15118]

Washington Disaster #WA–00068

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Washington (FEMA–4309–DR), dated 04/21/2017.

Incident: Severe Winter Storms, Flooding, Landslides, and Mudslides.

Incident Period: 01/30/2017 through 02/22/2017.

Effective Date: 04/21/2017.

Physical Loan Application Deadline Date: 06/20/2017.

Economic Injury (EIDL) Loan Application Deadline Date: 01/22/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 04/21/2017, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adams, Benton, Columbia, Franklin, Grant, Lewis, Lincoln, Pend Oreille, Skamania, Spokane, Wahkiakum, Walla Walla, Whatcom

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.500
Non-Profit Organizations Without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 151176 and for economic injury is 151186.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–08593 Filed 4–27–17; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #15119 and #15120]

IDAHO Disaster #ID–00065

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of IDAHO (FEMA–4310–DR), dated 04/21/2017.

Incident: Severe Winter Storms and Flooding.

Incident Period: 02/05/2017 through 02/27/2017.

Effective Date: 04/21/2017.

Physical Loan Application Deadline Date: 06/20/2017.

Economic Injury (EIDL) Loan Application Deadline Date: 01/22/2018.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 04/21/2017, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Bingham, Cassia, Elmore, Franklin, Gooding, Jefferson, Jerome, Lincoln, Minidoka, Twin Falls, Washington

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations With Credit Available Elsewhere	2.500
Non-Profit Organizations Without Credit Available Elsewhere	2.500
For Economic Injury:	
Non-Profit Organizations Without Credit Available Elsewhere	2.500

The number assigned to this disaster for physical damage is 151196 and for economic injury is 151206.

(Catalog of Federal Domestic Assistance Number 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2017–08592 Filed 4–27–17; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice: 9979]

Shipping Coordinating Committee; Notice of Public Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 9:00 a.m. on Wednesday, June 28, 2017, in room 6I10–01–b 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 seventy-first session of the International Maritime Organization's (IMO) Marine Environment Protection Committee to be held at the IMO Headquarters, United Kingdom, July 3–7, 2017.

The agenda items to be considered include:

—Adoption of the agenda
—Decisions of other bodies
—Consideration and adoption of amendments to mandatory instruments
—Harmful aquatic organisms in ballast water
—Air pollution and energy efficiency
—Further technical and operational measures for enhancing the energy efficiency of international shipping
—Reduction of GHG emissions from ships
—Identification and protection of Special Areas and PSSAs
—Pollution prevention and response (report of the fourth session of the Sub-Committee)
—Reports of other sub-committees
—Technical cooperation activities for the protection of the marine environment
—Capacity building for the implementation of new measures
—Application of the Committees' Guidelines
—Work program of the Committee and subsidiary bodies
—Election of the Chair and Vice-Chair for 2018
—Any other business
—Consideration of the report of the Committee

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 (855) 475–2447 and use Participant Code: 993 678 424. To facilitate the building security process, and to request reasonable accommodation, those who plan to attend should contact the meeting coordinator, LCDR Staci Weist, by email at *Eustacia.y.weist@uscg.mil,* by phone at (202) 372–1376, or in writing at 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509 no later than June 21, 2017. Requests made after June 21, 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. It is recommended that attendees arrive to the Headquarters building no later than 30 minutes ahead of the scheduled meeting for the security screening process. The building is accessible by taxi, public transportation, and privately owned conveyance (upon request). Parking in the vicinity of the building is extremely limited and not guaranteed. Additional information regarding this and other SHC public meetings may be found at: *www.uscg.mil/imo.*

Jonathan W. Burby,

Executive Secretary, Shipping Coordinating Committee, Department of State.

[FR Doc. 2017–08551 Filed 4–27–17; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 9978]

Shipping Coordinating Committee; Notice of Public Meeting

The Shipping Coordinating Committee (SHC) will conduct an open meeting at 9:00 a.m. on May 23, 2017, in the CDR Raymond J. Evans Conference Center, Room 6i10–01–a, 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 ninety-eighth session of the International Maritime Organization's (IMO) Maritime Safety Committee to be held at the IMO Headquarters, United Kingdom, June 7–16, 2017.

The agenda items to be considered include:

—Adoption of the agenda; report of credentials
—Decisions of other IMO bodies
—Consideration and adoption of amendments to mandatory instruments
—Early implementation/application of IMO instruments
—Measures to enhance maritime security
—Goal-based new ship construction standards

—Carriage of cargoes and containers (report of the third session of the Sub-Committee)
—Pollution prevention and response (report of the fourth session of the Sub-Committee)
—Human element, training and watch keeping (report of the fourth session of the Sub-Committee)
—Navigation, communications, search and rescue (report of the fourth session of the Sub-Committee)
—Ship systems and equipment (report of the fourth session of the Sub-Committee)
—Capacity building for the implementation of new measures
—Formal safety assessment
—Piracy and armed robbery against ships
—Unsafe mixed migration by sea
—Implementation of instruments and related matters
—Relations with other organizations
—Committee's organization and method of work
—Work program
—Any other business
—Consideration of the report of the Committee on its ninety-eighth session

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. In order to ensure reasonable accommodation for all meeting participants, those who plan to attend should contact the meeting coordinator, LCDR Tiffany Duffy, by email at *tiffany.a.duffy@uscg.mil,* by phone at (202) 372–1376, or in writing at 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509 no later than May 15, 2017. Requests made after May 15, 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. It is recommended that attendees arrive to the Headquarters building no later than 30 minutes ahead of the scheduled meeting for the security screening process. The Headquarters building is accessible by taxi, public transportation, and privately owned conveyance (upon request). Parking in the vicinity of the building is extremely limited and not guaranteed. Additional information regarding this and other SHC public meetings may be found at: *www.uscg.mil/imo.*

Jonathan W. Burby,

Executive Secretary, Shipping Coordinating Committee, Department of State.

[FR Doc. 2017–08552 Filed 4–27–17; 8:45 am]

BILLING CODE 4710–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 35283 (Sub-No. 1)]

The Indiana Rail Road Company—Amended Trackage Rights Exemption—CSX Transportation, Inc.

Pursuant to a written Supplemental Agreement, dated February 16, 2017, The Indiana Rail Road Company (INRD) seeks to acquire approximately 30.6 miles of limited and amended overhead trackage rights from CSX Transportation, Inc. (CSXT),[1] between the INRD–CSXT connection near INRD's Senate Avenue Yard and CSXT's Avon Yard in Indianapolis, Ind. INRD presently holds overhead trackage rights over the subject lines, which it can utilize in conjunction with specified categories of traffic.[2] INRD states that the proposed transaction would amend those existing trackage rights to allow INRD to handle interchange traffic between CSXT and Louisville & Indiana Railroad Company in intermediate switching service.

The additional restricted overhead trackage rights to be acquired are over the following CSXT line segments: (1) Between the INRD–CSXT connection south of INRD's Senate Avenue Yard at milepost QIB 5.3 and the Hamilton Connection at milepost QIB 9.0, a distance of approximately 3.7 miles; (2) over CSXT's Hamilton Connection between milepost QIB 9.0 and milepost BD 122.0, a distance of approximately 0.5 miles; (3) between milepost BD 122.0 and milepost QS 12.5 at CP AN near the west end of Avon Yard, a distance of approximately 14.4 miles, with two milepost equations where milepost BD 123.7 = milepost QI 283.7 and milepost QI 283.9 = milepost QS 0.0; (4) between milepost QSC 0.7 at CP IJ and milepost QSC 8.6 at CP South Hunt, a distance of approximately 7.9 miles, connecting at both ends with Line Segment #3; (5) between milepost QSL 1.7 at CP Dale and milepost QSL 0.0 at CP IU, a distance of approximately 1.7 miles, connecting Line Segment #1 to Line Segment #3; and (6) between milepost QSS 106.9 at Belt Crossing and milepost QSS 109.3 at CP IU, a distance of approximately 2.4 miles, connecting Line Segment #1 to Line Segment #3.

The earliest this transaction may be consummated is May 13, 2017, the effective date of the exemption (30 days after the verified notice of exemption was filed).

As a condition to this exemption, any employees affected by the trackage rights will be protected by the conditions imposed in *Norfolk & Western Railway—Trackage Rights—Burlington Northern, Inc.,* 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Railway—Lease & Operate—California Western Railroad,* 360 I.C.C. 653 (1980).

This notice is filed under 49 CFR 1180.2(d)(7). If the notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Stay petitions must be filed by May 5, 2017 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings, referring to Docket No. 35283 (Sub-No. 1), must be filed with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001. In addition, a copy of each pleading must be served on Thomas J. Litwiler, Fletcher & Sippel LLC, 29 North Wacker Drive, Suite 920, Chicago, IL 60606–2832.

Board decisions and notices are available on our Web site at ''*WWW.STB.GOV.*''

Decided: April 25, 2017.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Raina S. Contee,

Clearance Clerk.

[FR Doc. 2017–08632 Filed 4–27–17; 8:45 am]

BILLING CODE 4915–01–P

[1] INRD is indirectly controlled by CSXT and operates as an independent Class II rail carrier.

[2] Pursuant to an August 22, 1996 trackage rights agreement and a September 1, 2009 Supplemental Agreement between INRD and CSXT, INRD holds trackage rights over several CSXT line segments in the Indianapolis terminal for the purpose of handling certain limited categories of overhead traffic. *See Ind. R.R.—Trackage Rights Exemption—CSX Transp., Inc.,* FD 35283 (STB served Sept. 3, 2009); *Ind. R.R.—Trackage Rights Exemption—Consol. Rail Corp.,* FD 33380 (STB served Apr. 30, 1997).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee (ARAC)—ARAC Input To Support Regulatory Reform of Aviation Regulations—New Task

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of a new task assignment for the Aviation Rulemaking Advisory Committee (ARAC).

SUMMARY: The FAA assigned the Aviation Rulemaking Advisory Committee (ARAC) a new task to consider (1) recommendations on existing regulations that are good candidates for repeal, replacement, or modification and (2) recommendations on regulatory action identified in FAA's regulatory agenda. Pursuant to the February 24, 2017, Executive Order titled ''Enforcing the Regulatory Reform Agenda,'' each agency is required to establish a Regulatory Reform Task Force (RRTF) to evaluate existing regulations, and make recommendations for their repeal, replacement, or modification. As part of this process, the RRTF is required to seek input/assistance from entities significantly affected by its regulations. Since the ARAC's membership represents a broad spectrum of entities significantly affected the FAA's regulations, the Department, through the FAA, assigned this task to ARAC. This notice informs the public of the new ARAC activity.

FOR FURTHER INFORMATION CONTACT: Nikeita Johnson, Management and Program Analyst, Federal Aviation Administration, Room 810, 800 Independence Avenue SW., Washington, DC 20591, *Nikeita.Johnson@faa.gov,* (202) 267–4977.

SUPPLEMENTARY INFORMATION:

ARAC Acceptance of Task

At the April 20, 2017, ARAC meeting, the FAA assigned and ARAC accepted this task to evaluate the FAA's regulations in Title 14 of the Code of Federal Regulations to determine any and all regulations that should be repealed, replaced or modified, and to provide feedback on the regulatory actions identified in the FAA's regulatory agenda. ARAC will then provide advice and recommendations on the assigned task and submit a recommendation report to the FAA.

Background

The FAA established ARAC to provide information, advice, and recommendations on aviation related issues that could result in rulemaking to the FAA Administrator, through the Associate Administrator of Aviation Safety.

Improvement of regulations is a continuous focus for the Department. Accordingly, the Department regularly makes a conscientious effort to review its rules in accordance with the Department's 1979 Regulatory Policies and Procedures (44 FR 11034, 2/26/1979), Executive Order 12866, Executive Order 13563, and section 610 of the Regulatory Flexibility Act. Through two new Executive Orders, President Trump directed agencies to further scrutinize its regulations. On January 30, 2017, President Trump signed an Executive Order titled ''Reducing Regulation and Controlling Regulatory Costs (EO).'' Under Section 2a of that Executive Order, unless prohibited by law, whenever an executive department or agency publicly proposes for notice and comment or otherwise promulgates a new regulation, it shall identify at least two existing regulations to be repealed.

In addition, on February 24, 2017, President Trump signed Executive Order 13777 titled ''Enforcing the Regulatory Reform Agenda.'' Under this Executive Order, each agency is required to establish a Regulatory Reform Task Force (RRTF) to evaluate existing regulations, and make recommendations for their repeal, replacement, or modification. As part of this process, the Department is directed to seek input/assistance from entities significantly affected by its regulations.

Accordingly, the Department, through the FAA, tasked ARAC to consider (1) recommendations on existing regulations that are good candidates for repeal, replacement, or modification and (2) recommendations on regulatory action identified in FAA's regulatory agenda.

The Task

The ARAC is tasked to:

1. Evaluate the FAA's regulations in Title 14 of the Code of Federal Regulations to determine any and all regulations that should be repealed, replaced or modified. This evaluation will attempt to identify regulations that:

a. Eliminate jobs, or inhibit job creation;

b. Are outdated, unnecessary, or ineffective;

c. Impose costs that exceed benefits; or

d. Create a serious inconsistency or otherwise interfere with regulatory reform initiatives and policies.

For purposes of this evaluation, a regulation means any regulatory provision and could include a regulatory section (*e.g.,* § 121.xxx), paragraph (*e.g.,* § 121.xxx(y)), or subparagraph (*e.g.,* § 121.xxx(y)(z)).

2. Provide a detailed explanation for recommending the repeal, replacement or modification of each regulation. This explanation will include any examples of why the regulation falls into one or more of the categories listed in paragraph 1.

3. Provide quantitative data on the costs and benefits of either repealing, replacing or modifying each regulation in the recommendation report.

4. Review the FAA's current regulatory actions identified in the regulatory agenda, and provide feedback on the current program as appropriate.

5. Develop both an initial report and an addendum report containing recommendations on the findings and results of the tasks explained above. This data will be provided in two recommendation reports. In the first recommendation report, ARAC will provide a list of regulations that are considered to address the criteria of paragraph 1 of this tasking. A second addendum recommendation report will provide details to supplement the first submittal by ARAC to the FAA, and will provide the additional and detailed data as described in paragraph 2, 3 and 4 of this tasking.

a. The recommendation report should document both majority and dissenting positions on the findings and the rationale for each position.

b. Any disagreements should be documented, including the rationale for each position and the reasons for the disagreement.

Schedule

This tasking notice requires two recommendation reports.

- The initial recommendation report must be submitted to the FAA no later than June 1, 2017, to allow for consideration of ARAC approval at the June 15, 2017 meeting.

After the initial recommendation report is submitted, the addendum recommendation report must be submitted to the FAA no later August 31, 2017, to allow for consideration of ARAC approval at the September 14, 2017, meeting. The Secretary of Transportation determined the formation and use of the ARAC is necessary and in the public interest in connection with the performance of duties imposed on the FAA by law. ARAC meetings are open to the public.

Issued in Washington, DC, on April 21, 2017.

Dale Bouffiou,

Alternate Designated Federal Officer, Aviation Rulemaking Advisory Committee.

[FR Doc. 2017–08564 Filed 4–27–17; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[FHWA Docket No. FHWA–2017–0006]

Fixing America's Surface Transportation Act (FAST Act); Equal Access for Over-the-Road Buses

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice; request for comment.

SUMMARY: The FHWA invites interested parties to review and comment on definitions and applicable facilities related to requirements contained in Section 1411(a) and (b) of the Fixing America's Surface Transportation (FAST) Act regarding the treatment of over-the-road buses (OTRBs). In addition, FHWA invites interested parties to review and comment on a listing of covered Section 129 Federal-aid toll facilities in the United States.

DATES: Comments must be received by May 30, 2017.

ADDRESSES: To ensure that you do not duplicate your docket submissions, please submit them by only one of the following means:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- *Mail:* U.S. Department of Transportation, Dockets Management Facility, Room W12–140, 1200 New Jersey Ave. SE., Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Ave. SE., between 9 a.m. 5p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 366–9329.

All comments must include the docket number DOT–FHWA–2017–0006 at the beginning of the submission.

Electronic Access: This document may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov.* Electronic submission and retrieval help and guidelines are available on the Web site. It is available 24 hours each day, 365 days each year. Please follow the instructions. An electronic copy of this document may also be downloaded from the Office of the Federal Register's Web site at: *http://www.archives.gov/federalregister* and the Government Publishing Office's Web site at: *http://www.gpo.gov/fdsys.*

FOR FURTHER INFORMATION CONTACT: Ms. Cynthia Essenmacher, Federal Tolling Program Manager, Center for Innovative Finance Support, Office of Innovative Program Delivery, Federal Highway Administration, 315 W. Allegan St., Room 201, Lansing, MI 48933, (517) 702–1856. For legal questions: Mr. Steven Rochlis, Office of the Chief Counsel, Federal Highway Administration, 1200 New Jersey Avenue SE., Washington, DC 20590, (202) 366–1395. Office hours are from 8:00 a.m. to 4:30 p.m. E.T., Monday through Friday, except for Federal holidays.

SUPPLEMENTARY INFORMATION:

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A. Background

The FAST Act includes a number of provisions that modify Federal requirements related to high-occupancy vehicle (HOV) facilities and the tolling of highways. Sections 1411(a) and (b) of the FAST Act contained new requirements regarding the treatment of over-the-road buses (OTRBs) that access toll highways and HOV facilities. Specifically, the FAST Act amended 23 U.S.C. 129 and 23 U.S.C. 166 to address access to toll or HOV facilities for OTRBs.

For HOV facilities, 23 U.S.C. 166(b)(3) was amended by the FAST Act, adding subparagraph (C) to grant HOV authorities an exception to allow public transportation vehicles (which FHWA interprets to include all public transportation vehicles, including public transportation buses) that do not meet the minimum occupancy requirements to use HOV lanes, but only if the HOV authority also gives equal access to OTRBs that serve the public. Under this exception provided in 23 U.S.C. 166(b), HOV authorities may allow all public transportation vehicles to use HOV lanes, whether they meet the minimum occupancy requirements, as long as they provide equal access to OTRBs serving the public, under the same rates, terms, and conditions as all other public transportation vehicles.

Additionally, 23 U.S.C. 166(b)(4)(C) was also amended by the FAST Act, adding subparagraph (iii), to grant HOV authorities the alternative to toll vehicles not meeting the minimum occupancy requirements in HOV lanes. In that case, HOV authorities are required to provide access to OTRBs that serve the public under the same rates, terms, and conditions as public transportation buses (which FHWA interprets to exclude other types of public transportation vehicles, which may be treated differently by the HOV authority). Similarly, on toll facilities subject to 23 U.S.C. 129, the FAST Act amended 23 U.S.C. 129(a) by adding paragraph (9) to also require that OTRBs that serve the public be provided access to the toll facility under the same rates, terms, and conditions as public transportation buses.

In preparing guidance to assist in the implementation of Section 1411 of the FAST Act, FHWA considered how to define key terms in Section 1411 as well as which facilities are governed by the new requirements. The FHWA is seeking comment on implementation of these terms as they relate to FAST Act Section 1411 amendments to 23 U.S.C. 129 and 166.

B. Applicable Definitions for Implementing Section 1411 of the FAST Act

For the purposes of implementing FAST Act Section 1411 amendments to 23 U.S.C. 129 and 166, FHWA intends to use definitions where they exist in relevant statutes and regulations. Where FHWA found no existing definition, such as for the term ''public transportation bus,'' FHWA developed a definition based on its interpretation of Congress's intent. The definitions for the key terms, are:

''*Over-the-road bus*'' is defined as a bus characterized by an elevated passenger deck located over a baggage compartment. *Source:* As amended by FAST Act Section 1411, 23 U.S.C. 129(a)(10)(C) and 23 U.S.C. 166(f)(4) define this term, giving it the same meaning as in Section 301 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12181).

''*Public Transportation Bus*'' is a category of public transportation vehicle (as defined in 23 U.S.C. 166(f)(6)), consisting of a motor vehicle with motive power, except a trailer, designed for carrying more than 10 persons. *Source:* The FHWA developed this definition by drawing upon definitions of similar or related terms. The FHWA incorporated the definition of ''public transportation vehicle'' in 23 U.S.C. 166(f)(6), and the definition of ''bus'' in 49 CFR 571.3.

''*Public Transportation Vehicle*'' means a vehicle that (A) provides designated public transportation (as defined in section 221 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12141)) or provides public school transportation (to and from public or private primary, secondary, or tertiary schools); and (B)(i) is owned or operated by a public entity; (ii) is operated under a contract with a public entity; or (iii) is operated pursuant to a license by the Secretary or a State agency to provide motorbus or school vehicle transportation services to the public. *Source:* This term is defined in 23 U.S.C. 166(f)(6).

''*Serve/Serving the Public*'' means provision of service to the general public, including general or special service (including charter service) on a regular and continuing basis. *Source:* This term has a similar meaning as the term ''designated public transportation'' in Section 221 of the Americans with Disabilities Act of 1990 (42 U.S.C. 12141).

''*Toll Facility*'' means a toll highway, bridge, or tunnel or approach to the highway, bridge, or tunnel constructed under 23 U.S.C. 129(a). *Source:* This term has the same meaning as the term is given in 23 U.S.C. 129(a)(10)(E).

C. Covered Facilities Subject to OTRB Equal Access

Section 129 Facilities

Section 1411(a) of the FAST Act amends 23 U.S.C. 129 to provide that, ''An over-the-road bus that serves the public shall be provided access to a toll facility under the same rates, terms, and conditions as public transportation buses.'' 23 U.S.C. 129(a)(9). A toll facility is defined in 23 U.S.C. 129(a)(10)(E) (as amended by the FAST Act) as: ''a toll highway, bridge, or tunnel or approach to the highway, bridge, or tunnel constructed under [section 129(a)].''

Facilities ''constructed under'' Section 129 includes both facilities subject to Section 129 tolling agreements executed prior to the Moving Ahead for Progress in the 21st Century Act (MAP–21)(Pub. L. 112–141) (which eliminated the statutory requirement for a Section 129 toll agreement), and facilities that have become (or will become) subject to Section 129 post-MAP–21 (which may, or may not, have a tolling Memorandum of Understanding with FHWA). This would include a facility that either uses Federal-aid funds on an existing toll facility in accordance with Section 129(a), or imposes tolls on a facility constructed with Federal-aid funds pursuant to Section 129(a).

Section 166 Facilities

For HOV facilities under 23 U.S.C. 166, Section 1411(b) of the FAST Act added Section 166(b)(3)(C), which requires any authority that allows public transportation vehicles to use an HOV facility to provide equal access to the facility under the same rates, terms, and conditions for all public transportation vehicles and OTRBs serving the public. The FAST Act also added Section 166(b)(4)(C)(iii), which provides that if an authority operates HOT lanes that allow vehicles not otherwise exempt under 23 U.S.C. 166(b) to pay a toll to use the facility, the authority must ensure that OTRBs serving the public are provided access to the facility under the same rates, terms, and conditions as public transportation buses.

Under 23 U.S.C. 166(f)(2), the term ''HOV facility'' means a high occupancy vehicle facility. There are no exclusions or exceptions under this definition based on Federal-aid participation in the construction or operation of the HOV facility. Therefore, FHWA believes amendments made by Section 1411 of the FAST Act are applicable to all Section 166 HOV facilities, regardless of Federal-aid participation in the project.

D. Covered Section 129 Facilities List

The Section 129 Covered Facilities list can be found on the docket for this **Federal Register** Notice. Federal-aid toll facilities that were constructed under other Federal tolling authorities and not subject to Section 1411 of the FAST Act are also included in the docket list of covered facilities for reference. Other Federal tolling authorities include the Surface Transportation and Uniform Relocation Assistance Act of 1987 (Pub. L. 100–17) and the Intermodal Surface Transportation Efficiency Act of 1991 (Pub. L. 102–240).

The FHWA invites comment on the accuracy and completeness of the list of facilities subject to OTRB equal access.

E. Request for Comment

The FHWA is seeking public comment on the following specific sections of this **Federal Register** Notice:

(1) Applicable definitions for implementing Section 1411 of the FAST Act,

(2) Covered facilities subject to OTRB equal access, and

(3) OTRB Section 129 Covered Facilities list.

The OTRB Section 129 Covered Facilities list can be found on the docket for this **Federal Register** Notice.

Commenters are encouraged to address any or all of the areas listed above. Commenters are also encouraged to provide specific information on toll facilities subject to OTRB requirements that are not included on the Section 129 Covered Facilities-OTRB list. Commenters may also describe why they believe certain facilities should be included in the Section 129 Covered Facilities-OTRB list. This description should include such information as the facility name, location, route designation, and owner/operator.

Commenters are also encouraged to focus on matters within the control of FHWA. (Matters not within the control of FHWA include such items as HOV occupancy requirements at specific facilities, setting of toll rates, or Federal Transit Administration laws.) The FHWA will consider public comment before adopting its final guidance on OTRBs.

Issued on: April 24, 2017.

Walter C. Waidelich, Jr.,

Acting Deputy Administrator, Federal Highway Administration.

[FR Doc. 2017–08587 Filed 4–27–17; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket Number NHTSA–2016–0131]

Reports, Forms and Recordkeeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) this notice announces NHTSA has submitted to the Office of Management and Budget (OMB) a request for emergency clearance and review for existing information collection 2127–0025. Approval of this collection is essential to the mission of the agency.

While NHTSA has requested a temporary emergency clearance for this collection, the agency is also in the process of requesting a full clearance for this collection and has already published a 30-day **Federal Register** notice requesting comment. This notice repeats that request for comments.

DATES: Comments on the already published request for comments must be received on or before May 22, 2017. We

have requested that OMB take action on the emergency collection by April 30, 2017.

ADDRESSES: Send comments, by May 22, 2017, to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: NHTSA Desk Officer.

FOR FURTHER INFORMATION CONTACT: Michael Kuppersmith, National Highway Traffic Safety Administration, Office of the Chief Counsel (NCC–0010), (202) 366–5263, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION: NHTSA has requested emergency Paperwork Reduction Act clearance for its confidential business information collection (2127–0025) given the agency's current collection expires April 30, 2017, and use of this collection is essential to the mission of the agency. NHTSA published a 60-day renewal for this collection on December 28, 2016 (81 FR 95729), and received no comments. NHTSA published a 30-day notice for this collection on April 21, 2017 (82 FR 18825), and the comment period remains open until May 22, 2017. The agency again requests any comments from the public on this request by that date.

NHTSA expects that it will receive approximately 500 requests for confidentiality per year. With an estimated eight hours of preparation to collect and provide the information for each request, at an assumed rate of $24.92 per hour, the annual estimated cost of collecting and preparing the information necessary for 500 complete requests for confidential treatment is about $99,680 (8 hours of preparation × 500 requests × $24.92). Adding in a postage cost of $3,325 (500 requests at a cost of $6.65 for postage (priority flat rate envelope from USPS)), we estimate that it will cost $103,005 per year for persons to prepare and submit the information necessary to satisfy the confidential business information provisions of 49 CFR part 512.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimate of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. A comment to OMB is most effective if OMB receives it by May 22, 2017.

Issued in Washington, DC, under authority delegated in 49 CFR 1.95.

Jack Danielson,

Acting Deputy Administrator, NHTSA.

[FR Doc. 2017–08641 Filed 4–27–17; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Sanctions Actions Pursuant to Executive Order 13582

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of 271 persons whose property and interests in property are blocked pursuant to E.O. 13582.

DATES: OFAC's actions described in this notice were effective on April 24, 2017.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel. 202–622–4855; 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 Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's Web site (*www.treasury.gov/ofac*).

Notice of OFAC Actions

On April 24, 2017, OFAC designated the following 271 persons pursuant to section 1(b)(i) of E.O. 13582, ''Blocking Property of the Government of Syria and Prohibiting Certain Transactions with Respect to Syria'' (E.O. 13582) for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services in support of, the Government of Syria, a person whose property and interests in property are blocked pursuant to E.O. 13582. OFAC also designated the following 271 persons pursuant to section 1(b)(ii) of E.O. 13582 for having acted or purported to act for or on behalf of, directly or indirectly, Government of Syria, a person whose property and interests in property are blocked pursuant to E.O. 13582:

Individuals

1. AL–BAKKUR, 'Abd-al-'Azim, Syria; DOB 14 Nov 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
2. 'ABD–AL–QADIR, Abd-al-'Aziz, Syria; DOB 01 Feb 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
3. SHURUF, 'Abd-al-Hakim, Syria; DOB 25 Apr 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
4. 'ABDU, Abdallah, Syria; DOB 05 Dec 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
5. JUNDIYAH, Abdallah, Syria; DOB 01 Nov 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
6. HAFIZ, Abdallah, Syria; DOB 27 Jun 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
7. AL-HASAN, Abdallah, Syria; DOB 15 Jun 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
8. KITU', 'Abd-al-Latif, Syria; DOB 28 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
9. ZAMR, 'Abd-al-Nasir Ibbi, Syria; DOB 01 Jul 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
10. BASAL, Abd-al-Rahman, Syria; DOB 03 Mar 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
11. AL-RASLAN, Abd-al-Salam, Syria; DOB 17 Nov 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
12. MA'RUF, Abd-al-Salam, Syria; DOB 04 Apr 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
13. SHURAYQI, 'Abd-al-Salam, Syria; DOB 14 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
14. AL-MATAR, 'Abdu Tahir, Syria; DOB 17 Oct 1965; nationality Syria; Scientific Studies and Research

Center Employee (individual) [SYRIA].
15. KHAYMI, Abir 'Abd-al-Karim, Syria; DOB 01 Dec 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
16. AL-JUBBAH, Adnan, Syria; DOB 11 Apr 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
17. AL-MASRI, Ahd, Syria; DOB 01 May 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
18. BITAR, Ahd, Syria; DOB 23 Jun 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
19. JADDU', Ahd, Syria; DOB 22 Apr 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
20. HAMDAN, Ahmad, Syria; DOB 15 Mar 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
21. 'ALI, Ahmad, Syria; DOB 02 Dec 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
22. ZARIFAH, Ahmad, Syria; DOB 09 Nov 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
23. DAHIR, Ahmad, Syria; DOB 20 Jun 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
24. DAWARAH, Ahmad, Syria; DOB 21 Feb 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
25. SABUNI, Ahmad, Syria; DOB 23 Dec 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
26. SALIM, Ahmad, Syria; DOB 29 Aug 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
27. ASWAD, Ahmad, Syria; DOB 21 Aug 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
28. NAJIB, Ahmad, Syria; DOB 04 Oct 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
29. HAMAWI, Ahmad, Syria; DOB 15 Jul 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
30. 'ABD-AL-WAHHAB, Ahmad, Syria; DOB 01 Jan 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
31. KHALALU, Ahmad, Syria; DOB 01 Jan 1978; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
32. AL-'ABD, Ahmad, Syria; DOB 28 Jan 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
33. 'ABUD, Ahmad, Syria; DOB 28 May 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
34. AL-SILMU, Ahmad al-Hasan, Syria; DOB 28 Jun 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
35. BASHA, Ahmad Nadir Ibrahim, Syria; DOB 15 Apr 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
36. SULAYMAN, Akram, Syria; DOB 14 Apr 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
37. AL-QUTMAH, Akram, Syria; DOB 04 Dec 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
38. JUKHDAR, 'Ala'-al-Din, Syria; DOB 03 Mar 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
39. DARWISH, Ali, Syria; DOB 02 Mar 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
40. ASWAD, Ali, Syria; DOB 10 Nov 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
41. IBRAHIM, Ali, Syria; DOB 28 Feb 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
42. JUMUL, Ali, Syria; DOB 07 Feb 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
43. HUSAYN, 'Ali, Syria; DOB 20 Mar 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
44. IBRAHIM, 'Ali, Syria; DOB 25 Mar 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
45. MUHAMMAD, 'Ali Hajj, Syria; DOB 05 Mar 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
46. HUDBAH, Amin, Syria; DOB 09 Nov 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
47. MAJRUD, Amin, Syria; DOB 03 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
48. AL-MUKAHHAL, Aminah, Syria; DOB 01 Jan 1988; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
49. MUSHRIF, Amir, Syria; DOB 10 Jun 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
50. HASAN, Ammar, Syria; DOB 01 Jul 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
51. DAYRI, Ammar, Syria; DOB 06 Mar 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
52. AL-ISMA'IL, Ammar Fu'ad, Syria; DOB 25 Sep 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
53. AL-WADI, Anas, Syria; DOB 21 May 1987; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
54. MIRKAN, Anas 'Adil, Syria; DOB 01 Jul 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
55. HASAN, As'ad, Syria; DOB 24 Dec 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
56. HALLAQ, As'ad 'Adnan, Syria; DOB 08 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
57. ISMA'IL, Ayham, Syria; DOB 20 Jan 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
58. MUSTAFA, Ayham Hajj, Syria; DOB 16 Aug 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
59. AL-DALATI, Ayman, Syria; DOB 20 Aug 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
60. AHMAD, Ayman, Syria; DOB 01 Feb 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
61. RASHID, Badr, Syria; DOB 01 Jan 1987; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
62. AL-LAYIQ, Baha', Syria; DOB 31 Aug 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
63. SA'ADAT, Bashar, Syria; DOB 16 Jul 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].

64. AL-HALABI, Basil, Syria; DOB 01 Feb 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
65. SHA'BAN, Basil, Syria; DOB 25 Jan 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
66. WARDAH, Bassam, Syria; DOB 20 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
67. HASAN, Bilal, Syria; DOB 01 Jan 1978; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
68. SULAYMAN, Dayma, Syria; DOB 29 Sep 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
69. WAFA'I, Diya', Syria; DOB 07 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
70. AL-SHAYKH, Diyab, Syria; DOB 11 Dec 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
71. AL-RAHYAH, Fadi, Syria; DOB 27 Dec 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
72. ZA'RURAH, Fadiyah, Syria; DOB 26 Jan 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
73. MAHFUD, Farhan, Syria; DOB 11 Sep 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
74. FADUL, Farhub, Syria; DOB 15 Jul 1951; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
75. MUSTAFA, Fayiz, Syria; DOB 01 Jan 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
76. BUZ-AL-JUDDI, Fayiz, Syria; DOB 22 Feb 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
77. BU'AYTI, Faysal, Syria; DOB 01 Jan 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
78. MUHAMMAD, Faysal, Syria; DOB 20 Feb 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
79. KHALUF, Faysal, Syria; DOB 21 May 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
80. MUSA, Firas, Syria; DOB 13 Jul 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
81. SALIM, Firas Hajj, Syria; DOB 10 May 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
82. QATISH, Firiyal, Syria; DOB 26 Jan 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
83. 'AZIZI, Fu'ad, Syria; DOB 28 Mar 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
84. IBRAHIM, Fu'ad 'Abd-al-Qadir, Syria; DOB 24 Nov 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
85. SAFTALI, Ghassan, Syria; DOB 20 Feb 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
86. AL-SHAWWA, Ghayth, Syria; DOB 13 Apr 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
87. AL-FAWAKHIRI, Ghusn al-Zuhur, Syria; DOB 01 Jan 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
88. SHUAYHANAH, Hadil, Syria; DOB 20 May 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
89. SIRHAN, Hala, Syria; DOB 05 Jan 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
90. FARAJ, Hala, Syria; DOB 22 Mar 1987; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
91. JUM'AH, Hamid, Syria; DOB 01 Mar 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
92. AL-'AZBAH, Hana, Syria; DOB 15 Feb 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
93. HUSAYN, Hanan, Syria; DOB 20 Apr 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
94. JAHHAR, Hannan, Syria; DOB 02 Jan 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
95. AHMAD, Hasan, Syria; DOB 13 May 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
96. KHADDUR, Hasan, Syria; DOB 26 Aug 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
97. ZAYD, Hasan Muhammad, Syria; DOB 15 Feb 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
98. AL-RAYS, Hassan, Syria; DOB 03 Nov 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
99. ASMAR, Haytham, Syria; DOB 02 Nov 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
100. SHUNATI, Haytham, Syria; DOB 04 Jun 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
101. AL-HURANI, Haytham Ahmad, Syria; DOB 05 Jan 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
102. 'ABDU, Hikmat, Syria; DOB 12 Mar 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
103. 'ABBUD, Hikmat, Syria; DOB 01 Jan 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
104. JIRJIS, Hiyam, Syria; DOB 07 Oct 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
105. HAMSHU, Hudu' Nayif, Syria; DOB 08 Jan 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
106. AL-FAKHURI, Husam 'Adbd-al-Barr, Syria; DOB 10 Feb 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
107. TAHA, Husam a-Sahykh, Syria; DOB 14 Jan 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
108. JALAL, Husam-al-Din, Syria; DOB 01 Aug 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
109. KALALAH, Husam-al-Din Walid, Syria; DOB 04 Jan 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
110. JAWISH, Husayn Rida, Syria; DOB 07 Apr 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
111. AL-BAYKU, Husayn-Ahmad, Syria; DOB 10 May 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].

112. IDRIS, Ibrahim, Syria; DOB 05 Apr 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
113. AL-KHUWAYLID, Ibrahim, Syria; DOB 25 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
114. MUSTAFA, Ibrahim, Syria; DOB 06 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
115. JAZBAH, Ibrahim Sa'd Zayn-al-'Abidin, Syria; DOB 02 Apr 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
116. NUR-AL-DIN, Imad, Syria; DOB 29 Jul 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
117. BASHA, Imad Isma'il, Syria; DOB 12 May 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
118. AL-TAWWAKHI, Iman, Syria; DOB 04 Mar 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
119. NASR, Isa, Syria; DOB 20 Apr 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
120. KHIDR, Isa, Syria; DOB 27 Jan 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
121. 'ALI, Isma'il, Syria; DOB 20 Jun 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
122. AL-SHURAYQI, Isma'il, Syria; DOB 14 Jul 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
123. SALIM, Iyad, Syria; DOB 12 Dec 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
124. JIJAH, Jalal-al-Din 'Adil, Syria; DOB 20 Jan 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
125. AL-AQRA', Jamal 'Ali, Syria; DOB 17 Apr 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
126. SHAHT, Jamal Zaydan, Syria; DOB 06 Feb 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
127. TAHA, Jamilah, Syria; DOB 09 Oct 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
128. NA'SANI, Jawdat, Syria; DOB 08 Jun 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
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130. AL-SASI, Jumanah, Syria; DOB 05 Oct 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
131. AL-MAHMUD, Khalid, Syria; DOB 20 Sep 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
132. AL-BAKUR, Khalid, Syria; DOB 25 Jan 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
133. AL-'AYSH, Khalid al-Hajj Muhammad, Syria; DOB 05 Jun 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
134. QANBAR, Khalid Zaki, Syria; DOB 20 Apr 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
135. MANSUR, Khalil, Syria; DOB 11 Mar 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
136. DA'UD, Lu'ay, Syria; DOB 13 Oct 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
137. FU'ANI, Lu'ay, Syria; DOB 02 Apr 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
138. AL-HARZRURI, Mahmubd, Syria; DOB 19 Nov 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
139. ZANBU'AH, Mahmud, Syria; DOB 30 Jul 1974; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
140. RAHHAL, Mahmud, Syria; DOB 25 Jun 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
141. SA'ID, Majd, Syria; DOB 25 Nov 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
142. KARIM, Malik 'Adil, Syria; DOB 16 May 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
143. GHANIM, Ma'n, Syria; DOB 03 May 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
144. AL-HUSAYN, Mashhur, Syria; DOB 01 Jan 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
145. DIB, Mashhur, Syria; DOB 20 May 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
146. QATTAN, Maysa', Syria; DOB 25 Feb 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
147. 'ALYA, Mazin, Syria; DOB 28 Feb 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
148. MAWAS, Milad, Syria; DOB 25 Dec 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
149. MIRDASH, Misbah, Syria; DOB 02 Jan 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
150. AL-IBRAHIM, Muhammad, Syria; DOB 08 Mar 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
151. SALLUM, Muhammad, Syria; DOB 31 Oct 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
152. HUSAYN, Muhammad, Syria; DOB 25 Feb 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
153. BIZRAH, Muhammad, Syria; DOB 12 Mar 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
154. HAWWAT, Muhammad, Syria; DOB 10 Mar 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
155. SALMAN, Muhammad, Syria; DOB 03 Mar 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
156. AL-RAHHAL, Muhammad, Syria; DOB 01 Mar 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
157. AL-SHAYKH, Muhammad, Syria; DOB 08 Mar 1971; nationality Syria; Scientific Studies and Research

Center Employee (individual) [SYRIA].
158. 'ABDALLAH, Muhammad, Syria; DOB 05 Apr 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
159. HAMANDUSH, Muhammad, Syria; DOB 09 Jan 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
160. SA'DU, Muhammad, Syria; DOB 20 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
161. AL-MUHAMMAD, Muhammad, Syria; DOB 02 Feb 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
162. 'ARAFAT, Muhammad, Syria; DOB 28 Jul 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
163. 'ALI, Muhammad, Syria; DOB 01 Aug 1979; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
164. HAITANI, Muhammad, Syria; DOB 03 Sep 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
165. HARIRI, Muhammad, Syria; DOB 27 Aug 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
166. 'ALI, Muhammad, Syria; DOB 30 Aug 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
167. AL-BURSHAH, Muhammad Akram, Syria; DOB 30 Aug 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
168. KHASHAFI, Muhammad al-Khalid, Syria; DOB 21 May 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
169. NAJJAR, Muhammad Amin, Syria; DOB 08 Nov 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
170. AL-KHUDAYR, Muhammad 'Arif al-Hasan, Syria; DOB 05 Sep 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
171. SALIM, Muhammad Ayman Nasir-al-Din, Syria; DOB 23 Jun 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
172. SHI'AR, Muhammad 'Azzam, Syria; DOB 02 Sep 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
173. HAJJI, Muhammad Fawzi, Syria; DOB 25 Jun 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
174. TALLUJ, Muhammad Ghassan, Syria; DOB 15 Jan 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
175. 'ABD-AL-SAMAD, Muhammad Haytham, Syria; DOB 05 Sep 1947; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
176. YUSUF, Muhammad Hisham Fu'ad, Syria; DOB 29 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
177. AL-NA'IMI, Muhammad Iyad, Syria; DOB 29 Oct 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
178. HILALI, Muhammad Jalal, Syria; DOB 10 Nov 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
179. SUKHAYTAH, Muhammad Khayr, Syria; DOB 18 May 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
180. QURJU, Muhammad Mu'ammar, Syria; DOB 02 Aug 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
181. ZIHAR, Muhammad Nadim Subhi, Syria; DOB 29 Mar 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
182. SABBAGH, Muhammad Nasir, Syria; DOB 26 Nov 1954; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
183. MUHAYIRI, Muhammad Nasir, Syria; DOB 29 Nov 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
184. DABBAGH, Muhammad Nazmi 'Ulwani, Syria; DOB 01 Jan 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
185. QUDAYMATI, Muhammad Ridwan, Syria; DOB 12 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
186. HIMSI, Muhammad Riyad, Syria; DOB 08 Nov 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
187. AL-HAKIM, Muhammad Sa'id, Syria; DOB 01 Apr 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
188. AL-FAQIR, Muhammad Samir, Syria; DOB 21 Jan 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
189. NASR, Muhammad Sayyah, Syria; DOB 23 Aug 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
190. TURAYSI, Muhammad Wa'il, Syria; DOB 14 Feb 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
191. AL-MUDALLAL, Muhammad Zuhayr, Syria; DOB 24 May 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
192. YUSUF, Muhsin, Syria; DOB 17 May 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
193. AL-FIRAS, Muhsin, Syria; DOB 20 Jan 1979; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
194. KHABIYYAH, Muna, Syria; DOB 01 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
195. AS'AD, Murad, Syria; DOB 28 Jan 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
196. AL-HARIRI, Musa, Syria; DOB 19 Jun 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
197. AL-'UBAYSI, Mus'id, Syria; DOB 01 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
198. ZAYDAN, Mustafa, Syria; DOB 09 Jan 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
199. RABI', Mustafa Dib, Syria; DOB 10 Nov 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
200. AL-DAGHISTANI, Muzayyin, Syria; DOB 03 Apr 1959; nationality Syria; Scientific Studies and Research

Center Employee (individual) [SYRIA].
201. SHARBA, Muzhir, Syria; DOB 23 Feb 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
202. AL-DAWUD, Nariman, Syria; DOB 16 Feb 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
203. 'AWDAH, Nasim, Syria; DOB 19 Feb 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
204. MUTAWIJ, Nawar, Syria; DOB 23 Sep 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
205. AL-ID, Nawras, Syria; DOB 13 Aug 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
206. AL-SA'ID, Nidal, Syria; DOB 18 Apr 1976; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
207. 'ID, Nisrin Bubhi, Syria; DOB 26 May 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
208. BAWADUQJI, Nur-al-Din, Syria; DOB 07 Jan 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
209. AL-NAJJAR, Qasim, Syria; DOB 01 Feb 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
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212. DAYYUB, Rajab, Syria; DOB 01 Jan 1963; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
213. BUNDUQJI, Rana, Syria; DOB 09 Jan 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
214. SAQR, Rana, Syria; DOB 01 Oct 1979; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
215. 'ULAYSHAH, Rana, Syria; DOB 25 Oct 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
216. AYYUBI, Rashid, Syria; DOB 25 Jul 1954; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
217. NI'MA, Rashid Rashid, Syria; DOB 01 Dec 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
218. AL-KHATIB, Ridwan, Syria; DOB 03 Sep 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
219. AL-JIBAWI, Ridwan 'Ali, Syria; DOB 25 Mar 1959; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
220. 'ALLUSH, Ridwan Hasan, Syria; DOB 20 May 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
221. 'ABBAS, Rim, Syria; DOB 25 Mar 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
222. AL-TAQI, Rim Nadir, Syria; DOB 15 Sep 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
223. AL–AHMAD, Riyad, Syria; DOB 15 Mar 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
224. DUWAYR, Ruba, Syria; DOB 19 Apr 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
225. KIWAN, Rula, Syria; DOB 10 May 1974; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
226. SA'ADAH, Ruwaydah, Syria; DOB 10 Feb 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
227. NASIF, Saba, Syria; DOB 12 Sep 1986; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
228. AL–TABBAL, Saba, Syria; DOB 08 Apr 1972; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
229. MUSATTIT, Sabir Khayr, Syria; DOB 20 Feb 1977; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
230. LABABIDI, Sa'dallah 'Atif, Syria; DOB 22 Sep 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
231. AL–AKHRAS, Safwan, Syria; DOB 27 Jan 1950; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
232. SINDID, Sa'id, Syria; DOB 27 Nov 1952; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
233. SA'ID, Sa'id, Syria; DOB 11 Dec 1955; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
234. FARMAND, Sa'id, Syria; DOB 10 Oct 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
235. AL-'ALI, Salih, Syria; DOB 05 Jul 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
236. DUMIT, Salim, Syria; DOB 11 Jul 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
237. AL–JABI, Salma, Syria; DOB 02 Apr 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
238. MUKHAYBIR, Salma, Syria; DOB 21 Jul 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
239. JAWISH, Samar Shakir, Syria; DOB 01 May 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
240. ANIS, Samih, Syria; DOB 19 Jul 1957; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
241. AL–SHA'IR, Samir, Syria; DOB 12 Sep 1978; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
242. 'ALI, Samir, Syria; DOB 12 May 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
243. AL–YUSUF, Samir al-Ahmad, Syria; DOB 02 May 1975; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
244. BABA, Samiya, Syria; DOB 26 Feb 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
245. 'ABDALLAH, Sayyar, Syria; DOB 15 May 1973; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
246. SALMAN, Shadi, Syria; DOB 26 Oct 1982; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
247. SAQR, Sinan, Syria; DOB 15 Apr 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
248. MUHANNA, Siwumar, Syria; DOB 03 Dec 1984; nationality Syria; Scientific Studies and Research

Center Employee (individual) [SYRIA].
249. AL–HUSAYN, Suhayr, Syria; DOB 17 Feb 1983; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
250. AL–JANAN, Sulsubayla, Syria; DOB 04 Jan 1964; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
251. LAYLA, Susan, Syria; DOB 12 Jul 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
252. AL–DARWISH, Tamam, Syria; DOB 23 Jul 1969; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
253. SULAYMAN, Taysir, Syria; DOB 22 Aug 1968; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
254. DAYYUB, Tha'ir, Syria; DOB 01 Dec 1971; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
255. HIJAZI, Umar, Syria; DOB 01 Jun 1962; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
256. MALA'IKAH, Usamah Ramadan, Syria; DOB 27 Aug 1984; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
257. NAJJAR, Wafa', Syria; DOB 01 May 1953; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
258. HUSAYN, Wahid, Syria; DOB 01 Apr 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
259. AL–SA'ID, Wasim, Syria; DOB 02 Jan 1980; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
260. SALMAN, Wasim, Syria; DOB 05 May 1985; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
261. 'ABD–AL–JALIL, Yahya, Syria; DOB 26 Sep 1960; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
262. AL–ATASI, Yumna Marwan al-Sayyid Sulayman, Syria; DOB 07 Jan 1967; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
263. SA'UD, Yunus, Syria; DOB 01 Apr 1958; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
264. AL–HATUM, Yusuf, Syria; DOB 05 Jan 1966; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
265. MA'TUQ, Yusuf, Syria; DOB 30 May 1981; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
266. AL-'ASALI, Zakariya, Syria; DOB 03 Jun 1961; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
267. AL-'ALI, Zakariya, Syria; DOB 05 May 1970; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
268. AL–ISMA'IL, Zakariya 'Ali, Syria; DOB 14 Aug 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
269. 'AQQAD, Ziyad, Syria; DOB 02 Aug 1950; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
270. LULAH, Ziyad Ramadan, Syria; DOB 01 Jan 1965; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].
271. RABAH, Zuhayr, Syria; DOB 07 Jan 1956; nationality Syria; Scientific Studies and Research Center Employee (individual) [SYRIA].

Dated: April 24, 2017.

Andrea M. Gacki,

Acting Director, Office of Foreign Assets Control.

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DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury.

ACTION: Notice of availability; request for comments.

SUMMARY: The Board of Trustees of the Alaska Ironworkers Pension Trust, a multiemployer pension plan, has submitted an application to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014. The purpose of this notice is to announce that the application submitted by the Board of Trustees of the Alaska Ironworkers Pension Trust has been published on the Treasury Web site, and to request public comments on the application from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Alaska Ironworkers Pension Trust.

DATES: Comments must be received by June 12, 2017.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov,* in accordance with the instructions on that site. Electronic submissions through *www.regulations.gov* are encouraged.

Comments may also be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue NW., Room 1224, Washington, DC 20220. Attn: Eric Berger. Comments sent via facsimile and email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on *www.regulations.gov* or upon request. Comments posted on the Internet can be retrieved by most Internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the Alaska Ironworkers Pension Trust, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The Multiemployer Pension Reform Act of 2014 (MPRA) amended the Internal Revenue Code to permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which Treasury, in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor, is required to approve or deny.

On March 30, 2017, the Board of Trustees of the Alaska Ironworkers Pension Trust submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's Web site at *https://auth.treasury.gov/services/Pages/Plan-Applications.aspx.* Treasury is publishing this notice in the **Federal Register**, in consultation with the PBGC and the Department of Labor, to solicit

public comments on all aspects of the Alaska Ironworkers Pension Trust application.

Comments are requested from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the Alaska Ironworkers Pension Trust. Consideration will be given to any comments that are timely received by Treasury.

Dated: April 25, 2017.

Robert J. Neis,

Benefits Tax Counsel, Office of Tax Policy.

[FR Doc. 2017–08714 Filed 4–27–17; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Multiemployer Pension Plan Application To Reduce Benefits

AGENCY: Department of the Treasury.

ACTION: Notice of availability; request for comments.

SUMMARY: The Board of Trustees of the International Association of Machinists Motor City Pension Fund (IAM Motor City Pension Fund), a multiemployer pension plan, has submitted an application to reduce benefits under the plan in accordance with the Multiemployer Pension Reform Act of 2014. The purpose of this notice is to announce that the application submitted by the Board of Trustees of the IAM Motor City Pension Fund has been published on the Treasury Web site, and to request public comments on the application from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the IAM Motor City Pension Fund.

DATES: Comments must be received by June 12, 2017.

ADDRESSES: You may submit comments electronically through the Federal eRulemaking Portal at *http://www.regulations.gov,* in accordance with the instructions on that site. Electronic submissions through *www.regulations.gov* are encouraged.

Comments may also be mailed to the Department of the Treasury, MPRA Office, 1500 Pennsylvania Avenue NW., Room 1224, Washington, DC 20220. Attn: Eric Berger. Comments sent via facsimile and email will not be accepted.

Additional Instructions. All comments received, including attachments and other supporting materials, will be made available to the public. Do not include any personally identifiable information (such as Social Security number, name, address, or other contact information) or any other information in your comment or supporting materials that you do not want publicly disclosed. Treasury will make comments available for public inspection and copying on *www.regulations.gov* or upon request. Comments posted on the Internet can be retrieved by most Internet search engines.

FOR FURTHER INFORMATION CONTACT: For information regarding the application from the IAM Motor City Pension Fund, please contact Treasury at (202) 622–1534 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The Multiemployer Pension Reform Act of 2014 (MPRA) amended the Internal Revenue Code to permit a multiemployer plan that is projected to have insufficient funds to reduce pension benefits payable to participants and beneficiaries if certain conditions are satisfied. In order to reduce benefits, the plan sponsor is required to submit an application to the Secretary of the Treasury, which Treasury, in consultation with the Pension Benefit Guaranty Corporation (PBGC) and the Department of Labor, is required to approve or deny.

On March 29, 2017, the Board of Trustees of the IAM Motor City Pension Fund submitted an application for approval to reduce benefits under the plan. As required by MPRA, that application has been published on Treasury's Web site at *https://auth.treasury.gov/services/Pages/Plan-Applications.aspx.* Treasury is publishing this notice in the **Federal Register**, in consultation with the PBGC and the Department of Labor, to solicit public comments on all aspects of the IAM Motor City Pension Fund application.

Comments are requested from interested parties, including participants and beneficiaries, employee organizations, and contributing employers of the IAM Motor City Pension Fund. Consideration will be given to any comments that are timely received by Treasury.

Dated: April 25, 2017.

Robert J. Neis,

Benefits Tax Counsel, Office of Tax Policy.

[FR Doc. 2017–08715 Filed 4–27–17; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Meeting of the Cooperative Studies Scientific Evaluation Committee

The Department of Veterans Affairs gives notice under the Federal Advisory Committee Act, 5 U.S.C. App. 2, that the Cooperative Studies Scientific Evaluation Committee will hold a meeting on June 29, 2017, at the American Association of Airport Executives, 601 Madison Street, Alexandria, VA. The meeting will begin at 8:30 a.m. and end at 12:30 p.m.

The Committee advises the Chief Research and Development Officer on the relevance and feasibility of proposed projects and the scientific validity and propriety of technical details, including protection of human subjects.

The session will be open to the public for approximately 30 minutes at the start of the meeting for the discussion of administrative matters and the general status of the program. The remaining portion of the meeting will be closed to the public for the Committee's review, discussion, and evaluation of research and development applications.

During the closed portion of the meeting, discussions and recommendations will deal with qualifications of personnel conducting the studies, staff and consultant critiques of research proposals and similar documents, and the medical records of patients who are study subjects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy. As provided by section 10(d) of Public Law 92–463, as amended, closing portions of this meeting is in accordance with 5 U.S.C. 552b(c)(6) and (c)(9)(B).

The Committee will not accept oral comments from the public for the open portion of the meeting. Those who plan to attend or wish additional information should contact Dr. Grant Huang, Acting Director, Cooperative Studies Program (10P9CS), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, at (202) 443–5700 or by email at *grant.huang@va.gov.* Those wishing to submit written comments may send them to Dr. Huang at the same address and email.

Dated: April 25, 2017.

LaTonya L. Small, Ed.D.,

Federal Advisory Committee Management Officer.

[FR Doc. 2017–08653 Filed 4–27–17; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Availability of a Final Environmental Impact Statement for a Replacement Robley Rex Veterans Affairs Medical Center, Louisville, Kentucky

AGENCY: Department of Veterans Affairs.

ACTION: Notice of availability.

SUMMARY: The Department of Veterans Affairs (VA) announces the availability of the Final Environmental Impact Statement (EIS) for the siting, construction, and operation of a new campus to replace the existing Robley Rex VA Medical Center (VAMC), Veterans Benefits Administration (VBA) regional office, and three community-based outpatient clinics (CBOC) in Louisville, Kentucky. Pursuant to the National Environmental Policy Act (NEPA) of 1969, as amended, the Council on Environmental Quality's (CEQ's) regulations for implementing the procedural provisions of NEPA, and VA's NEPA regulations titled ''Environmental Effects of the Department of Veterans Affairs Actions,'' VA has considered comments received on the Draft EIS, which was issued in October 2016 and identifies VA's preferred alternative in the Final EIS.

DATES: VA will publish a Record of Decision no sooner than 30 days after publication of the U.S. Environmental Protection Agency's Notice of Availability in the **Federal Register**.

ADDRESSES: The 2017 Final EIS is available for viewing on the Web site *www.louisville.va.gov/newmedicalcenter/*. Copies are also available at the St. Matthews and Westport Branches of the Louisville Free Public Library located at 3940 Grandview Avenue, Louisville, KY 40207 and 8100 Westport Road, Louisville, KY 40222.

FOR FURTHER INFORMATION CONTACT: Replacement VAMC Activation Team Office, 800 Zorn Avenue, Louisville, KY 40206 or by email to *Louisville ReplacementHospitalComments@va.gov.*

SUPPLEMENTARY INFORMATION: VA plans to site, construct, and operate a VAMC and VBA regional office to replace the existing Robley Rex VAMC located on Zorn Avenue in Louisville, KY. The existing 63-year-old VAMC facilities have reached the end of their serviceable lives and need to be replaced. The existing building conditions and site configuration are inadequate to effectively and efficiently meet the expanding needs of VA's health care mission in the region. The replacement campus will include diagnostic and treatment facilities and required site amenities and improvements needed to provide sufficient capacity to meet the current and projected future health care needs of Veterans in the Louisville service area.

In the Final EIS, VA has analyzed the environmental impacts of three alternatives for the replacement VAMC. Alternative A proposes construction and operation of a replacement VAMC campus at the Brownsboro Site at 4906 Brownsboro Road, Louisville, KY. Alternative B would construct and operate a replacement VAMC campus at the St. Joseph site on a parcel located east of I–265 and south of Factory Lane in Louisville, KY. Alternative C is the No Action alternative, which would consist of not constructing and operating a new replacement VAMC and VBA but continuing to operate the existing Louisville VAMC at 800 Zorn Avenue, all eight CBOCs and the VBA regional office at 321 West Main Street. The No Action alternative is required by NEPA and its regulations and also provided a baseline for comparing potential impacts from the action alternatives.

VA's preferred alternative is Alternative A, the construction and operation of a replacement VAMC campus at the Brownsboro Site at 4906 Brownsboro Road, in Louisville, KY. VA will relocate medical facility operations to the Brownsboro Site from Zorn Avenue and a later process will evaluate the future use or disposition of the Zorn Avenue property.

Environmental topics addressed in the Final EIS include aesthetics, air quality, cultural resources, geology and soils, hydrology and water quality, wildlife and habitat, noise, land use, floodplains and wetlands, socioeconomics, community services, solid waste and hazardous materials, transportation and parking, utilities, and environmental justice.

Best management practices and mitigation measures that could alleviate environmental effects have been considered and are included where relevant within the Final EIS. Unavoidable adverse impacts include effects to air quality, aesthetics, noise, land use, solid waste and hazardous materials, utilities, and transportation and traffic. With the exception of aesthetics and land use, implementation of specified mitigation measures, including the Kentucky Transportation Cabinet's planned construction (2019) of the single point urban interchange (SPUI) at the KY 22 Brownsboro site location, would substantially decrease the magnitude of these impacts.

The Final EIS considers comments on the Draft EIS, including those submitted during the public comment period that officially began on October 27, 2016, and ended on January 11, 2017, following a 30-day comment period extension that VA determined was sufficient in response to requests from the public for a 60-day extension.

The 2017 Replacement Robley Rex VAMC Final EIS is available for viewing on the VA Web site at *www.louisville.va.gov/newmedicalcenter/* and at the St. Matthews and Westport Branches of the Louisville Free Public Library located at 3940 Grandview Avenue, Louisville, KY 40207 and 8100 Westport Road, Louisville, KY 40222, respectively. Information related to the EIS process is also available for viewing on the VA Web site at *www.louisville.va.gov/newmedicalcenter/.*

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on April 21, 2017, for publication.

Dated: April 21, 2017.

Jeffrey Martin,

Office Program Manager, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

[FR Doc. 2017–08562 Filed 4–27–17; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 82 Friday,

No. 81 April 28, 2017

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 Proposed 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; Proposed 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–P]

RIN 0938–AS98

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed 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: Proposed rule.

SUMMARY: We are proposing to revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals to implement changes arising from our continuing experience with these systems for FY 2018. Some of these proposed changes would 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 proposals 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 proposed estimated market basket update that would 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 proposing to update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs) for FY 2018.

In addition, we are proposing to establish new requirements or revise existing requirements for quality reporting by specific Medicare providers (acute care hospitals, PPS-exempt cancer hospitals, LTCHs, and inpatient psychiatric facilities). We also are proposing to establish new requirements or revise 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 proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program.

We also are proposing 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: *Comment Period:* To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 13, 2017.

ADDRESSES: In commenting, please refer to file code CMS–1677–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1677–P, P.O. Box 8011, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1677–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call the telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

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.

Delia Houseal, (410) 786–2724, 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:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection, generally beginning approximately 3 weeks after publication of the rule, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244, on Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Electronic Access

This **Federal Register** document is 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 proposed rule are available through the Internet on the CMS Web site at: *http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2018 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''. The LTCH PPS tables for this FY 2018 proposed rule are available through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1677–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS Web sites identified above should contact Michael Treitel at (410) 786–4552.

Acronyms

3M 3M Health Information System
AAMC Association of American Medical Colleges
ACGME Accreditation Council for Graduate Medical Education
ACoS American College of Surgeons
AHA American Hospital Association
AHIC American Health Information Community
AHIMA American Health Information Management Association
AHRQ Agency for Healthcare Research and Quality
AJCC American Joint Committee on Cancer
ALOS Average length of stay
ALTHA Acute Long-Term Hospital Association
AMA American Medical Association
AMGA American Medical Group Association
AMI Acute myocardial infarction
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

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 Insight, 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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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This proposed rule would make payment and policy changes under the Medicare inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. We also are making proposals 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 would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). It also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs.

We are proposing to establish 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 proposing to establish new requirements or revise existing requirements for eligible professionals (EPs), eligible hospitals, and CAHs participating in the Medicare and Medicaid EHR Incentive Programs. We are proposing to update policies relating to the Hospital Value-Based Purchasing (VBP) Program, the Hospital Readmissions Reduction Program, and the Hospital-Acquired Condition (HAC) Reduction Program. We also are proposing 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 proposing to make 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; long-term care neoplastic disease 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). 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 long-term care hospitals (LTCHs) described in section 1886(d)(1)(B)(iv) of the Act.
- Sections 1814(l), 1820, and 1834(g) of the Act, which specify that payments are made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services and that these payments are generally based on 101 percent of reasonable cost.
- Section 1866(k) of the Act, as added by section 3005 of the Affordable Care Act, which establishes a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(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 points 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(a)(1) 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 the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act, Pub. L. 113–185), which imposes data reporting requirements 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 (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 (MACRA) of 2015 (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 proposing to make 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 proposing to make 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 proposed rule, we are proposing the following policies: (1) Specify applicable time period for FY 2018; (2) specify the calculation of aggregate payments for excess readmissions for FY 2018; (3) propose changes to the payment adjustment factor in accordance with the 21st Century Cures Act for FY 2019; and (4) update the Extraordinary Circumstances Exception 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 proposed rule, we are proposing to remove 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 proposing to adopt 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 to adopt 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 proposing two modifications to our domain scoring policies beginning with the FY 2019 program year, and further proposing a new weighting methodology for the Efficiency and Cost Reduction domain. We also are inviting public comment on the appropriateness of accounting for social risk factors in the Hospital VBP Program, including which social risk factors should be included; and how to account for these 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 proposed rule, we are proposing the following policies: (1) Specifying the dates of the time period used to calculate hospital performance for the FY 2020 HAC Reduction Program; (2) requesting comments on additional measures for potential future adoption; (3) requesting comments on social risk factors; (4) requesting comments on accounting for disability and medical complexity in the CDC NHSN measures in Domain 2; and (5) updating the HAC Reduction Program's Extraordinary Circumstances Exception policy.

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 proposed rule, we are proposing to update 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 proposing to use 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 proposing to begin incorporating 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. The proposal to continue to use data from three cost reporting periods to calculate Factor 3 would have the effect of transitioning from the use of the proxy data on low-income insured days toward use of uncompensated care data from Worksheet S–10. As part of this proposal, we are proposing a definition of uncompensated care costs consisting of the sum of charity care and bad debt and a trim methodology to address anomalous charges. We also are proposing that, for Puerto Rico hospitals and Indian Health Service and Tribal hospitals, we would substitute data regarding low-income insured days for FY 2013 for the Worksheet S–10 data from FY 2014 cost reports.

We are proposing to continue 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 proposing to continue 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 proposing to annualize hospital cost reports that do not span 12 months. We also are proposing to apply 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. Proposed Changes to the LTCH PPS

In this proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2018; proposed changes to the payment methodology under the short-stay outlier (SSO) policy; proposals to implement several provisions of the 21st Century Cures Act; and a proposal to adopt 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 proposed rule, we are proposing to make several changes. First, we are proposing to refine two previously adopted measures. Specifically, we are proposing to update 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. In addition, we are proposing to update the stroke mortality measure to include the use of NIH Stroke Scale claims data for risk adjustment, beginning with the FY 2023 payment determination.

Second, we are proposing to adopt the Hospital-Wide All-Cause Unplanned Readmission Hybrid Measure as a voluntary measure for the CY 2018 reporting period and note that we are considering proposing this measure as a required measure as early as the CY 2021 reporting period/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.

Third, we are proposing modifications of our previously finalized eCQM reporting requirements. For the CY 2017 reporting period/FY 2019 payment determination, we are proposing that hospitals would be required to select and submit six of the available eCQMs included in the Hospital IQR Program measure set and provide two, self-selected, calendar year quarters of data. For the CY 2018 reporting period/FY 2020 payment determination, we are proposing that hospitals would be required to select and submit six of the available eCQMs, and provide data for the first three calendar quarters (Q1–Q3). These modifications are being proposed in alignment with proposals for the Medicare and Medicaid EHR Incentive Programs, and would 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.

Fourth, we are proposing modifications to the eCQM validation process if our proposals to modify the eCQM reporting requirements for the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination are finalized as proposed, whereby hospitals would be required to submit a reduced number of cases for eCQM data validation for the FY 2020 and FY 2021 payment determinations. In addition, we are proposing policies related to the exclusion criteria for hospital selection and the data submission requirements for participating hospitals.

Fifth, we are proposing to modify our educational review process for chart-abstracted measures for the FY 2020 payment determination and subsequent years, such that educational reviews would be offered quarterly for the first three quarters of validation. Hospitals would be allowed 30 calendar days following the date the results of validation are posted to request an educational review. Also, we are proposing that if an educational review demonstrates that the abstraction score calculated by CMS is incorrect, we would use the corrected quarterly score to compute the final confidence interval.

Sixth, we are making proposals related to our Hospital IQR Program Extraordinary Circumstances Extension or Exemptions (ECE) policy, including a change to the name of the policy to Extraordinary Circumstances Exceptions policy.

Finally, we are inviting 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) eleven 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 proposed rule, we are proposing to adopt one new outcome measure related to pressure ulcers and two new measures (one process and one outcome) related to ventilator weaning. We also are proposing 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. Finally, we are proposing to 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 proposals. First, beginning with the FY 2020 payment determination, we are proposing the Medication Continuation following Inpatient Psychiatric Discharge measure. Second, beginning with the FY 2019 payment determination (that is, for extraordinary circumstances occurring during CY 2018), we are proposing to update the IPFQR Program's extraordinary circumstances exception (ECE) policy by: (1) Allowing designated personnel to provide their contact information and sign the ECE request in lieu of the 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 requests for ECEs within 90 days of receiving these requests. Third, we are proposing to change 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. Fourth, we are proposing to align our deadline for submission of a Notice of Participation (NOP) or

program withdrawal with this proposed data submission timeframe. Finally, we are proposing factors by which we will evaluate measures for removal from the IPFQR Program. These factors align with those in use in other quality reporting programs.

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 proposing to make 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 proposing 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, would 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 0.8 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.

• *Proposed 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 proposed rule, we estimate that 2,591 hospitals would 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 would 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 would 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.

• *Proposed 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 proposed 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 proposed changes to the payment rates and factors that we are presenting in the preamble and Addendum of this proposed 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 proposed 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 would result in an estimated decrease in payments from FY 2017 of approximately $238 million.

• *Proposed Changes to the 25-Percent Threshold Policy.* In this proposed rule, we estimate our proposal to adopt a 1-year regulatory delay of the full implementation of the 25-percent threshold policy for discharges occurring in FY 2018 would increase payments to LTCHs in FY 2018 by $50 million.

• *Proposed Changes to the Hospital Inpatient Quality Reporting (IQR) Program.* Across 3,300 IPPS hospitals, we estimate that our policy proposals would result in the following changes to costs and benefits in the Hospital IQR Program compared to previously finalized requirements: (1) A cost reduction of $361,240 for the FY 2019 payment determination due to the proposed updates to the eCQM reporting requirements; (2) a total net cost reduction of $392,963 for the FY 2020 payment determination due to the proposed updates to the eCQM reporting requirements, the proposed updates to the eCQM validation procedures, and the proposed voluntary reporting of the new Hybrid Hospital-Wide Readmission measure; and (3) a total cost reduction of $70,048 for the FY 2021 payment determination due to

the proposed updates to the eCQM validation procedures.

• *Proposed Changes Related to the LTCH QRP.* In this proposed rule, we are proposing one outcome measure related to pressure ulcers and two new measures (one process and one outcome) related to ventilator weaning. We also are proposing to specify the use of the 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 proposed changes to the LTCH QRP is estimated at an additional $3,187.15 per LTCH annually, or $1,357,726 for all LTCHs annually.

• *Proposed Changes to the IPFQR Program.* In this proposed rule, we are proposing to adopt one claims based measure, update our ECE process, change the specification of the data submission period, align the timeframe for submission of the NOP or program withdrawal with the data submission period, and establish criteria 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; long-term care neoplastic

disease hospitals (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 now included as part of the IPPS annual update document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, 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 LTCH 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 Proposed To Be Implemented in This Proposed Rule

1. The American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240), the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (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 (enacted on April 16, 2015) 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 proposed rule, we are continuing to provide clarifications to prior policy changes 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 proposed rule, we are proposing to continue to implement portions of section 1899B of the Act, as added by section 2 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 proposed rule, consistent with this requirement, we are proposing to update

the LTCH standard Federal payment rate by 1.0 percent for FY 2018.

The MACRA also extended the MDH program and changes to the payment adjustment for low-volume hospitals through FY 2017. In this proposed 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 and the Hospital Readmissions Reduction Program and the Medicare EHR Incentive Program, which we are proposing to implement in this proposed 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 proposed rule, we are proposing to implement 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 proposing to implement 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 proposed 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 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 proposed rule, we are proposing to implement 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 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.

Public Law 114–255 also amended section 1886(q)(3) of the Act by adding subparagraphs (D) and (E), which requires the Secretary to develop a methodology for the Hospital Readmissions Reduction Program that accounts for 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 proposed rule, we are proposing to implement 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 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. Summary of Provisions of This Proposed Rule

In this proposed rule, we are setting 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 are setting 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 are proposing to make:

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include—

- Proposed changes to MS–DRG classifications based on our yearly review 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 recalibrations 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 this proposed rule, we are proposing 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 Revising and Rebasing of Hospital Market Basket

In section IV. of this proposed rule, we are proposing 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 this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed changes to 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 MDH program and 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 are proposing 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 this proposed rule, we discuss 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 this proposed rule, we discuss—

- 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 this proposed rule, we set forth—

- Proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 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 address—
• 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 this proposed rule, we present 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 this 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 this 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 are proposing to establish the threshold amounts for outlier cases. In addition, we are addressing 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 this 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 are proposing 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 this 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 this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we are providing 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 address these recommendations in Appendix B of this 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. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

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. Proposed 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 (Pub. L. 110–90). Section 7(a) of Public Law 110–90 reduced the documentation and coding adjustment made as a result of the MS–DRG system that we adopted in the FY 2008 IPPS final rule with comment period to −0.6 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 proposed 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. Proposed 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, for FY 2018, we are proposing to implement the required +0.4588 percentage point adjustment to the standardized amount. This is a permanent adjustment to payment rates. 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 percentage point adjustments to the standardized amounts for FYs 2019 through 2023.

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 proposed 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 proposed 19 CCRs and the proposed MS–DRG relative weights for FY 2018 is included in section II.G. of the preamble to this FY 2018 IPPS/LTCH PPS proposed rule. As we did with the FY 2017 IPPS/LTCH PPS final rule, for this proposed rule, we are providing the version of the HCRIS from which we calculated these proposed 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 Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

F. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed 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 Proposed 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 proposed 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. 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: *MSDRGClassificationChange@cms.hhs.gov*.

Following are the changes that we are proposing to the MS–DRGs for FY 2018 in this FY 2018 IPPS/LTCH PPS proposed rule. We are inviting 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 this proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data. In other cases, we are proposing to maintain the existing MS–DRG classification based on our analysis of claims data. For this FY 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''.

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.

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.

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).

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. 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
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. 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. 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, we are proposing 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 are inviting public comments on our proposal.

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, and is the first and only FDA-approved device used to provide responsive stimulation directly to the seizure onset zone in the brain. 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.

ICD–10–CM code	ICD–10–CM code title
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).

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–DRGs 023 AND 024—Continued

[Neurostimulator Cases]

MS–DRG	Number of cases	Average length of stay	Average costs
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). 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 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 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, we are proposing 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 are proposing 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 are inviting public comments on our proposals.

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.

ICD–10–CM code	Code description
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.
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.

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–DRGs for Precerebral Occlusion With Use of Thrombolytic Agent—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 068—Cases with tPA	33	4.3	13,814

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.

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 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, for FY 2018, we are proposing 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 are inviting public comments on our proposal.

We also are proposing 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 are inviting public comments on our proposals.

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).

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 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, we are proposing 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 are inviting public comments on our proposal.

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. 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, 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, for FY 2018, we are proposing 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 are inviting public comments on our proposal to remove the six procedure codes listed above from MS–DRGs 246 through 249. We also are inviting public comments on our proposal to maintain their current assignment in MS–DRG 264.

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)

We are proposing 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 are proposing to revise the title of MS–DRG 246 to ''Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents''. We are proposing 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 are inviting public comments on our proposals.

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).

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

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, we are not proposing to create new MS–DRGs for cases involving TAVR and LAAC procedures when performed in combination in the same operative episode. We are inviting 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.

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 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 this proposed 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 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, we are proposing 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 are proposing 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 are inviting public comments on our proposals.

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. However, the FORMA system is presently available for compassionate use purposes. 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.

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–DRGs FOR CARDIAC VALVE AND OTHER MAJOR CARDIOTHORACIC PROCEDURES—Continued

MS–DRG	Number of cases	Average length of stay	Average costs
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–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). 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, we are not proposing to reassign cases reporting procedure code 02UJ3JZ from MS–DRGs 216 through 221 to MS–DRGs 228 and 229.

We are inviting public comments on our proposal to maintain the current MS–DRG assignment for cases reporting procedure code 02UJ3JZ.

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.

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). 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.

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, we are proposing 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 are proposing 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 are inviting public comments on our proposals.

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 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 for revision of TAR procedures, which are assigned to MS–DRGs 515, 516, and 517:

- 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.

We examined claims data from the December 2016 update of the FY 2016 MedPAR file on reported cases of revision of TAR procedures, 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 representing revisions of TAR procedures with no cases in MS–DRG 515, two cases in MS–DRG 516, and four cases in MS–DRG 517. 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 the revision of TAR 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 the revision of TAR 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). The data do not support reassigning the cases from MS–DRGs 515, 516, and 517.

Furthermore, the average length of stay and average costs of cases in MS–DRGs 466, 467, 468, and 469 are significantly higher than those for the revision of TAR procedures in MS–DRG 516 and 517. 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 revision of TAR 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 revision of TAR procedures in MS–DRGs 516 and 517, respectively. Therefore, the data do not support reassigning the cases to MS–DRGs 466, 467, 468, or 469.

Our clinical advisors reviewed the clinical issue and the claims data and agreed that the revision of TAR procedures 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, we are proposing to maintain the current MS–DRG assignment for revision of TAR procedures within MS–DRGs 515, 516, and 517 for FY 2018.

We are inviting public comments on our proposal.

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.

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 note that cases are assigned to MS–DRGs 456, 457, and 458 when an actual spinal fusion procedure is performed. 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 are no claims data available at this time and based on the advice of our clinical advisors, we are not proposing to add the six procedure codes to MS–DRGs 456, 457, or 458. 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 are inviting 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 are inviting public comments on our proposal to maintain the assignment of the six procedure codes in MS–DRGs 518, 519, and 520.

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. 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. 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. We are proposing to move the 149 ICD–10–PCS procedure codes listed in Table 6P.3a. associated with this 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.
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.

We are proposing to delete these 33 procedure codes from MS–DRGs 453, 454, and 455 for FY 2018. We also note 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 are proposing to delete the 33 procedure codes from the logic for those spinal fusion MS–DRGs as well. In addition, we are proposing to delete the 33 procedure codes from the ICD–10–PCS classification as shown in Table 6D.—Invalid Procedure Codes associated with this 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 are inviting 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 are inviting 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 are inviting 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.

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 believe that the Version 34 Definitions Manual and GROUPER logic for MS–DRG 774 continue 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.

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. 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. Upon review and discussion, our clinical advisors recommended, and we agree, 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, we are soliciting 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), public comments that we receive from this solicitation will be helpful in determining what proposed revisions to the current logic should be made. 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 are requesting that all comments be directed to the CMS MS–DRG Classification Change Request Mailbox located at: *MSDRGClassificationChange@cms.hhs.gov* by November 1, 2017.

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, we have 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 this 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 are proposing 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. This would enable more appropriate MS–DRG assignments and payment for these cases. We are inviting public comments on our proposal.

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 earlier in section II.F.6.b. of the preamble of this proposed rule, the supervision of pregnancy codes are accurately reflected in the MCE code edit list for Unacceptable principal diagnosis. Therefore, it is not appropriate to include the three above listed codes in MS–DRG 782.

We are proposing 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 are inviting public comments on our proposal.

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 earlier in section II.F.14.a. of the preamble of this proposed 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/AcuteInpatient*

PPS/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.

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 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, we are proposing 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 are inviting public comments on our proposals.

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).

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.

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 and our clinical advisors also agree that the above list of diagnosis codes should be added to MS–DRG 795. Therefore, we are proposing 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 are inviting public comments on our proposals.

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.

ICD–10–CM diagnosis code	Code description
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.

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 agree 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.

We are inviting 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 that we are seeking public comment on 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
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

ICD–10–CM code	Code description	Current V34 MDC	Current V34 MS–DRG	Proposed V35 MDC	Proposed V35 MS–DRG
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

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 this 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 will be 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 will be included in the FY 2018 IPPS/LTCH PPS final rule.

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.

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.

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 are 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 are inviting public comments on our proposal not to update MS–DRGs 945 and 946 for FY 2018.

10. Proposed 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.

For this FY 2018 IPPS/LTCH PPS proposed rule, below we address the MCE requests we received by the December 7, 2016 deadline. We also discuss the proposals we are making based on our internal review and analysis.

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.

(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, we are proposing to not add these two diagnosis codes to the Perinatal/Newborn Diagnosis category under the Age Conflict edit. We are inviting public comments on our proposal.

(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, we are proposing to remove diagnosis code L21.0 from the list of diagnosis codes for the Pediatric diagnosis category under the Age Conflict edit. We are inviting public comments on our proposal.

(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 this proposed 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 this 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 are proposing to add to the Age Conflict edit list. We are inviting public comments on our proposal.

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.

We agree 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 agree 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 agree 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, we are proposing 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 are proposing 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 this proposed 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 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 this 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 are proposing to add to the list of diagnosis codes for the Diagnoses for Males Only category.

We are inviting public comments on our proposals.

(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.

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 are proposing to remove these three diagnosis codes from the list of diagnosis codes for the Diagnoses for Females Only edit. We are inviting public comments on our proposals.

In addition, we are proposing 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 refer readers to Table 6A.—New Diagnosis Codes associated with this 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 finalized to date. We are inviting public comments on our proposal.

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/Determination Process/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–CM 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, we are proposing 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 are inviting public comments on our proposal.

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)

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. We are proposing to add the 45 ICD–10–CM diagnosis codes shown in Table 6P.1c. associated with this 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 are inviting public comments on our proposal.

(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.'' 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, we are proposing to add the 19 ICD–10–CM diagnosis codes shown in Table 6P.1d. associated with this 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 are inviting public comments on our proposal.

(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 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). We are proposing to add ICD–10–CM diagnosis code O94 to the list of codes for the Unacceptable Principal Diagnosis edit. We are inviting public comments on our proposal.

(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 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. We are proposing to add the 96 ICD–10–CM diagnosis codes shown in Table 6P.1e. associated with this 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 are inviting public comments on our proposal.

(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.

We are proposing 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 are inviting public comments on our proposal.

(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. We are proposing to add the 996 ICD–10–CM diagnosis codes shown in Table 6P.1f. associated with this 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 are inviting public comments on our proposal.

(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.

We are proposing 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 are inviting public comments on our proposal.

(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, diagnosis code Z00.6 should not be reported as a principal/first-listed diagnosis. We are proposing to add ICD–10–CM diagnosis code Z00.6 to the list of codes for the Unacceptable Principal Diagnosis edit. We are inviting public comments on our proposal.

To address a separate issue, we are proposing 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 are proposing 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 are inviting public comments on our proposal.

(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, ICD–10–CM diagnosis code Z52.9 should not be reported as a principal/first-listed diagnosis. We are proposing to add ICD–10–CM diagnosis code Z52.9 to the list of codes for the Unacceptable Principal Diagnosis edit. We are inviting public comments on our proposal.

(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), we are proposing to add new diagnosis code Z71.82 (Exercise counseling) to the list of codes for the Unacceptable Principal Diagnosis edit. We refer readers to Table 6A.—New Diagnosis Codes associated with this 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 finalized to date. We are inviting public comments on our proposal.

(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), we are proposing 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 refer readers to Table 6A.—New Diagnosis Codes associated with this 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 finalized to date. We are inviting public comments on our proposal.

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 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.

11. Proposed Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

Because the relative resource intensity of surgical classes can shift as a function of MS–DRG reclassification and recalibrations, for FY 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.

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 this FY 2018 IPPS/LTCH PPS proposed rule, we are proposing 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 are inviting public comments on our proposal.

12. Proposed 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. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2018

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 are inviting public comments on our proposed severity level designations for the diagnosis codes listed in Table 6I.1. and Table 6J.1. We note that, for Table 6I.2. and Table 6J.2., the proposed deletions are 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.

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&DLfxsp0;Entries=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.

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, we are not proposing 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 are not proposing any changes to Table 6L.—Principal Diagnosis Is Its Own MCC List and Table 6M.—Principal Diagnosis Is Its Own CC List. We are inviting public comments on our proposal to maintain the existing lists of principal diagnosis codes in Tables 6L. and 6M for FY 2018.

d. Proposed 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.

For FY 2018, we are proposing changes to the ICD–10 MS–DRGs Version 35 CC Exclusion List. Therefore, we have 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 this 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*.

To identify new, revised and deleted diagnosis and procedure codes, for FY 2018, we have 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 this proposed rule.

These tables are not published in the Addendum to this proposed 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 proposed rule. As discussed in section II.F.15. of the preamble of this proposed 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 are inviting 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 are inviting 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.

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 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 are inviting public comments regarding other possible ways we can incorporate meaningful indicators of clinical severity.

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.

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 is associated with this 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, for FY 2018, we are not proposing to change the procedures assigned among these MS–DRGs. We are inviting public comments on our proposal to maintain the current structure of these MS–DRGs.

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. 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 are not proposing to remove any procedures from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis is assigned. We are inviting public comments on our proposal to maintain the current structure of these MS–DRGs.

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, we are proposing 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. 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 are proposing 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 are inviting public comments on our proposals.

15. Proposed 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, 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 this proposed 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 this proposed 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 proposed rule. Rather, they are available via the Internet as discussed in section VI. of the Addendum to this proposed rule.

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: *nchsicd10@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 new April update would have on providers.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting are considered for an April 1 update if a strong and convincing case is made by the 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	71,772	+286
ICD–10–PCS	78,299	+2,510

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.

16. Proposed 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. Proposed Changes for FY 2018

For FY 2018, we are not proposing to add any MS–DRGs to the policy for replaced devices offered without cost or with a credit. We are proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the table below.

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/Acute Complex CNS Principal Diagnosis with MCC or Chemo Implant.
1	024	Craniotomy with Major Device Implant/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.

MDC	MS–DRG	MS–DRG title
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.
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 Joint Replacement or Reattachment of Lower Extremity with MCC.
8	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC.

We are soliciting 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 note that, as discussed in section II.F.2.b. and in section II.F.5.a. of the preamble of this proposed rule, we are proposing to revise the titles for MS–DRG 023 and MS–DRGs 469 and 470. We refer readers to those discussions of the specific proposed MS–DRG titles. The final list of MS–DRGs subject to the payment policy for devices provided at no cost or with a credit for FY 2018 will be listed in the FY 2018 IPPS/LTCH PPS final rule, as well as issued to providers through guidance and instructions in the form of a Change Request (CR).

17. Other Policy Changes: Other Operating Room (O.R.) and Non-O.R. Issues

a. O.R. Procedures to Non-O.R. Procedures

For this FY 2018 IPPS/LTCH PPS proposed rule, we 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.

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 are shown in Tables 6P.4a. through 6P.4p. (Proposed ICD–10–CM and ICD–10–PCS Code Designations, MCE and MS–DRG Changes—FY 2018) associated with this proposed 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*).

(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 agree with the commenter. Therefore, we are proposing that the 135 ICD–10–PCS procedure codes listed in Table 6P.4a. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 28 ICD–10–

PCS procedure codes listed in Table 6P.4b. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 22 ICD–10–PCS procedure codes listed in Table 6P.4c. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the four ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 28 ICD–10–PCS procedure codes listed in Table 6P.4d. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 20 ICD–10–PCS procedure codes listed in Table 6P.4e. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the four ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the four ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 40 ICD–10–PCS procedure codes listed in Table 6P.4f. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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.
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 agree with the commenter. Therefore, we are proposing that the nine ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 16 ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the two ICD–10–PCS procedure codes shown in the table above be designated non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 18 ICD–10–PCS procedure codes listed in Table 6P.4g. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that ICD–10–PCS procedure code 0DBQ8ZZ be designated as a non-O.R. procedure. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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

ICD–10–PCS code	Code description
0DPD8UZ	Removal of feeding device from lower intestinal tract, via natural or artificial opening endoscopic.

We agree with the commenter. Therefore, we are proposing that the six ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 41 ICD–10–PCS procedure codes listed in Table 6P.4h. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 disagree 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, we are proposing that the six ICD–10–PCS procedure codes shown in the table above remain designated as O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 25 ICD–10–PCS procedure codes listed in Table 6P.4i. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the two ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 22 ICD–10–PCS procedure codes listed in Table 6P.4j. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be

designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 disagree 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, we are proposing that the 22 ICD–10–PCS procedure codes listed in Table 6P.4k. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) remain designated as O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 44 ICD–10–PCS procedure codes listed in Table 6P.4l. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 28 ICD–10–PCS procedure codes listed in Table 6P.4m. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(36) External Repair

One commenter identified 135 ICD–10–PCS procedure codes that describe procedures involving external repair of various bones and joints. We believe that these procedures generally would not be performed in the operating room. We are proposing that the 135 ICD–10–PCS procedure codes listed in Table 6P.4n. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 believe that these procedures generally would not be performed in the operating room. Therefore, we are proposing that the 14 ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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.

ICD–10–PCS code	Code description
0T7B8ZZ	Dilation of bladder, via natural or artificial opening endoscopic.

We agree with the commenter. Therefore, we are proposing that the eight ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 disagree with the commenter because, depending on the medical reason for the excision, the procedures may require an O.R. setting. Therefore, we are proposing that the three ICD–10–PCS procedure codes shown in the table above remain designated as O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that these three ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 20 ICD–10–PCS procedure codes listed in Table 6P.4o. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the 51 ICD–10–PCS procedure codes listed in Table 6P.4p. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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.

ICD–10–PCS code	Code description
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 agree with the commenter. Therefore, we are proposing that the 15 ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the six ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

(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 agree with the commenter. Therefore, we are proposing that the five ICD–10–PCS procedure codes shown in the table above be designated as non-O.R. procedures. We are inviting public comments on our proposal.

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), 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.

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 (Diseases and Disorders of the Nervous System) 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 (Diseases and Disorders of the Circulatory System) 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.

After review of the claims data and discussion with our clinical advisors, we agree with and support 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 are inviting public comments on our proposal.

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.

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 agree with the requestor that reporting of this procedure code should not affect assignment to one of the MS–DRGs for vaginal delivery. As discussed earlier in section II.F.15.a. of the preamble of this proposed rule, we are proposing to change the designation for a number of procedure codes from O.R. procedures to non-O.R. procedures. Included in that proposal are 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 are proposing 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, we are proposing to change the designation of ICD–10–PCS procedure code 0UQKXZZ (Repair hymen, external approach) to a non-O.R. procedure. This redesignation will enable more appropriate MS–DRG assignment for these cases by eliminating erroneous assignment to MS–DRGs 987 through 989. We are inviting public comments on our proposal.

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, we are proposing that the 55 ICD–10–PCS procedure codes listed in Table 6P.3c. associated with this proposed rule (which is available via the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*) 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 are proposing to revise the titles for these five MS–DRGs by deleting the reference to ''O.R.'' in the title. Specifically, we are proposing 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 are proposing 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 are inviting public comments on our proposals.

G. Recalibration of the Proposed FY 2018 MS–DRG Relative Weights

1. Data Sources for Developing the Proposed Relative Weights

In developing the proposed FY 2018 system of weights, we used two data sources: Claims data and cost report data. As in previous years, the claims data source is the MedPAR file. This file is based on fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2016 MedPAR data used in this proposed rule include discharges occurring on October 1, 2015, through September 30, 2016, based on bills received by CMS through December 31, 2016, 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 proposed relative weights includes data for approximately 9,607,103 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 31, 2016 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 proposed 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 proposed 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 proposed 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 used cost report data from the December 31, 2016 update of the FY 2015 HCRIS for calculating the proposed FY 2018 cost-based relative weights.

2. Methodology for Calculation of the Proposed Relative Weights

As we explain in section II.E.2. of the preamble of this proposed rule, we calculated the proposed FY 2018 relative weights based on 19 CCRs, as we did for FY 2017. The methodology we are proposing to use 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. We note that we have provided additional precision in our description of the methodology for FY 2018.

- To the extent possible, all the claims were regrouped using the proposed FY 2018 MS–DRG classifications discussed in sections II.B. and II.F. of the preamble of this proposed rule.
- The transplant cases that were used to establish the proposed 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, we are are proposing to continue to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on

the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's Web site at: *http://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in proposed area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable proposed 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 proposed 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 proposed national average CCRs developed from the FY 2015 cost report data.

The 19 cost centers that we used in the proposed relative weight calculation are shown in the following table. The table shows the lines on the cost report and the corresponding revenue codes that we used to create the proposed 19 national cost center CCRs. If stakeholders have comments about the groupings in this table, we may consider those comments as we finalize our policy.

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″CCRs>>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
	Coronary Care Charges.	021X	Coronary Care Unit	C_1_C5_32	C_1_C6_32	D3_HOS_C2_32
			Burn Intensive Care Unit	C_1_C5_33	C_1_C6_33	D3_HOS_C2_33
			Surgical Intensive Care Unit.	C_1_C5_34	C_1_C6_34	D3_HOS_C2_34
			Other Special Care Unit	C_1_C5_35	C_1_C6_35	D3_HOS_C2_35
Drugs	Pharmacy Charges	025X, 026X and 063X.	Intravenous Therapy	C_1_C5_64	C_1_C6_64 C_1_C7_64	D3_HOS_C2_64
			Drugs Charged to Patient	C_1_C5_73	C_1_C6_73 C_1_C7_73	D3_HOS_C2_73
Supplies and Equipment.	Medical/Surgical Supply Charges.	0270, 0271, 0272, 0273, 0274, 0277, 0279, and 0621, 0622, 0623.	Medical Supplies Charged to Patients.	C_1_C5_71	C_1_C6_71 C_1_C7_71	D3_HOS_C2_71
	Durable Medical Equipment Charges.	0290, 0291, 0292 and 0294–0299.	DME–Rented	C_1_C5_96	C_1_C6_96 C_1_C7_96	D3_HOS_C2_96
	Used Durable Medical Charges.	0293	DME–Sold	C_1_C5_97	C_1_C6_97 C_1_C7_97	D3_HOS_C2_97
Implantable Devices		0275, 0276, 0278, 0624.	Implantable Devices Charged to Patients.	C_1_C5_72	C_1_C6_72 C_1_C7_72	D3_HOS_C2_72
Therapy Services	Physical Therapy Charges.	042X	Physical Therapy	C_1_C5_66	C_1_C6_66 C_1_C7_66	D3_HOS_C2_66
	Occupational Therapy Charges.	043X	Occupational Therapy	C_1_C5_67	C_1_C6_67 C_1_C7_67	D3_HOS_C2_67
	Speech Pathology Charges.	044X and 047X	Speech Pathology	C_1_C5_68	C_1_C6_68 C_1_C7_68	D3_HOS_C2_68
Inhalation Therapy	Inhalation Therapy Charges.	041X and 046X	Respiratory Therapy	C_1_C5_65	C_1_C6_65 C_1_C7_65	D3_HOS_C2_65
Operating Room	Operating Room Charges.	036X	Operating Room	C_1_C5_50	C_1_C6_50 C_1_C7_50	D3_HOS_C2_50
		071X	Recovery Room	C_1_C5_51	C_1_C6_51 C_1_C7_51	D3_HOS_C2_51
Labor & Delivery	Operating Room Charges	072X	Delivery Room and Labor Room	C_1_C5_52	C_1_C6_52 C_1_C7_52	D3_HOS_C2_52
Anesthesia	Anesthesia Charges	037X	Anesthesiology	C_1_C5_53	C_1_C6_53 C_1_C7_53	D3_HOS_C2_53
Cardiology	Cardiology Charges	048X and 073X	Electrocardiology	C_1_C5_69	C_1_C6_69 C_1_C7_69	D3_HOS_C2_69

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
Cardiac Catheterization.		0481	Cardiac Catheterization	C_1_C5_59	C_1_C6_59 C_1_C7_59	D3_HOS_C2_59
Laboratory	Laboratory Charges	030X, 031X, and 075X	Laboratory	C_1_C5_60	C_1_C6_60 C_1_C7_60	D3_HOS_C2_60
			PBP Clinic Laboratory Services	C_1_C5_61	C_1_C6_61 C_1_C7_61	D3_HOS_C2_61
		074X, 086X	Electroencephalography	C_1_C5_70	C_1_C6_70 C_1_C7_70	D3_HOS_C2_70
Radiology	Radiology Charges	032X, 040X	Radiology—Diagnostic	C_1_C5_54	C_1_C6_54 C_1_C7_54	D3_HOS_C2_54
		028x, 0331, 0332, 0333, 0335, 0339, 0342	Radiology—Therapeutic	C_1_C5_55	C_1_C6_55	D3_HOS_C2_55
		0343 and 344	Radioisotope	C_1_C5_56	C_1_C6_56 C_1_C7_56	D3_HOS_C2_56
Computed Tomography (CT) Scan.	CT Scan Charges	035X	Computed Tomography (CT) Scan	C_1_C5_57	C_1_C6_57 C_1_C7_57	D3_HOS_C2_57
Magnetic Resonance Imaging (MRI).	MRI Charges	061X	Magnetic Resonance Imaging (MRI)	C_1_C5_58	C_1_C6_58 C_1_C7_58	D3_HOS_C2_58
Emergency Room	Emergency Room Charges	045x	Emergency	C_1_C5_91	C_1_C6_91 C_1_C7_91	D3_HOS_C2_91
Blood and Blood Products.	Blood Charges	038x	Whole Blood & Packed Red Blood Cells	C_1_C5_62	C_1_C6_62 C_1_C7_62	D3_HOS_C2_62
	Blood Storage/Processing	039x	Blood Storing, Processing, & Transfusing	C_1_C5_63	C_1_C6_63 C_1_C7_63	D3_HOS_C2_63
Other Services	Other Service Charge	0002–0099, 022X, 023X, 024X,052X,053X 055X–060X, 064X–070X, 076X–078X, 090X–095X and 099X				
	Renal Dialysis	0800X	Renal Dialysis	C_1_C5_74	C_1_C6_74 C_1_C7_74	D3_HOS_C2_74
	ESRD Revenue Setting Charges	080X and 082X–088X				
			Home Program Dialysis	C_1_C5_94	C_1_C6_94 C_1_C7_94	D3_HOS_C2_94
	Outpatient Service Charges	049X	ASC (Non Distinct Part)	C_1_C5_75	C_1_C6_75 C_1_C7_75	D3_HOS_C2_75
	Lithotripsy Charge	079X				
			Other Ancillary	C_1_C5_76	C_1_C6_76 C_1_C7_76	D3_HOS_C2_76
	Clinic Visit Charges	051X	Clinic	C_1_C5_90	C_1_C6_90 C_1_C7_90	D3_HOS_C2_90
			Observation beds	C_1_C5_92.01	C_1_C6_92.01 C_1_C7_92.01	D3_HOS_C2_92.01
	Professional Fees Charges	096X, 097X, and 098X	Other Outpatient Services	C_1_C5_93	C_1_C6_93 C_1_C7_93	D3_HOS_C2_93
	Ambulance Charges	054X	Ambulance	C_1_C5_95	C_1_C6_95 C_1_C7_95	D3_HOS_C2_95
			Rural Health Clinic	C_1_C5_88	C_1_C6_88 C_1_C7_88	D3_HOS_C2_88
			FQHC	C_1_C5_89	C_1_C6_89 C_1_C7_89	D3_HOS_C2_89

3. Development of Proposed National Average CCRs

We developed the proposed 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 proposed relative weight.

The proposed FY 2018 cost-based relative weights were then normalized by a proposed adjustment factor of 1.736047 so that the average case weight after recalibration was equal to the average case weight before recalibration. The proposed normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

The proposed 19 national average CCRs for FY 2018 are as follows:

Group	CCR
Routine Days	0.449
Intensive Days	0.375
Drugs	0.197
Supplies & Equipment	0.300
Implantable Devices	0.327
Therapy Services	0.314
Laboratory	0.116
Operating Room	0.186
Cardiology	0.108
Cardiac Catheterization	0.115
Radiology	0.149
MRIs	0.077
CT Scans	0.037
Emergency Room	0.166
Blood and Blood Products	0.309
Other Services	0.352
Labor & Delivery	0.363
Inhalation Therapy	0.163
Anesthesia	0.080

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. We are proposing to use that same case threshold in recalibrating the MS–DRG relative weights for FY 2018. Using data from the FY 2016 MedPAR file, there were 10 MS–DRGs that contain fewer than 10 cases. 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 are proposing to compute proposed relative weights for the low-volume MS–DRGs by adjusting their final FY 2017 relative weights by the percentage change in the average weight of the cases in other MS–DRGs. The crosswalk table is shown:

Low-volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
016	Autologous bone marrow transplant w CC/MCC	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
017	Autologous bone marrow transplant w/o CC/MCC	Final FY 2017 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility.	Final FY 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).

We are inviting public comments on our proposals.

H. Proposed 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 this 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 are not summarizing these comments in this proposed rule. We summarize below a general comment that does not relate to a specific application for FY 2018 new technology add-on payments. We also summarize comments regarding individual applications, or, if applicable, indicate that there were no comments received in section II.H.5. of the preamble of this proposed rule 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. Proposal To Revise the Reference to an ICD–9–CM Code in § 412.87(b)(2) of the Regulations

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 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, we are proposing 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 are inviting public comments on our proposal.

5. Proposed 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. The 3-year anniversary date of the entry of the CardioMEMS™ HF Monitoring System onto the U.S. market (May 28, 2017) will occur prior to the beginning of FY 2018. Therefore, we are proposing to discontinue new technology add-on payments for this technology for FY 2018. We are inviting public comments on this proposal.

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® was granted 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 are proposing to continue new technology add-on payments for this technology for FY 2018. The maximum payment for a case involving Defitelio® would remain at $75,900 for FY 2018. We are inviting public comments on our proposal to continue new technology add-on payments for Defitelio®.

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 to 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), we are proposing to continue new technology add-on payments for this technology for FY 2018. The maximum payment for a case involving the GORE IBE device would remain at $5,250 for FY 2018. We are inviting public comments on our proposal to continue new technology add-on payments for the GORE IBE device.

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 to: (1) Reduce the risk of stroke and systemic embolism in patients who have been diagnosed with nonvalvular atrial fibrillation (NVAF); (2) treat deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients who have been administered a parenteral anticoagulant for 5 to 10 days; and (3) reduce the risk of recurrence of DVT and PE in patients who have been previously diagnosed with NVAF. Currently, unlike the anticoagulant Warfarin, there is no specific way to reverse the anticoagulant effect of Dabigatran in the event of a major bleeding episode. Idarucizumab is a humanized fragment antigen binding (Fab) molecule, which specifically binds to Dabigatran to deactivate the anticoagulant effect, thereby allowing thrombin to act in blood clot formation. The applicant stated that Idarucizumab represents a new pharmacologic approach to neutralizing the specific anticoagulant effect of Dabigatran in emergency situations.

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), we are proposing to continue new technology add-on payments for this technology for FY 2018. The maximum payment for a case involving Idarucizumab would remain at $1,750 for FY 2018. We are inviting public comments on our proposal to continue new technology add-on payments for Idarucizumab.

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]

[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.

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 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 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.

[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.*

ICD–10–PCS code	Code description
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 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, we are proposing to discontinue new technology add-on payments for both the LUTONIX® and IN.PACT™ Admiral™ technologies for FY 2018. We are inviting public comments on this proposal.

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) will occur prior to the beginning of FY 2018, we are proposing to discontinue new technology add-on payments for this technology for FY 2018. We are inviting public comments on this proposal.

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 antidote to 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 antidote to 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, we are proposing to continue new technology add-on payments for this technology for FY 2018. The maximum payment for a case involving the Vistogard™ would remain at $37,500 for FY 2018. We are inviting public comments on our proposal to continue new technology add-on payments for the Vistogard™.

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), we are proposing to discontinue new technology add-on payments for this technology for FY 2018. We are inviting public comments on this proposal.

6. FY 2018 Applications for New Technology Add-On Payments

We received nine applications for new technology add-on payments for FY 2018. In accordance with the regulations under § 412.87(c), applicants for new technology add-on payments must have received FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year that the application is being considered. Three applicants withdrew their applications prior to the issuance of this proposed rule. We are addressing the remaining six applications below.

a. Bezlotoxumab (ZINPLAVA™)

Merck & Co., Inc. submitted an application for new technology add-on payments for ZINPLAVA™ for FY 2018. ZINPLAVA™ is indicated for use in adult patients who are receiving antibacterial drug treatment for a diagnosis of *Clostridium difficile* infection (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 cell 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™ is anticipated to be commercially available as of February 2017. We note that the applicant anticipates submitting a request for a unique ICD–10–PCS code for the administration of ZINPLAVA™. Currently, there is a pending ICD–10–CM request to differentiate CDI recurrence. If approved, the codes will become effective on October 1, 2017 (FY 2018).

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 treat the same or similar type of disease (recurrent CDI) and a similar patient population receiving SOC therapy for the treatment of recurrent CDI.

Based on the applicant's statements presented above, because ZINPLAVA™ has a unique mechanism of action, we do not believe that the technology is substantially similar to existing technologies and, therefore, meets the newness criterion. We are inviting public comments on whether ZINPLAVA™ meets the newness criterion.

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 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. We are inviting public comments on whether 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

[3] Wilcox MH et al. Bezlotoxumab for Prevention of Recurrent Clostridium difficile Infection. N Engl J Med. 2017 Jan 26;376(4):305–317.

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 are concerned regarding the safety of ZINPLAVA™ in patients diagnosed with CHF. In regard 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 are 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 are concerned with regard to the adverse event of cardiac failure of ZINPLAVA™.

We are inviting public comments on whether ZINPLAVA™ meets the substantial clinical improvement criterion.

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.

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, 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 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).

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. 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.

After considering the materials included with both applications, we remain 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 do 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 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.

We are inviting public comments on whether the mechanisms 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.

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 3.00 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.

We thank the applicant for the analysis above. However, 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 are inviting public comments on whether the INTUITY valve meets the cost criterion.

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 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. We are inviting public comments on whether the Perceval technology meets 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 (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, we are 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.

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 [10] (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

[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.

[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] Pollari, F. (2014), Better short-term outcome by using sutureless valves: a propensity-matched score analysis, Ann Thorac Surg, 98; 611–6.

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 [11] (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 [12] (2013) found that a MIS approach resulted in improved outcomes, albeit longer aortic cross-clamp times. A meta-analysis by Hurley and colleagues [13] (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 [14] (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.

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 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.

We are inviting public comments on whether rapid deployment valves, specifically the INTUITY and Perceval valves, meet the substantial clinical improvement criterion.

We did not receive any written public comments regarding the INTUITY and Perceval valves in response to the New Technology Town Hall meeting notice.

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 and psoriatic arthritis 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

[11] 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.

[12] Gilmanov, D. (2013), Minimally invasive and conventional aortic valve replacement: a propensity score analysis, Ann Thorac Surg, 96, 837–843.

[13] Hurley et al, ''A Meta-Analysis Examining Differences in Short-Term Outcomes Between Sutureless and Conventional Aortic Valve Prostheses,'' Innovations 2015; 10:375–382.

[14] Dalén, 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.

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 are 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 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 IgG1κ 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. 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. 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. 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 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.

We are inviting public comments on whether the Stelara® meets the newness criterion.

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 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 2017 OPPS 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. We are inviting public comments whether 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 90mg 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.[15] 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®.[16] We are 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 are concerned that the study did not include a significant amount of older patients.

We also are 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 note 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 are 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[17] therapy. We recognize 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 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 recognize the nonresponder patient population as described by Simon et al.[18] as those patients who are TNF inhibitor immunogenicity failures, pharmacokinetic failures, and/or pharmacodynamics failures. We also note the supplement data in Feagan et al.'s publication[19] summarized the primary and secondary nonresponders in UNITI–1. However, we are not clear how the inclusion of the TNF alpha

[15] 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.

[16] Ibid.

[17] Ibid.

[18] 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.

[19] 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.

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 note 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 are 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 are 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®.

We are inviting public comments on whether the Stelara® meets the substantial clinical improvement criterion.

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.

d. KTE–C19 (Axicabtagene Ciloleucel)

Kite Pharma, Inc. submitted an application for new technology add-on payments for KTE–C19 (axicabtagene ciloleucel) for FY 2018. The KTE–C19 technology has not received FDA approval as of the time of the development of this proposed rule. KTE–C19 is an engineered autologous T-cell immunotherapy used for the treatment of adult patients with relapsed/refractory aggressive B-cell non-Hodgkin lymphoma (NHL) who are ineligible for autologous stem cell transplant (ASCT). KTE–C19 is a single intravenous infusion of T-cell immunotherapy.

The applicant noted that KTE–C19 was granted Breakthrough Therapy Designation by the FDA on December 3, 2015, for the treatment of patients with refractory DLBCL, PMBCL, and TFL forms of aggressive B-cell NHL. The applicant submitted a request for priority review by the FDA in December 2016. The applicant stated that, when approved by the FDA, KTE–C19 would represent the only FDA-approved treatment for adult patients with relapsed refractory aggressive B-cell NHL who are ineligible for ASCT. Currently, there are no ICD–10–CM/PCS codes that describe the administration and use of KTE–C19. The applicant has submitted an application for a unique ICD–10–PCS procedure code to uniquely identify KTE–C19. If approved, the code will be effective October 1, 2017 (FY 2018).

According to the applicant, adult NHL represents by a heterogeneous group of B-cell malignancies with varying patterns of behavior and response to treatment. B-cell NHL can be classified as either aggressive, or indolent disease, with aggressive variants including diffuse large B-cell lymphoma (DLBCL); primary mediastinal large B cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL). Within NHL, DLBCL is the most common subtype of NHL, accounting for approximately 30 percent of patients with NHL, and survival without treatment is measured in months.[20] [21]

The applicant stated that, since the 1970s, cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) has been the mainstay of therapy with more intensive regimens failing to show improved overall survival. The applicant further stated that the approval in 2006 of the anti-CD20 monoclonal antibody rituximab and its addition to the traditional CHOP regimen, R–CHOP, for patients with newly diagnosed aggressive NHL resulted in a dramatic improvement in NHL therapy. The combination of CHOP and R–CHOP is now first-line therapy for treatment of patients diagnosed with DLBCL with complete response rates upwards of 76 percent.[22] Data from the Surveillance, Epidemiology and End Results (SEER) registries have reflected an observed increase of the median overall survival from 20 to 47 months over the last two decades. Despite the improved therapies, only 50 to 70 percent of newly diagnosed patients are cured by standard first-line therapy alone.[23] Furthermore, relapsed or refractory (r/r) disease continues to carry a poor prognosis because only 50 percent of patients are eligible for more intensive second-line regimens, followed by high dose chemotherapy (HDT) and ASCT. Second-line chemotherapy regimens studied to date include rituximab, ifosfamide, carboplatin and etoposide (R–ICE) and rituximab, dexamethasone, cytarabine, and cisplatin (R–DHAP), followed by consolidative HDT/ASCT. Both regimens offer similar overall response rates (ORR) of 51 percent with 1 in 4 patients achieving long-term complete response (CR) at the expense of increased toxicity.[24] Given the modest response to second line therapy and/or HDT/ASCT, the population of patients with the highest unmet need is those with chemorefractory disease, which include DLBCL, PMBCL and TFL. These patients are defined as either progressive disease (PD) as best response to chemotherapy, stable disease as best response following 4 cycles of first-line or 2 cycles of later-line therapy, or relapse within 12 months of ASCT.[25] [26] Based on these definitions and available data from a multicenter retrospective study (SCHOLAR–1), chemorefractory disease treated with current and historical standards of care has consistently poor

[20] Food and Drug Administration. Available at: *http://www.accessdata.fda.gov/scripts/opdlisting/oopd/*.

[21] SEER Stat Fact Sheets—NHL. (2016). Available at: *http://seer.cancer.gov/statfacts/html/nhl.html*.

[22] Coiffier B et al. (2002). CHOP chemotherapy plus rituximab compared with CHOP alone in elderly patients with diffuse large B-cell lymphoma. *N Eng. J Med* 2002; 346(4): 235–242.

[23] Crump M, et al. (2016). Outcomes in refractory aggressive diffuse large B-cell lymphoma (DLBCL): results from the international SCHOLAR–1 study. Abstract 7516, poster and oral presentation at American Society of Clinical Oncology (ASCO) conference, June 2016

[24] Matasar M, et al. (2013). Ofatumumab in combination with ICE or DHAP chemotherapy in relapsed or refractory intermediate grade B-cell lymphoma. *Blood*. 25 July 2013. Vol 122, No 4.

[25] Crump M, et al. (2016). Outcomes in patients with refractory aggressive diffuse large B-cell lymphoma (DLBCL): results from the international scholar-1 study. Abstract and poster presented at Pan Pacific Lymphoma Conference (PPLC), July 2016

[26] Gisselbrecht C, et al. (2016). Results from SCHOLAR–1: Outcomes in patients with refractory aggressive diffuse large B-cell lymphoma (DLBCL). Oral presentation at European Hematology Association conference, July 2016

outcomes with an ORR of 26 percent and median OS of 6.6 months.

According to the applicant, KTE–C19 is a different pathway to treat patients diagnosed with relapsed or refractory disease. KTE–C19 is supplied as a T-cell suspension for infusion. With KTE–C19 treatment, a patient's own T-cells are harvested and engineered ex vivo by retroviral transduction of a chimeric antigen receptor (CAR) construct encoding an anti-CD19 CD28/CD3-zeta. The anti-CD19 CAR T-cells are expanded and infused back into the patient. The new anti-CD19 CAR T-cells can recognize and eliminate CD19 antigen expressing target cells, an antigen also expressed on the cell surface of B-cell lymphomas and leukemias. According to the applicant, prior to KTE–C19 immunotherapy, the patient would have received outpatient administration of a non-myeloablative conditioning chemotherapy regimen consisting of cyclophosphamide 500 mg/m2 IV and fludarabine 30 mg/m2 IV for 3 days at days -5, -4, and -3 before the infusion of KTE–C19 at Day 0. The applicant noted that, if KTE–C19 infusion is delayed more than 2 weeks, readministration of the conditioning chemotherapy regimen may be required. Hospitalization is recommended for the infusion of KTE–C19.

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 regard to the first criterion, the applicant stated that KTE–C19 does not use the same or similar mechanism of action to achieve a therapeutic outcome as any other drug or therapy assigned to the same or a different MS–DRG. The applicant further stated that KTE–C19 is the first engineered autologous cellular immunotherapy comprised of CAR T-cells that recognizes CD19 express cancer cells and normal B-cells; therefore, the applicant believed that KTE–C19's mechanism of action is distinct and unique from any other cancer drug or biologic that is currently approved for use in the treatment of aggressive B-cell NHL, namely single-agent or combination chemotherapy regimens.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant noted that based on the 2014 and 2015 100 Percent Inpatient Standard Analytic files, cases potentially eligible for treatment using the KTE–C19 and representing the target patient population span 50 unique MS–DRGs and 73 percent of all of the cases within these 50 unique MS–DRGs that represent potentially eligible cases for treatment using KTE–C19 map to the following 4 MS–DRGs: MS–DRG 840 (Lymphoma & Non-Acute Leukemia with MCC); MS–DRG 841 (Lymphoma & Non-Acute Leukemia with CC); MS–DRG 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC); and MS–DRG 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC). The applicant stated that, with the assignment of the unique KTE–C19-specific ICD–10–PCS code, patient cases where KTE–C19 is used will be distinguishable. However, patient cases where KTE–C19 is used and patient cases that are treated for DLBCL map to the same MS–DRGs.

With regard 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, the applicant asserted that when approved by the FDA, KTE–C19 would represent the only FDA-approved treatment for adult patients diagnosed with relapsed or refractory aggressive B-cell NHL who are ineligible for ASCT. As a result, the applicant stated that KTE–C19 is not substantially similar to any existing technology and meets the newness criterion. CMS is concerned the CAR technology used in KTE–C19 may have a mechanism of action similar to that seen with the use of bispecific T cell engager (BiTE) technology.

We are inviting public comments on whether KTE–C19 meets the substantial similarity criteria and the newness criterion.

With respect to the cost criterion, the applicant provided an analysis to demonstrate that KTE–C19 meets the cost criterion. The applicant used the 2014 and 2015 100 Percent Inpatient Standard Analytic File (SAF) to assess the MS–DRGs that are most relevant to patients that may be potentially eligible for treatment using KTE–C19. The sample was restricted to patients discharged in FY 2015. The applicant searched for cases with an ICD–9–CM diagnosis code from the series of 200.7x (large cell lymphoma).

The applicant sought to ensure that claims included in the cost criterion analysis reflected charges for treating patients diagnosed with DLBCL and, therefore, minimized the chance that charges were related to other conditions. Therefore, the applicant searched for cases with the following criteria:

- A primary diagnosis with a ICD–9–CM diagnosis code from the series of 200.7x (large cell lymphoma) to identify cases of DLBCL with or without chemotherapy; or
- A secondary diagnosis with a ICD–9–CM diagnosis code from the series of 200.7x (large cell lymphoma) combined with an ICD–9–CM diagnosis code of V58.11, or V58.12, or ICD–9–CM procedure code 99.25, 99.28, 00.15 or 00.10 to identify cases of DLBCL that received chemotherapy during their hospitalization.

The applicant excluded claims where the MS–DRG was missing, Medicare was not the primary payer, there were zero covered charges or zero covered days, or the provider was not in the FY 2017 IPPS/LTCH PPS Final Rule Impact File. Additionally, patients under age 18 were excluded to align with the proposed label that is being prepared for submission with the KTE–C19 Biologics License Application (BLA). After applying the trims above, the results showed 762 cases that mapped to 50 MS–DRGs with 11 MS–DRGs containing more than 10 cases. The 11 MS–DRGs contained a total of 702 cases.

The applicant noted that MS–DRGs 840, 841, 846, and 847 accounted for 554 (73 percent) of the 762 cases in the cohort.

Using the 702 identified cases, the average unstandardized case-weighted charge per case was $71,725. The applicant then standardized the charges. The applicant noted that adult patients with relapsed/refractory aggressive B-cell NHL who are ineligible for ASCT would generally not be receiving treatment with both chemotherapy and KTE–C19. Therefore, all charges listed in the chemotherapy revenue centers (331, 332, and 335) were removed. The applicant then applied the 2-year inflation factor of 1.098446 from the FY 2017 IPPS/LTCH final rule (81 FR 57286) to inflate the charges from FY 2015 to FY 2017. 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. The applicant noted that it was not necessary to take into account the average per patient cost of the technology because 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.

The applicant provided the following three sensitivity analyses to further demonstrate that the technology meets

the cost criterion. The three sensitivity analyses consisted of: (1) cases representing patients identified with an ICD–9–CM diagnosis code 200.7x (large cell lymphoma) and cases representing patients identified with a secondary DLBCL diagnosis who did not receive chemotherapy; (2) cases representing patients identified with a primary or secondary ICD–9–CM diagnosis code from the series of 200.7x (large cell lymphoma) who received chemotherapy; and (3) cases representing patients under a broader ICD–9–CM diagnosis code range to capture other types of lymphoma. In all three of the sensitivity analyses, the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. We are inviting public comments on whether KTE–C19 meets the cost criterion.

According to the applicant, KTE–C19 represents a substantial clinical improvement over existing technologies used in the treatment of patients with aggressive B-cell NHL. The applicant asserted that KTE–C19 can benefit the patient population with the highest unmet need, patients with refractory or relapsed disease after failure of first-line or second-line therapy, and patients who have failed or are ineligible for ASCT. These patients otherwise have adverse outcomes as demonstrated by historical control data.

Regarding clinical data for KTE–C19, the applicant stated that historical control data was the only ethical and feasible comparison information for these chemorefractory, aggressive NHL patients who have no other available treatment options and have a very short lifespan without therapy. According to the applicant, based on meta-analysis of outcomes in chemorefractory DLBCL, there are no curative options for aggressive B-cell NHL patients regardless of refractory subgroup, line of therapy, and disease stage with their median overall survival being 6.6 months.

The applicant provided clinical data from the pivotal Study 1 (ZUMA–1, KTE–C19–101), Phase I and II. The applicant also provided supportive evidence from Study 2 (NCI 009–C–0082). Study 1 is a Phase I–II multicenter, open label study evaluating the safety and efficacy of the use of KTE–C19 in patients diagnosed with aggressive refractory NHL. The trial consists of two distinct phases designed as Phase I (n=7) and Phase II (n=92). Phase II is a multi-cohort open label study evaluating the efficacy of KTE–C19. Study 1 subjects were treated with cyclophosphamide and fludarabine conditioning chemotherapy, followed by a target dose of 2 × 10 anti-CD19 CAR T-cells per kg body weight. Study 2 subjects were treated with cryopreserved autologous anti-CD19 CAR T cells, which were manufactured by a similar, but different process than that used for KTE–C19. The applicant noted that, as of the analysis cutoff date for the interim analysis, the results of Study 1 demonstrated rapid and substantial improvement in objective, or overall response rate. The overall response rate was 79 percent (49 responders among 62 subjects), with 76 percent overall response rate in Cohort 1 (39 responders among 51 subjects) and 91 percent in Cohort 2 (10 responders among 11 subjects) versus historical control of 26 percent. According to the applicant, Study 1 overall response rates were consistent across all age groups, with those patients greater than 65 years of age responding at the rates consistent with those under age 65 years and consistent with earlier, positive results from Study 2. The applicant further stated that pre-specified criteria for demonstration of early efficacy were met and an independent safety monitoring board (DSMB) confirmed the efficacy results and found no additional safety signals.

The applicant further stated that evidence of substantial improvement regarding the efficacy of KTE–C19 for the treatment of chemorefractory, aggressive B-cell NHL is supported by the complete response rates of KTE–C19 in Study 1 (52 percent) versus the historical control (8 percent). Additionally, the applicant noted that the results of Study 1 have demonstrated that treated patients experienced a rapid response to KTE–C19 with 52 percent showing complete response at 3 months, and 41 percent at 1 month.

As noted above, the applicant cited data results from Study 2, which is an ongoing Phase 1 safety and efficacy study in which anti-CD19 CAR T-cells were manufactured using a process similar to, but different from, KTE–C19 to yield cryopreserved autologous anti-CD19 CAR T cells. From Study 2, a subset of 13 patients with a diagnosis of DLBCL/PMBCL was noted to be comparable to those treated in Study 1. The applicant noted that all patients were diagnosed with refractory DLBCL, received similar doses of conditioning chemotherapy, and were infused with the cryopreserved autologous anti-CD19 CAR T-cells (which have been shown to result in an immunotherapy comparable to KTE–C19). The applicant noted that the results from Study 2 demonstrated the following: (a) an overall response rate of 69 percent (9 responders among 13 patients) (95 percent CI 38.6, 90.9); (b) 47 percent of patients had complete response at month 3 (ongoing 6+ to 20+ months); and (c) complete response was observed as early as 1 month in 57 percent of patients in Study 2. According to the applicant, further results will be reported in February 2017.

The applicant also cited safety results from the pivotal Study 1, Phase II. According to the applicant, almost all patients in Study 1 (95 percent) experienced Grade 3 or higher adverse events with onset on or after commencement of conditioning chemotherapy, including cytopenias (Grade 3 and 4 anemia, neutropenia, thrombocytopenia, and lymphopenia were 40 percent, 40 percent, 29 percent, and 5 percent respectively), and infection (Grade 3 or worse urinary tract infection, clostridium difficile colitis and lung infection were 5 percent, 5 percent, and 6 percent respectively). All patients were treated according to standard of care. The clinical trial protocol stipulated that patients were infused with KTE–C19 in the hospital inpatient setting and were monitored in the inpatient setting for at least 7 days for early identification and treatment of KTE–C19 related toxicities, which primarily include cytokine release syndrome and neurotoxicities. The applicant stated that KTE–C19 is expected to be administered in the hospital inpatient setting to assure appropriate monitoring of patient adverse events. The applicant noted that the interim analysis of Study 1 showed the following: length of stay following KTE–C19 infusion was a median of 15 days; cytokine release syndrome (Grade 3 or higher, 18 percent) and neurotoxicity (Grade 3 or higher, 34 percent) were self-limiting and generally reversible; two patients died from KTE–C19 related adverse events (hemophagocytic lymphohistiocytosis and cardiac arrest in the setting of cytokine release syndrome). The medications most often used to treat KTE–C19 clinical trial complications included growth factors, blood products, anti-infectives, steroids, tocilizumab, and vasopressors. In the majority of patients (92 percent), the applicant noted that predominant toxicities associated with the use of KTE–C19, cytokine release syndrome and neurologic events, resolved by data cutoff. Median days to resolution of cytokine release syndrome complications post-KTE–C19 infusion was 9 days, with median days to resolution of KTE–C19-related

neurologic events post-KTE–C19 infusion of 18 days. According to the applicant, there were no clinically important differences in adverse event rates across age groups (younger than 65; 65 or older), including cytokine release syndrome and neurotoxicity, and KTE–C19-related adverse events in Study 1 were consistent with the earlier Study 2 experience.

The applicant further noted that by the cutoff date for the interim analysis of Study 1, among all KTE–C19 treated patients, 12 patients in Study 1, Phase II, including 10 from Cohort 1 and 2 from Cohort 2, died. Eight of these deaths were due to disease progression. One subject had disease progression after KTE–C19 treatment and subsequently had ASCT. After ASCT, the subject died due to sepsis. Two subjects (3 percent) died due to KTE–C19 related AEs (Grade 5 hemophagocytic lymphohistiocytosis event and Grade 5 anoxic brain injury), and one died due to an AE deemed unrelated to KTE–C19 (Grade 5 pulmonary embolism), without disease progression.

We are concerned that there are no published results showing any survival benefit from the treatment. We also are concerned with the limited number of subjects (n=82) that were studied after infusion of KTE–C19 T-cell immunotherapy. Although the applicant references Study 2, we are concerned that the applicant has included data on DLBCL/PMBCL patients that did not specifically receive KTE–C19. Additionally, we are concerned that Study 2 was based on 13 patients which can result in skewed outcomes due to a small patient population. Finally, we note that, for Study 1 and Study 2, the data on overall survival are not reported.

We are inviting public comments on whether KTE–C19 meets the substantial clinical improvement criterion.

Comment: The applicant stated that it has been notified by the United States Adopted Names Council (USAN Council) that the technology's name for KTE–C19 has been revised from ''axicabtagene ciloretroleucel'' to ''axicabtagene ciloleucel.'' In addition, the applicant requested that all references by CMS to the technology's name of KTE–C19 use this final naming convention of ''axicabtagene ciloleucel.''

Response: We appreciate the applicant's updated information and have correlated the name of the technology throughout the discussion above.

e. VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection)

Celator Pharmaceuticals, Inc. submitted an application for new technology add-on payments for VYXEOS™ for FY 2018. The proposed indication for the use of VYXEOS™, which has not received FDA approval as of the time of the development of this proposed rule, is the treatment of adult patients diagnosed with acute myeloid leukemia (AML).

AML is a type of cancer in which the bone marrow makes abnormal myeloblasts (immature bone marrow white blood cells), red blood cells, and platelets. If left untreated, AML progresses rapidly. Normally, the bone marrow makes blood stem cells that develop into mature blood cells over time. Stem cells have the potential to develop into many different cell types in the body. Stem cells can act as an internal repair system, dividing, essentially without limit, to replenish other cells. When a stem cell divides, each new cell has the potential to either remain a stem cell or become a specialized cell, such as a muscle cell, a red blood cell or a brain cell, etc. A blood stem cell may become a myeloid stem cell or a lymphoid stem cell. Lymphoid stem cells become white blood cells. A myeloid stem cell becomes one of three types of mature blood cells: (1) red blood cells that carry oxygen and other substances to body tissues; (2) white blood cells that fight infection; or (3) platelets that form blood clots and help to control bleeding. In patients diagnosed with AML, the myeloid stem cells usually become a type of myeloblast. The myeloblasts in patients diagnosed with AML are abnormal and do not become healthy white blood cells. Sometimes in patients diagnosed with AML, too many stem cells become abnormal red blood cells or platelets. These abnormal cells are called leukemia cells or blasts.

AML is defined by the World Health Organization (WHO) as >20 percent blasts in the bone marrow or blood. AML can also be diagnosed if the blasts are found to have a chromosome change that occurs only in a specific type of AML, even if the blast percentage does not reach 20 percent. Leukemia cells can build up in the bone marrow and blood, resulting in less room for healthy white blood cells, red blood cells, and platelets. When this occurs, infection, anemia, or increased risk for bleeding may result. Leukemia cells can spread outside the blood to other parts of the body, including the central nervous system (CNS), skin, and gums.

Treatment of AML diagnoses usually consists of two phases; remission induction and post-remission therapy. Phase one, remission induction, is aimed at eliminating as many myeloblasts as possible. The most common used remission induction regimens for AML diagnoses are the ''7+3'' regimens using an antineoplastic and an anthracycline. Cytarabine and daunorubicin are two commonly used drugs for ''7+3'' remission induction therapy. Cytarabine is continuously administered intravenously over the course of 7 days, while daunorubicin is intermittently administered intravenously for the first 3 days. The ''7+3'' regimen typically achieves a 70 to 80 percent complete remission (CR) rate in most patients under 60 years of age.

High rates of CR are not generally seen in older patients for a number of reasons, such as different leukemia biology, much higher incidence of adverse cytogenetic abnormalities, higher rate of multidrug resistant leukemic cells, and comparatively lower patient performance status (the standard criteria for measuring how the disease impacts a patient's daily living abilities). Intensive induction therapy has worse outcomes in this patient population.[27] The applicant asserted that many older adults diagnosed with AML have a poor performance status[28] at presentation and multiple medical comorbidities that make the use of intensive induction therapy quite difficult or contraindicated altogether. Moreover, the CR rates of poor-risk patients diagnosed with AML are substantially higher in patients >60 years old; owing to a higher proportion of secondary AML, disease developing in the setting of a prior myeloid disorder, or prior cytotoxic chemotherapy. Therefore, less than half of older adults diagnosed with AML achieve CR with combination induction regimens.[29]

The combination of cytarabine and an anthracycline, either as ''7+3'' regimens or as part of a different regimen incorporating other cytotoxic agents, may be used as so-called ''salvage'' induction therapy in the treatment of adults diagnosed with AML who experience relapse in an attempt to

[27] Juliusson G, Lazarevic V, Horstedt AS, Hagberg O, Hoglund M. Acute myeloid leukemia in the real world: why population-based registries are needed. Blood. 2012 Apr 26; 119(17):3890–9.

[28] Stone RM, *et al.* (2004). Acute myeloid leukemia. Hematology Am Soc Hematol Educ Program. 2004:98–117.

[29] Appelbaum FR, Gundacker H, Head DR. ''Age and acute myeloid leukemia.'' *Blood* 2006; 107:3481–3485.

achieve CR. According to the applicant, while CR rates of success vary widely depending on underlying disease biology and host factors, there is a lower success rate overall in achievement of CR with ''7+3'' regimens compared to VYXEOS™ therapy. In addition, ''7+3'' regimens produce a CR rate of approximately 50 percent in younger adult patients who have relapsed, but were in CR for at least 1 year.[30]

VYXEOS™ is a nano-scale liposomal formulation containing a fixed combination of cytarabine and daunorubicin in a 5:1 molar ratio. This formulation was developed by the applicant using a proprietary system known as CombiPlex. According to the applicant, CombiPlex addresses several fundamental shortcomings of conventional combination regimens, specifically the conventional ''7+3'' free drug dosing, as well as the challenges inherent in combination drug development, by identifying the most effective synergistic molar ratio of the drugs being combined *in vitro,* and fixing this ratio in a nano-scale drug delivery complex to maintain the optimized combination after administration and ensuring exposure of this ratio to the tumor.

Cytarabine and daunorubicin are co-encapsulated inside the VYXEOS™ liposome at a fixed ratiometrically, optimized 5:1 cytarabine:daunorubicin molar ratio. According to the applicant, encapsulation maintains the synergistic ratios, reduces degradation, and minimizes the impact of drug transporters and the effect of known resistant mechanisms. The applicant stated that the 5:1 molar ratio has been shown, *in vitro,* to maximize synergistic antitumor activity across multiple leukemic and solid tumor cell lines, including AML, and in animal model studies to be optimally efficacious compared to other cytarabine:daunorubicin ratios. In addition, the applicant stated that in clinical studies, the use of VYXEOS™ has demonstrated consistently more efficacious results than the conventional ''7+3'' free drug dosing. VYXEOS™ is intended for intravenous administration after reconstitution with 19 mL sterile water for injection. VYXEOS™ is administered as a 90-minute intravenous infusion on days 1, 3, and 5 (induction therapy), as compared to the ''7+3'' free drug dosing, which consists of two individual drugs administered on different days, including 7 days of continuous infusion.

With regard to the ''newness'' criterion, the applicant indicated that the rolling New Drug Application (NDA) submission to the FDA for VYXEOS™ began on September 30, 2016. The applicant stated that it intends to request Priority Review from the FDA. VYXEOS™ is currently available in the United States only on an investigational basis, under an Investigational New Drug (IND) designation. Breakthrough Therapy designation was granted on May 19, 2016, for the treatment of adults diagnosed with therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML–MRC). Fast Track designation was granted by the FDA in January 2015 for the treatment of elderly patients diagnosed with secondary AML. Orphan Drug designation was granted by the FDA on August 22, 2008, for the treatment of acute AML. VYXEOS™ had not received pre-market (PMA) approval from the FDA at the time of development of this proposed rule. However, the applicant anticipates receiving approval from the FDA by July 1, 2017. The applicant also has submitted a request for a unique ICD–10–PCS code, beginning with FY 2018.

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 regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant asserted that VYXEOS™ does not use the same or similar mechanism of action to achieve a therapeutic outcome as any other drug assigned to the same or a different DRG. The applicant stated that no other AML treatment is designed, nor is able, to deliver a fixed, ratiometrically optimized and synergistic drug:drug ratio of 5:1 cytarabine to daunorubicin, and selectively target and accumulate at the site of malignancy, while minimizing unwanted exposure, which the applicant based on the data results of preclinical and clinical studies of the use of VYXEOS™. The applicant indicated that VYXEOS™ is a nano-scale liposomal formulation of a fixed combination of cytarabine and daunorubicin. Further, the applicant stated that the rationale for the development of VYXEOS™ is based on prolonged delivery of synergistic drug ratios utilizing the applicant's proprietary, ratiometric CombiPlex technology. According to the applicant, conventional ''7+3'' free drug dosing has no delivery complex, and these individual drugs are administered without regard to their ratio dependent interaction. According to the applicant, enzymatic inactivation and imbalanced drug efflux and transporter expression reduce drug levels in the cell. Decreased cytotoxicity leads to cell survival, emergence of drug resistant cells, and decreased overall survival.

The applicant provided the results of clinical studies to demonstrate that the CombiPlex technology and the ratiometric dosing of VYXEOS™ represent a shift in anticancer agent delivery, whereby the fixed, optimized dosing provides less drug to achieve improved efficacy, while maintaining a favorable risk-benefit profile. The results of this ratiometric dosing approach are in contrast to the typical combination chemotherapy development that establishes the recommended dose of one agent and then adds subsequent drugs to the combination at increasing concentrations until the aggregate effects of toxicity are considered to be limiting (the ''7+3'' drug regimen). According to the applicant, this current approach to combination chemotherapy development assumes that maximum therapeutic activity will be achieved with maximum dose intensity for all drugs in the combination, and ignores the possibility that more subtle concentration-dependent drug interactions could result in frankly synergistic outcomes.

The applicant maintained that, while VYXEOS™ contains no novel active agents, its innovative drug delivery mechanism appears to be a superior way to deliver the two active compounds in an effort to optimize their efficacy in killing leukemic blasts. However, we are concerned it is possible that VYXEOS™ may use a similar mechanism of action compared to current treatment because both the current treatment regimen and VYXEOS™ are used in the treatment of AML by intravenous administration of cytarabin and daunorubicin.

With respect to the second criterion, whether a product is assigned to the same or a different MS–DRG, the applicant maintained that based on the 2014 and 2015 100 Percent Inpatient Standard Analytic files, cases representing patients potentially eligible for treatment using VYXEOS™ and the target patient population span 134 unique MS–DRGs, and 78 percent of all of the cases within these 134 unique MS–DRGs map to the following 4 MS–DRGs: 834 (Acute Leukemia Without Major O.R. Procedure With MCC), 837 (Chemotherapy With Acute Leukemia as SDX or With High Dose Chemotherapy

[30] Kantarjian H, Rayandi F, O'Brien S *et al.* ''Intensive chemotherapy does not benefit most older patients (age 70 years and older) with acute myeloid leukemia.'' *Blood* 2010; 116(22):4422.

Agent with MCC), 838 (Chemotherapy With Acute Leukemia as SDX With CC or High Dose Chemotherapy Agent), and 839 (Chemotherapy With Acute Leukemia as SDX Without CC/MCC). We believe that these are the same MS–DRGs that identify cases representing patients who are treated for AML.

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, the applicant asserted that VYXEOS™ is indicated for the use in patients diagnosed with high-risk AML. However, we believe that VYXEOS™ involves the treatment of the same patient population as other AML treatment therapies.

We are inviting public comments on whether VYXEOS™ is substantially similar to existing technology, including whether the mechanism of action of VYXEOS™ differs from the mechanism of action of the current treatment regimen. We also are inviting public comments on whether VYXEOS™ meets the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant used the 2014 and 2015 100 Percent Inpatient Standard Analytic Files (SAFs) to assess the MS–DRGs assigned for hospitalizations most likely to represent patients that may be eligible for treatment with VYXEOS™. The sample of claims was limited to discharges occurring in FY 2015 (that is, from October 1, 2014 to September 30, 2015).

The applicant identified patients as potential VYXEOS™ candidates by searching for cases indicating a diagnosis of AML. Specifically, the applicant searched for cases that met the following criteria:

- Had an ICD–9–CM diagnosis code of 205.00 (Acute myeloid leukemia, without mention of having achieved remission), or 205.02 (Acute myeloid leukemia, in relapse); or
- The patient received chemotherapy during their hospital stay as indicated by the following principal/secondary ICD–9–CM diagnosis codes or ICD–9–CM procedure codes: V58.11 (Encounter for antineoplastic chemotherapy); V58.12 (Encounter for antineoplastic immunotherapy; 00.10 (Implantation of chemotherapeutic agent); 00.15 (High-Dose infusion interleukin-2); 99.25 (Injection or Infusion of cancer chemotherapeutic substance); or 99.28 (Injection or infusion of biological response modifier as an antineoplastic agent); and
- Excluded cases that had a bone marrow transplant based on the following ICD–9–CM procedure codes: 41.00 (Bone marrow transplant, not otherwise specified); 41.01 (Autologous bone marrow transplant without purging); 41.02 (Allogeneic bone marrow transplant with purging); 41.03 (Allogeneic bone marrow transplant without purging); 41.04 (Autologous hematopoietic stem cell transplant without purging); 41.05 (Allogeneic hematopoietic stem cell transplant without purging); 41.06 (Cord blood stem cell transplant); 41.07 (Autologous hematopoietic stem cell transplant with purging); 41.08 (Allogeneic hematopoietic stem cell transplant); and 41.09 (Autologous bone marrow transplant with purging).

According to the applicant, the eligible cases span 134 unique MS–DRGs, 14 of which contain more than 10 cases. The most common MS–DRGs are MS–DRGs 834, 837, 838, and 839. These 4 MS–DRGs account for 3,601 (78 percent) of the 4,613 potential eligible cases.

Using the 4,613 identified cases, the average unstandardized case-weighted charge per case was $203,234. The applicant then standardized the charges. The applicant removed charges for the current treatment. The applicant then applied the 2-year inflation factor of 1.098446 from the FY 2017 IPPS/LTCH final rule (81 FR 57286) to inflate the charges from FY 2015 to FY 2017. Based on the FY 2017 IPPS/LTCH PPS Table 10 thresholds, the average case-weighted threshold amount was $84,639. The inflated average case-weighted standardized charge per case was $178,392. 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 average case-weighted standardized charge per case for the applicable MS–DRGs exceeds the average case-weighted threshold amount without taking into account the average per patient cost of the technology to the hospital. Therefore, the analysis above did not include the cost of VYXEOS™.

As previously stated, according to the applicant, the potentially eligible cases used for the cost criterion analysis included patients diagnosed with AML who received chemotherapy during their hospital stay, but did not receive a bone marrow transplant. The applicant asserted that this patient cohort is inclusive of all likely potential patients that may be eligible for treatment using VYXEOS™. The applicant conducted the same analysis, but excluded all pharmacy and IV therapy charges. Additionally, to test the sensitivity of cohort specification, the applicant conducted the following four additional sensitivity analyses that used alternative cohort definitions: (1) Included AML cases with ICD–9–CM diagnosis code 205.00 and chemotherapy; (2) included AML cases with ICD–9–CM diagnosis code 205.02 and chemotherapy; (3) included cases with AML principal diagnosis and chemotherapy; and (4) included AML cases without requiring chemotherapy. In all of these analyses, the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. We are inviting public comments whether VYXEOS™ meets the cost criterion.

With regard to substantial clinical improvement, according to the applicant, clinical data results have shown that the use of VYXEOS™ represents a substantial clinical improvement for the treatment of AML in newly diagnosed high-risk, older (60 years and older) patients, marked by statistically significant improvements in overall survival, event free survival and response rates, and in relapsed patients age 18 to 65 years of age, where a statistically significant improvement in overall survival was documented for the poor-risk subset of patients as defined by the European Prognostic Index. In both groups of patients, the applicant stated that there was significant improvement in survival for the high-risk patient group. The applicant provided the following specific clinical data results.

- The applicant stated the clinical data results show that treatment with VYXEOS™ in older patients (60 years of age and older) diagnosed with untreated, high-risk AML will result in superior survival rates, as compared to patients treated with conventional ''7+3'' free drug dosing. The applicant provided a summary of the pivotal Phase III Study 301 in which 309 patients were enrolled, with 153 patients randomized to the VYXEOS™ arm and 156 to the ''7+3'' free drug dosing arm. Among patients aged 60 to 69 years, there were 96 patients in the VYXEOS™ arm and 102 in the ''7+3'' free drug dosing arm; for patients aged 70 to 75 years, there were 57 and 54 patients in each arm, respectively. The applicant noted that the data results from the Phase III Study 301 demonstrated that first-line treatment of patients diagnosed with high-risk AML in the VYXEOS™ arm resulted in substantially greater median overall survival of 9.56 months versus 5.95 months in the ''7+3'' free drug dosing arm (hazard ratio of 0.69; p =0.005).

• The applicant further asserted that high-risk, older patients (60 years of age and older) previously untreated for diagnoses of AML will have a lower risk of early death when treated with VYXEOS™ than those treated with the conventional ''7+3'' free drug dosing. The applicant cited Medeiros, et al. 2015,[31] which reported a large observational study of Medicare beneficiaries and noted the following: The data result of the study showed that 50 to 60 percent of elderly patients diagnosed with AML remain untreated following diagnosis; treated patients were more likely younger, male, and married, and less likely to have secondary diagnoses of AML, poor performance indicators, and poor comorbidity scores compared to untreated patients; and in multivariate survival analyses, treated patients exhibited a significant 33 percent lower risk of death compared to untreated patients.

Based on data from the Phase III Study 301,[32] the applicant cited the following results: The rate of 60-day mortality was less in the VYXEOS™ arm (13.7 percent) versus the ''7+3'' free drug dosing arm (21.2 percent); the reduction in early mortality was due to fewer deaths from refractory AML (3.3 percent versus 11.3 percent), with very similar rates of 60-day mortality due to adverse events (10.4 percent versus 9.9 percent); there were fewer deaths in the VYXEOS™ arm versus the ''7+3'' free drug dosing arm during the treatment phase (7.8 percent versus 11.3 percent); and there were fewer deaths in the VYXEOS™ arm during the follow-up phase than in the ''7+3'' free drug dosing arm (59.5 percent versus 71.5 percent).

• The applicant asserted that high-risk, older patients (60 years of age and older) previously untreated for a diagnosis of AML exhibited statistically significant improvements in response rates after treatment with VYXEOS™ versus treatment with the conventional ''7+3'' free drug chemotherapy dosing, suggesting that the use of VYXEOS™ is a superior pre-transplant induction treatment versus ''7+3'' free drug dosing. Restoration of normal hematopoiesis is the ultimate goal of any therapy for AML diagnoses. The first phase of treatment consists of induction chemotherapy, in which the goal is to ''empty'' the bone marrow of all hematopoietic elements (both benign and malignant), and to allow repopulation of the marrow with normal cells, thereby yielding remission. According to the applicant, post-induction response rates were significantly higher following the use of VYXEOS™, which elicited a 47.7 percent total response rate and a 37.3 percent rate for CR, whereas the total response and CR rates for the ''7+3'' free drug dosing arm were 33.3 percent and 25.6 percent, respectively. The CR + CRi rates for patients aged 60 to 69 years were 50.0 percent in the VYXEOS™ arm and 36.3 percent in the ''7+3'' free drug dosing arm, with an odds ratio of 1.76 (95 percent CI, 1.00–3.10). For patients aged 70 to 75, the rates of CR + CRi were 43.9 percent in the VYXEOS™ arm and 27.8 percent in the ''7+3'' free drug dosing arm.

• The applicant asserted that VYXEOS™ treatment will enable high-risk, older patients (60 years of age and older) to bridge to allogeneic transplant, and VYXEOS™ responding patients will have markedly better outcomes following transplant. The applicant stated that diagnoses of secondary AML are considered incurable with standard chemotherapy approaches and, as with other high-risk hematological malignancies, transplantation is a useful treatment alternative. The applicant further stated that autologous HSCT has limited effectiveness and at this time, only allogeneic HSCT with full intensity conditioning has been reported to produce long-term remissions. However, the applicant stated that the clinical study by Medeiros et al., 2015, reported that, while the use of allogeneic HSCT is considered a potential cure for AML, its use is limited in older patients because of significant baseline comorbidities and increased transplant-related morbidity and mortality. Patients in either arm of the Phase III Study 301 responding to induction with a CR or CR+CRi (n=125) were considered for allogeneic hematopoietic cell transplant (HCT) when possible. In total, 91 patients were transplanted: 52 (34 percent) from the VYXEOS™ arm and 39 (25 percent) from the ''7+3'' free drug dosing arm. Patient and AML characteristics were similar according to randomized arm, including percentage of patients in each arm that underwent transplant in CR+CRi status. However, the applicant noted that the VYXEOS™ arm contained a higher percentage of older patients (aged 70 or greater) who were transplanted (VYXEOS™, 31 percent; ''7+3'' free drug dosing, 15 percent).[33]

According to the applicant, patient outcome following transplant strongly favored patients in the VYXEOS™ arm. The Kaplan-Meier analysis of the 91 transplanted patients landmarked at the time of HCT showed that patients in the VYXEOS™ arm had markedly better overall survival (hazard ratio 0.46; p=0.0046). The time-dependent Adjustment Model (Cox proportional hazard ratio) was used to evaluate the contribution of VYXEOS™ to overall survival rate after adjustment for transplant and showed that VYXEOS™ remained a significant contributor, even after adjusting for transplant. The time-dependent Cox hazard ratio for overall survival rates in the VYXEOS™ arm versus the ''7+3'' free drug dosing arm was 0.51 (95 percent CI, 0.35–0.75; P=.0007).

• The applicant asserted that VYXEOS™ treatment of previously untreated older patients (60 years of age and older) diagnosed with high-risk AML increases the response rate and improves survival compared to conventional ''7+3'' free drug dosing in patients diagnosed with FLT3 mutation. The applicant noted the following: approximately 20 to 30 percent of AML patients harbor some form of FLT3 mutation, AML patients with a FLT3 mutation have a higher relapse rate and poorer prognosis than the overall population diagnosed with AML, and the most common type of mutation is internal tandem duplication (ITD) mutation localized to a membrane region of the receptor.

The applicant cited Gordon et al., 2016,[34] which reported on the significant anti-leukemic activity of VYXEOS™ in AML blasts exhibiting high-risk characteristics, including FLT3–ITD, that are typically associated with poor outcomes when treated with conventional ''7+3'' free drug dosing. To determine whether the improved complete remission and overall survival rates of VYXEOS™ as compared to conventional ''7+3'' free drug dosing are attributable to liposome-mediated altered drug PK or direct cellular interactions with specific AML blast samples, the authors evaluated cytotoxicity in 53 AML patient specimens. Cytotoxicity results were correlated with patient characteristics,

[31] Medeiros B, *et al.* (2015). Big data analysis of treatment patterns and outcomes among elderly acute myeloid leukemia patients in the United States. *Ann Hematol.* 2015; 94(7): 1127–1138.

[32] Lancet J, et al. (2016). Final results of a Phase III randomized trial of VYXEOS (CPX–351) versus 7+3 in older patients with newly diagnosed, high-risk (secondary) AML. Abstract and oral presentation at American Society of Clinical Oncology (ASCO), June 2016.

[33] Stone Hematology 2004; Gordon AACR 2016; NCI, cancer.gov.

[34] Gordon M, Tardi P, Lawrence MD *et al.* ''CPX–351 cytotoxicity against fresh AML blasts increased for FLT3–ITD+ cells and correlates with drug uptake and clinical outcomes.'' Abstract 287 and poster presented at AACR (American Association for Cancer Research). April 2016.

as well as VYXEOS™ cellular uptake and molecular phenotype status including FLT3–ITD, which is a predictor of poor patient outcomes to conventional ''7+3'' free drug dosing. The applicant stated that a notable result from this research was the observation that AML blasts exhibiting the FLT3–ITD phenotype exhibited some of the lowest IC_{50} (the 50 percent inhibitory concentration) values and, as a group, were five-fold more sensitive to VYXEOS™ than those with wild type FLT3. In addition, there was evidence that increased sensitivity to VYXEOS™ was associated with increased uptake of the drug-laden liposomes by the patient-derived AML blasts. The applicant noted that Gordon, et al. 2016, concluded taken together, the data are consistent with clinical observations where VYXEOS™ retains significant anti-leukemic activity in AML patients exhibiting high-risk characteristics. The applicant also noted that a sub analysis of Phase III Study 301 identified 22 patients diagnosed with FLT3 mutation in the VYXEOS™ arm and 20 in the ''7+3'' free drug dosing arm, which resulted in the following response rates of FLT3 mutated patients, which were higher with VYXEOS™ (15 of 22, 68.2 percent) versus ''7+3'' free drug dosing (5 of 20, 25.0 percent); and the Kaplan-Meier analysis of the 42 FLT3 mutated patients showed that patients in the VYXEOS™ arm had a trend towards better overall survival rates (hazard ratio 0.57; p=0.093).

• The applicant asserted that younger patients (18 to 65 years of age) with poor risk first relapse AML have shown higher response rates with VYXEOS™ versus conventional ''salvage'' chemotherapy. Overall, the applicant stated that the use of VYXEOS™ had an acceptable safety profile in this patient population based on 60-day mortality data. Study 205 [35] was a randomized study comparing VYXEOS™ against the investigator's choice of first ''salvage'' chemotherapy in patients diagnosed with relapsed AML after a first remission lasting greater than 1 month (VYXEOS™ arm, n=81 and ''7+3'' free drug dosing arm, n=44; ages 18 to 65 year of age). Investigator's choice was almost always based on cytarabine + anthracycline, usually with the addition of one or two new agents. According to the applicant, VYXEOS™ demonstrated a higher rate of morphological leukemia clearance among all patients, 43.2 percent versus 40.0 percent, and the advantage was most apparent in poor-risk patients, 78.7 percent versus 44.4 percent, as defined by the European Prognostic Index (EPI). In the subset analysis of this EPI poor-risk patient subset, the applicant stated there was a significant improvement in survival rate (6.6 versus 4.2 months median, hazard ratio=0.55, p=0.02) and improved response rate (39.3 percent versus 27 percent). The applicant also noted the following: the safety profile for the use of VYXEOS™ was qualitatively similar to that of control ''salvage'' therapy, with nearly identical 60-day mortality rates (14.8 percent versus 15.9 percent); among VYXEOS™ treated patients, those with no history of prior HSCT (n=59) had higher response rates (54.2 percent versus 37.8 percent) and lower 60-day mortality (10.2 percent versus 16.2 percent); overall, the use of VYXEOS™ had acceptable safety based on 60-day mortality data, with somewhat higher frequency of neutropenia and thrombocytopenia-related grade 3–4 adverse events. Even though these patients are younger (18 to 65 years of age) than the population studied in Phase III Study 301 (60 years and older), Study 205 patients were at a later stage of disease and almost all had responded to first-line therapy (cytarabine + anthracycline) and had relapsed. The applicant also cited Cortes, et al. 2015,[36] which reported that patients diagnosed with first relapse AML have limited likelihood of response and short expected survival following ''salvage'' treatment with the results from literature showing that:

• Mitoxantrone, etoposide, and cytarabine induced response in 23 percent of patients, with median overall survival of only 2 months.

• Modulation of deoxycitidine kinase by fludarabine led to the combination of fludarabine and cytarabine, resulting in a 36 percent CR rate with median remission duration of 39 weeks.

• First salvage gemtuzumab ozogamicin induced CR+CRp (or CR+CRi) response in 30 percent of patients with CD33+ AML and, for patients with short first CR durations, appeared to be superior to cytarabine-based therapy.

The applicant noted that Study 205 results showed the use of VYXEOS™ retained greater anti-leukemic efficacy in patients diagnosed with poor-risk first relapse AML, and produced higher morphological leukemia clearance rates (78.7 percent) compared to conventional ''salvage'' therapy (44 percent). The applicant further noted that, overall, the use of VYXEOS™ had acceptable safety profile in this patient population based on 60-day mortality data.

Based on all of the data presented above, the applicant concluded that VYXEOS™ represents a substantial clinical improvement over existing technologies. However, we are concerned that, although there was an improvement in a number of outcomes in Phase III Study 301, specifically overall survival rate, lower risk of early death, improved response rates, better outcomes following transplant, increased response rate and overall survival in patients diagnosed with FLT3 mutation, and higher response rates versus conventional ''salvage'' chemotherapy in younger patients diagnosed with poor-risk first relapse, the improved outcomes may not be statistically significant. Furthermore, we are concerned that the overall improvement in survival from 5.95 months to 9.56 months may not represent a substantial clinical improvement. In addition, the rate of adverse events in both arms of Study 205, given the theoretical benefit of reduced toxicity with the liposomal formulation, was similar for both the VYXEOS™ and ''7+3'' free drug treatment groups. Therefore, we also are concerned that there is a similar rate of adverse events, such as febrile neutropenia (68 percent versus 71 percent), pneumonia (20 percent versus 15 percent), and hypoxia (13 percent versus 15 percent), with the use of VYXEOS™ as compared with the conventional ''7+3'' free drug regimen.

We are inviting public comments on whether the VYXEOS™ meets the substantial clinical improvement criterion.

Below we summarize and respond to comments submitted on VYXEOS™ during the open comment period in response to the New Technology Town Hall meeting notice.

Comment: The applicant provided a written response regarding the definition of ''free drug'' as ''Unbound drug pharmacology;'' an active drug or other compound that is not bound to a carrier protein–for example, albumin or alpha-1-acid glycoprotein. The applicant explained that the term ''free-drug dosing'' is used to describe the two different non-encapsulated, separately administered drugs in the ''7+3'' free drug regimen (cytarabine and daunorubicin), each an unrestricted uniform aqueous solution of the drug in water for continuous administration of cytarabine and separate intravenous

[35] Cortes J, *et al.* (2011). Significance of prior HSCT on the outcome of salvage therapy with CPX–351 or conventional chemotherapy among first relapse AML patients. Abstract and poster presented at ASH 2011.

[36] Cortes J, *et al.* (2015). Phase II, multicenter, randomized trial of CPX–351 (cytarabine:daunorubicin) liposome injection versus intensive salvage therapy in adults with first relapse AML. Cancer. January 2015, 234–42.

administration of daunorubicin according to the ''7+3'' dosing schedule. The applicant then stated that the fixed molar drug ratio delivered by VYXEOS™ is not relevant to the conventional dosing of the two free drugs, cytarabine and daunorubicin. The applicant explained that the doses of cytarabine and daunorubicin used in the conventional ''7+3'' free drug dosing regimen were based on the maximum tolerated dose of the two agents, not on any concept related to a drug ratio that provides optimal synergy. Finally, the ratio of cytarabine and daunorubicin administered in free (non-liposomal) form is irrelevant because the administered ratio cannot be maintained when these drugs are infused separately. This is because the drugs will be distributed and eliminated differentially and independently of one another and the ratio will change rapidly and continuously. Consequently, according to the applicant, the inability to control drug ratios following administration in conventional dosage forms likely results in exposure of tumor cells to antagonistic drug ratios with a corresponding loss of therapeutic activity.

Response: We appreciate the applicant's comments. We will take these comments into consideration when deciding whether to approve new technology add-on payments for VYXEOS™.

f. GammaTile™

Isoray Medical, Inc. & GammaTile, LLC submitted an application for new technology add-on payments for FY 2018 for the GammaTile™. The GammaTile™ is a brachytherapy technology for use in the treatment of patients diagnosed with brain tumors using cesium-131 radioactive sources embedded in a collagen matrix. GammaTile™ is designed to provide adjuvant radiation therapy to eliminate remaining tumor cells in patients who required surgical resection of brain tumors. According to the applicant, the GammaTile™ is a new vehicle of delivery for and inclusive of cesium-131 brachytherapy sources embedded within the product. The applicant stated that the technology has been manufactured for use in the setting of a craniotomy resection site where there is a high chance of local recurrence of a CNS or dual-based tumor. The applicant asserted that the use of GammaTile™ provides a new, unique modality for treating patients who require radiation therapy to augment surgical resection of malignancies of the brain. By offsetting the radiation sources with a 3mm gap of a collagen matrix, the applicant asserted that the use of GammaTile™ resolves issues with ''hot'' and ''cold'' spots associated with brachytherapy, improves safety, and potentially offers a treatment option for patients with limited, or no other, available options. The GammaTile™ is biocompatible and bioabsorbable, and is left in the body permanently without need for future surgical removal. The applicant asserted that the commercial manufacturing of the product will significantly improve on the process of constructing customized implants with greater speed, efficiency, and accuracy than is currently available, and require less surgical expertise in placement of the radioactive sources, allowing a greater number of surgeons to utilize brachytherapy techniques in a wider variety of hospital settings.

The applicant for GammaTile™ has applied for FDA approval and anticipated FDA approval by the spring of 2017. In its application, the applicant indicated that it anticipated that the product would be approved by the FDA for use in both the primary and salvage treatment of radiosensitive malignances of the brain. However, the applicant had not received FDA approval at the time of development of this proposed rule. In subsequent discussions with the applicant, the applicant indicated that it is only seeking FDA approval for use in the salvage treatment of recurrent radiosensitive malignances of the brain. The applicant submitted a request for a unique ICD–10–PCS code for the administration of GammaTile™. If approved, the procedure codes will be effective October 1, 2017 (FY 2018).

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 regard to the first criterion, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant stated that when compared to treatment using external beam radiation therapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. The applicant explained that the GammaTile™ is fundamentally different in structure, function, and safety from all external beam radiation therapies, and delivers treatment through a different mechanism of action. In contrast to external beam radiation modalities, the applicant further explained that the GammaTile™ is a form of internal radiation termed brachytherapy. Brachytherapy treatments are performed using radiation sources positioned very close to the area requiring radiation treatment and only deliver radiation to the tissues that are immediately adjacent to the margin of the surgical resection. For this reason, brachytherapy is a current standard of care treatment for many non-central nervous system tumors, including breast, cervical, and prostate cancers.

Due to the custom positioning of the radiological sources and the use of the cesium-131 isotope, the applicant noted that the GammaTile™ focuses therapeutic levels of radiation on an extremely small area of the brain. Unlike all external beam techniques, the applicant stated that this radiation does not pass externally inward through the skull and healthy areas of the brain to reach the targeted tissue and, therefore, may limit neurocognitive deficits seen with the use of external beam techniques. Because of the rapid reduction in radiation intensity that is characteristic of cesium-131, the applicant asserted that the GammaTile™ can target the margin of the excision with greater precision than any alternative treatment option, while sparing healthy brain tissue from unnecessary and potentially damaging radiation exposure.

The applicant also stated that, when compared to other types of brain brachytherapy, GammaTile™ uses a new and unique mechanism of action to achieve a therapeutic outcome. The applicant explained that cancerous cells at the margins of a tumor resection cavity can also be irradiated with the placement of brachytherapy sources in the tumor cavity. However, the applicant asserted that the GammaTile™ is a pioneering form of brachytherapy for the treatment of brain tumors that uses the isotope cesium-131 embedded in a collagen implant that is customized to the geometry of the brain cavity. According to the applicant, use of cesium-131 and the custom distribution of seeds in a three-dimensional collagen device result in a unique and highly effective delivery of radiation therapy to brain tissue.

With regard to the second criterion, whether a product is assigned to the same or a different MS–DRG, GammaTile™ is a treatment option for patients diagnosed with brain tumors that progress locally after initial treatment with external beam radiation therapy, and cases representing patients that may be eligible for treatment involving this technology are assigned to the same MS–DRGs (MS–DRGs 25, 26, and 27 (Craniotomy & Endovascular Intracranial Procedure with MCC, with CC, and without CC/MCC), respectively)

as other current treatment forms of brachytherapy and external beam radiation therapy.

With regard to 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, the applicant stated that the GammaTile™ offers a treatment option for a patient population with limited, or no other, available treatment options. The applicant explained that treatment options for patients diagnosed with brain tumors that progress locally after initial treatment with external beam radiation therapy are limited, and there is no current standard of care in this setting. According to the applicant, surgery alone for recurrent tumors may provide symptom relief, but does not remove all of the cancer cells. The applicant further stated that repeating external beam radiation therapy for adjuvant treatment is hampered by an increasing risk of brain injury because additional external beam radiation therapy will increase the total dose of radiation to brain tissue, as well as increase the total volume of irradiated brain tissue. Secondary treatment with external beam radiation therapy is often performed with a reduced and, therefore, less effective dose. The applicant asserted that brachytherapy with GammaTile™ may be the only effective treatment option for these patients.

Based on the above, the applicant concluded that the GammaTile™ is not substantially similar to other existing technologies and meets the newness criterion. However, we are concerned that the mechanism of action for this device may be the same or similar to current forms of radiation or brachytherapy. Specifically, while the placement of the cesium-131 source (or any radioactive source) in a collagen matrix offset may constitute a new delivery vehicle, we are concerned that this sort of improvement in brachytherapy for use in the salvage treatment of radiosensitive malignances of the brain may not represent a new mechanism of action. We also have concerns as to whether GammaTile™ would represent the first approved use of offset radioactive material in brachytherapy for recurrent brain malignancies. The applicant cited studies that used a similar predicate device, but did not indicate whether these researchers or institutions are seeking separate FDA approval.

We are inviting public comments on whether GammaTile™ meets the substantial similarity criteria and the newness criterion.

With regard to the cost criterion, the applicant conducted the following analysis. The applicant worked with the Barrow Neurological Institute at St. Joseph's Hospital and Medical Center (St. Joseph's) to obtain actual claims for craniotomies using a prototype brain brachytherapy device of stranded cesium-131 seeds held in place with a collagen tile. The application found a total of 23 claims from FY 2001 through FY 2016 data that used a cesium-131 brachytherapy predicate device. All 23 claims were assigned to MS–DRGs 25 through 27. Of the 23 cases, 13 cases were assigned to MS–DRG 25, 4 cases were assigned to MS–DRG 26, and 6 cases were assigned to MS–DRG 27. Using hospital data, the applicant estimated and then subtracted all charges for the predicate device and all charges for ancillary services associated with the device delivery for each case. The applicant standardized the remaining charges for each case and inflated each case's charges by applying the FY 2017 IPPS/LTCH PPS final rule outlier charge inflation factor of 1.043957 by the age of each case (that is, the factor was applied to FY 2011 claims six times, to FY 2012 claims five times, etc.). The applicant then calculated the average inflated standardized charges for the cases assigned to MS–DRG 25 ($124,064), MS–DRG 26 ($131,677) and MS–DRG 27 ($90,615). The applicant then calculated an estimate for ancillary charges associated with placement of the GammaTile™ device, as well as standardized charges for the GammaTile™ device itself. The applicant determined it meets the cost criterion because the final average case-weighted standardized charge per case (including the charges associated with the GammaTile™ device) of $226,741 exceeds the average case-weighted threshold amount of $95,783.

We are concerned that the applicant submitted a small sample of cases to determine it meets the cost criterion. A small sample size may not be statistically significant to determine if the GammaTile™ meets the cost criterion. We also note that, while the applicant has attributed reduced operating room times as a significant benefit to the GammaTile™, a reduction in the associated costs does not appear to be reflected in its calculations. We are inviting public comments on whether the GammaTile™ meets the cost criterion.

With regard to substantial clinical improvement, the applicant stated that the GammaTile™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments and significantly improves clinical outcomes when compared to currently available treatment options. The applicant explained that therapeutic options for patients diagnosed with large or recurrent brain metastases are limited. However, according to the applicant, the GammaTile™ provides a treatment option for patients diagnosed with radiosensitive recurrent brain tumors that are not eligible for treatment with any other currently available treatment option. Specifically, the applicant stated that GammaTile™ may provide the only radiation treatment option for patients diagnosed with tumors located close to sensitive vital brain sites (for example, brain stem); patients diagnosed with recurrent brain tumors may not be eligible for additional treatment involving the use of external beam radiation therapy. There is a lifetime limit for the amount of radiation therapy a specific area of the body can receive. Patients whose previous treatment includes external beam radiation therapy may be precluded from receiving high doses of radiation associated with subsequent external beam radiation therapy, and the GammaTile™ can also be used to treat tumors that are too large for treatment with external beam radiation therapy. These large tumors are not eligible for treatment with external beam radiation therapy because the radiation dose to healthy brain tissue would be too high.

The applicant described how the GammaTile™ improves clinical outcomes compared to existing treatment options, including external beam radiation therapy and other forms of brain brachytherapy. To demonstrate that the GammaTile™ represents a substantial clinical improvement over existing technologies, the applicant submitted data from three abstracts, with one associated paper demonstrating feasibility or superior progression-free survival compared to the patient's own historical control rate.

In a presentation at the Society for Neuro-Oncology in November 2014 (Dardis, Christopher; Surgery and permanent intraoperative brachytherapy improves time to progression of recurrent intracranial neoplasms), the outcomes of 20 patients diagnosed with 27 tumors covering a variety of histological types treated with the GammaTile™ prototype were presented. The applicant noted the following with regard to the patients: (1) All tumors were intracranial, supratentorial masses and included low and high-grade meningiomas, metastases from various primary cancers, high-grade gliomas, and others;

(2) all treated masses were recurrent following treatment with surgery and/or radiation and the group averaged two prior craniotomies and two prior courses of external beam radiation treatment; and (3) following surgical excision, prototype GammaTiles™ were placed in the resection cavity to deliver a dose of 60 Gray to a depth of 5 mm of tissue; and all patients had previously experienced re-growth of their tumors at the site of treatment and the local control rate of patients entering the study was 0 percent.

With regard to outcomes, the applicant stated that, after their initial treatment, patients had a median progression-free survival time of 5.8 months; post treatment with prototype GammaTiles™, at the time of this analysis, only one patient had progressed at the treatment site, for a local control rate of 96 percent; and median progression-free survival time, a measure of how long a patient lives without recurrence of the treated tumor, has not been reached (as this value can only be calculated when more than 50 percent of treated patients have failed the prescribed treatment).

A second set of outcomes on prototype GammaTiles™ was presented at the Society for Neuro-Oncology Conference on Meningioma in June 2016 (Brachman, David; Surgery and permanent intraoperative brachytherapy improves time to progress of recurrent intracranial neoplasms). This study enrolled 16 patients with 20 recurrent grade 2 or 3 meningiomas, who had undergone prior surgical excision external beam radiation therapy. These patients underwent surgical excision of the tumor, followed by adjuvant radiation therapy with prototype GammaTiles™. The applicant noted the following outcomes: (1) Of the 20 treated tumors, 19 showed no evidence of radiographic progression at last follow-up, yielding a local control rate of 95 percent; two of the 20 patients exhibited radiation necrosis (one symptomatic, one asymptomatic); and (2) the median time to failure from the prior treatment with external beam radiation therapy was 10.3 months and after treatment with prototype GammaTiles™ only one patient failed at 18.2 months. Therefore, the median time to same site failure after prototype GammaTile™ treatment has not yet been reached (average follow up of 16.7 months, range 1–37 months).

A third prospective study was accepted for presentation at the November 2016 Society for Neuro-Oncology annual meeting (Youssef, Emad; Cs131 implants for salvage therapy of recurrent high grade gliomas). In this study, 13 patients diagnosed with recurrent high-grade gliomas (9 with glioblastoma and 4 with grade 3 astrocytoma) were treated in an identical manner to the cases described above. Previously, all patients had failed the international standard treatment for high-grade glioma, a combination of surgery, radiation therapy, and chemotherapy referred to as the ''Stupp regimen.'' For the prior therapy, the median time to failure was 9.2 months (range 1–40 months). After therapy with a prototype GammaTile™, the applicant noted the following: (1) The median time to same site local failure has not been reached and one failure was seen at 18 months (local control 92 percent); and (2) with a median follow-up time of 8.1 months (range 1–23 months) one symptomatic patient (8 percent) and two asymptomatic patients (15 percent) had radiation-related MRI changes. However, no patients required re-operation for radiation necrosis or wound breakdown.

The applicant asserted that, when considered in total, the data reported in these three studies support the conclusion that a significant therapeutic effect results from the addition of GammaTile™ radiation therapy to the site of surgical removal. According to the applicant, the fact that these patients had failed prior best available treatments (aggressive surgical and adjuvant radiation management) presents the unusual scenario of a salvage therapy outperforming the current standard-of-care. The applicant noted that follow-up data continues to accrue on these patients. The applicant further noted that, although these reported experiences with the GammaTile™ are as a salvage therapy in patients who currently have no standard treatment options, it is anticipated GammaTile™ will also be used as first-line therapy due to these promising results.

The applicant stated that the use of GammaTile™ reduces rates of mortality compared to alternative treatment options. The applicant explained that clinical studies on GammaTile™ have shown improved local control of tumor recurrence. According to the applicant, the results of these studies showed local control rates of 92 percent to 96 percent for tumor sites that had local control rates of 0 percent from previous treatment. The applicant noted that these studies also have not reached median progression-free survival time with follow-up times ranging from 1 to 37 months. Previous treatment at these same sites resulted in median progression-free survival times of 5.8 to 10.3 months.

The applicant further stated that the use of GammaTile™ reduces rates of radiation necrosis compared to alternative treatment options. The applicant explained that the rate of symptomatic radiation necrosis in the GammaTile™ clinical studies of 5 to 8 percent is substantially lower than the 26 percent to 57 percent rate of symptomatic radiation necrosis requiring re-operation historically associated with brain brachytherapy, and lower than the rates reported for initial treatment of similar tumors with modern external beam and stereotactic radiation techniques. The applicant indicated that this is consistent with the customized and ideal distribution of radiation therapy provided by GammaTile™.

The applicant also asserted that the use of GammaTile™ reduces the need for re-operation compared to alternative treatment options. The applicant explained that patients receiving a craniotomy, followed by external beam radiation therapy or brachytherapy, could require re-operation in the following three scenarios:

- Tumor recurrence at the excision site could require additional surgical removal;
- Symptomatic radiation necrosis could require excision of the affected tissue; and
- Certain forms of brain brachytherapy require the removal of brachytherapy sources after a given period of time.

However, according to the applicant, because of the high local control rates, low rates of symptomatic radiation necrosis, and short half-life of cesium-131, GammaTile™ will reduce the need for re-operation compared to external beam radiation therapy and other forms of brain brachytherapy.

Additionally, the applicant stated that the use of GammaTile™ reduces the need for additional hospital visits and procedures compared to alternative treatment options. The applicant noted that the GammaTile™ is placed during surgery, and does not require any additional visits or procedures. The applicant contrasted this improvement with external beam radiation therapy, which is often delivered in multiple fractions that must be administered over multiple days. The applicant provided an example where WBRT is delivered over 2 to 3 weeks, while the placement of GammaTile™ occurs during the craniotomy and does not add any time to a patient's recovery.

The applicant further stated that the GammaTile™'s high local control rates and low rates of symptomatic radiation necrosis will reduce the need for

additional hospital visits and procedures, and provides a more rapid initiation and complement of the treatment compared to alternative treatment options.

Based on consideration of all of the data presented above, the applicant believed that the use of GammaTile™ represents a substantial clinical improvement over existing technologies. The studies were limited to patients diagnosed with recurrent tumors after previous surgical rescission. As previously discussed, the applicant explained that it is seeking FDA approval for the use of the GammaTile™ in the treatment of recurrent malignancies.

We are inviting public comments on whether GammaTile™ meets the substantial clinical improvement criterion.

We did not receive any written public comments in response to the New Technology Town Hall meeting notice regarding the application of GammaTile™ for new technology add-on payments.

III. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2018 hospital wage index based on the statistical areas appears under sections III.A.2. and G. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. (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 proposed adjustment for FY 2018 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.J. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2018 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2018 wage index, appears under sections III.E.3. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed 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, we are proposing 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 are proposing 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, we are proposing to implement these FIPS code updates, effective October 1, 2017, beginning with the FY 2018 wage indexes. We are proposing 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. For FY 2018, Tables 2 and 3 associated with this proposed 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. We are inviting public comments on our proposals.

B. Worksheet S–3 Wage Data for the Proposed FY 2018 Wage Index

The proposed 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 proposed 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 proposed 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 proposed 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 proposed 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. No. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the proposed FY 2018 wage index includes FY 2014 data submitted to us as of February 10, 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 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. 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. The revised data will be reflected in the 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 this 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, Part II and III wage data of 3,325 hospitals.

For the proposed 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 proposed FY 2018 wage index associated with proposed 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 Proposed FY 2018 Unadjusted Wage Index

1. Proposed Methodology for FY 2018

The method used to compute the proposed FY 2018 wage index without an occupational mix adjustment follows the same methodology that we used to compute the proposed wage indexes without an occupational mix adjustment since FY 2012 (76 FR 51591 through 51593).

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 are not proposing 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 proposed FY 2018 national average hourly wage (unadjusted for occupational mix) is $42.0043.

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 $42.0043 for this FY 2018 proposed rule) and the national wage index, which is applied to the national labor share of the national standardized amount. For FY 2018, we are not proposing 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 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, 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, we are seeking 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 this FY 2018 IPPS/LTCH PPS proposed rule, we are clarifying 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 costs, 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.

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 in this proposed rule, 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, 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, we are seeking 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, we are restating 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 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.

E. Proposed 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 are required to submit their completed 2016 surveys to their MACs by July 3, 2017. The preliminary, unaudited CY 2016 survey data will be posted on the CMS Web site in mid-July 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 Proposed Occupational Mix Adjustment for FY 2018

For FY 2018, we are proposing 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 are using the Worksheet S–3, Parts II and III wage data of 3,325 hospitals, and we are using 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 are applying 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 proposed FY 2018 occupational mix adjusted national average hourly wage is $41.9599.

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2018 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2018, we are proposing to apply the occupational mix adjustment to 100 percent of the FY 2018 wage index. We calculated the proposed occupational mix adjustment using data from the 2013 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586). Using the occupational mix survey data and applying the occupational mix adjustment to 100 percent of the FY 2017 wage index results in a proposed national average hourly wage of $41.9599.

The proposed 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	$38.84760578
National LPN and Surgical Technician	22.72715122
National Nurse Aide, Orderly, and Attendant	15.94890269
National Medical Assistant	17.97139786
National Nurse Category	32.84544016

The proposed national average hourly wage for the entire nurse category as computed in Step 5 of the occupational mix calculation is $32.84544016. 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 proposed occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. As a result of applying the proposed occupational mix adjustment to the wage data, the proposed wage index values for 223 (54.7 percent) urban areas and 23 (48.9 percent) rural areas would increase. The proposed wage index values for 108 (26.5 percent) urban areas would increase by greater than or equal to 1 percent but less than 5 percent, and the proposed wage index values for 6 (1.5 percent) urban areas would increase by 5 percent or more. The proposed wage index values for 10 (21.3 percent) rural areas would increase by greater than or equal to 1 percent but less than 5

percent, and no rural areas' proposed wage index values would increase by 5 percent or more. However, the proposed wage index values for 184 (45.1 percent) urban areas and 24 (51.1 percent) rural areas would decrease. The proposed wage index values for 85 (20.8 percent) urban areas would decrease by greater than or equal to 1 percent but less than 5 percent, and no urban areas' final wage index value would decrease by 5 percent or more. The proposed wage index values of 8 (17.0 percent) rural areas would decrease by greater than or equal to 1 percent and less than 5 percent, and no rural areas' final wage index values would decrease by 5 percent or more. The largest proposed positive impacts would be 17.4 percent for an urban area and 2.9 percent for a rural area. The largest proposed negative impacts would be 4.9 percent for an urban area and 2.3 percent for a rural area. One urban area's proposed wage index, but no rural area wage indexes, would remain unchanged by application of the occupational mix adjustment. These results indicate that a larger percentage of urban areas (54.7 percent) would benefit from the occupational mix adjustment than would rural areas (48.9 percent).

G. Proposed Application of the Rural, Imputed, and Frontier Floors

1. Proposed Rural Floor

Section 4410(a) of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the ''rural floor''. Section 3141 of Public Law 111–148 also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the proposed FY 2018 wage index associated with this proposed rule (which is available via the Internet on the CMS Web site), we estimated that 366 hospitals would receive an increase in their FY 2018 proposed wage index due to the application of the rural floor.

2. Proposed 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.J. of the preamble of this proposed rule.)

In computing the imputed floor for an all-urban State under the original methodology, which was established beginning in FY 2005, we calculated the ratio of the lowest-to-highest CBSA wage index for each all-urban State as well as the average of the ratios of lowest-to-highest CBSA wage indexes of those all-urban States. We then compared the State's own ratio to the average ratio for all-urban States and whichever is higher is multiplied by the highest CBSA wage index value in the State—the product of which established the imputed floor for the State. As of FY 2012, there were only two all-urban States—New Jersey and Rhode Island—and only New Jersey benefitted under this methodology. Under the previous OMB labor market area delineations, Rhode Island had only one CBSA (Providence-New Bedford-Fall River, RI–MA) and New Jersey had 10 CBSAs. Therefore, under the original methodology, Rhode Island's own ratio equaled 1.0, and its imputed floor was equal to its original CBSA wage index value. However, because the average ratio of New Jersey and Rhode Island was higher than New Jersey's own ratio, this methodology provided a benefit for New Jersey, but not for Rhode Island.

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53368 through 53369), we retained the imputed floor calculated under the original methodology as discussed above, and established an alternative methodology for computing the imputed floor wage index to address the concern that the original imputed floor methodology guaranteed a benefit for one all-urban State with multiple wage indexes (New Jersey) but could not benefit the other all-urban State (Rhode Island). The alternative methodology for calculating the imputed floor was established using data from the application of the rural floor policy for FY 2013. Under the alternative methodology, we first determined the average percentage difference between the post-reclassified, pre-floor area wage index and the post-reclassified, rural floor wage index (without rural floor budget neutrality applied) for all CBSAs receiving the rural floor. (Table 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 postreclassified 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.

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 we are not proposing 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 this proposed rule, we are proposing 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, 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, 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 would 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 this FY 2018 IPPS/LTCH PPS proposed rule (which are available via the Internet on the CMS Web site) do not reflect the imputed floor policy, and there is no proposed national budget neutrality adjustment for the imputed floor for FY 2018. We are inviting public comments on our proposal not to extend the imputed floor for FY 2018 and subsequent years.

3. Proposed 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).) Fifty-two hospitals would receive the frontier floor value of 1.0000 for their FY 2018 wage index in this proposed rule. These hospitals are located in Montana, Nevada, North Dakota, South Dakota, and Wyoming. We are not proposing any changes to the frontier floor policy for FY 2018. The areas affected by the proposed rural and frontier floor policies for the proposed FY 2018 wage index are identified in Table 2 associated with this proposed rule, which is available via the Internet on the CMS Web site.

H. Proposed 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 proposed rule for a discussion of the proposed 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 proposed rule was constructed, the MGCRB had completed its review of FY 2018 reclassification requests. Based on such reviews, there are 375 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 257 hospitals approved for wage index reclassifications in FY 2016 that will continue for FY 2018, and 274 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 proposed rule, 906 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 proposed rule, we are proposing 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. If finalized, that proposal would be effective beginning with the FY 2019 IPPS/LTCH PPS proposed rule.) For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 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 will be incorporated into the wage index values published in the 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.

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.

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 current information collection requirements for the MGCRB procedures and criteria and supporting regulations in 42 CFR 412.256 subject to the Paperwork Reduction Act provisions are currently approved under OMB Control Number 0938–0573 and expired on February 28, 2017. An extension of the currently approved collection is required in time for applications due to the MGCRB September 1, 2017 for FY 2019 reclassifications. As discussed in section XIII.B. of the preamble of this proposed rule, a request for an extension of the current information collection requirements for the MGCRB procedures and criteria and supporting regulations is currently awaiting approval by OMB and can be accessed at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201612-0938-023.*

c. Proposed 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 (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).

The current practice of accepting 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 note 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 believe that 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 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, we are proposing to revise the regulations at § 412.230(a)(3) and § 412.230(d)(3). We are proposing to revise the regulations at § 412.230(a)(3) in two ways. First, we are proposing 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 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 are proposing 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 are proposing 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 would also extend these exceptions to hospitals that were ever approved as RRCs. Similar to § 412.230(a)(3), we also are proposing 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. 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. 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. The proposed revisions to the regulations at § 412.230(a)(3) and (d)(3) 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, 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 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 are proposing 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 are proposing 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 are proposing 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 are proposing additional revisions to § 412.230(a)(3)(ii) as discussed in section III.I.2.d. of the preamble of this proposed 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 are proposing to revise the regulations at § 412.230(d)(3). Specifically, we are proposing 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 are proposing 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 are inviting public comments on these proposals.

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).

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.

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, we are proposing 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 are proposing 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.

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 proposed rule, we are proposing to revise this policy 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.

4. Proposed 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.

We are proposing 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 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 are proposing 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 are proposing 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 are proposing 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 proposed rule at the Office of the Federal Register. We are inviting public comments on these proposals.

J. Proposed 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 Pub. L. 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 we are proposing 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 are not proposing 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).) Table 2 associated with this proposed rule (which is available via the Internet on the CMS Web site) includes the proposed 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.

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 this proposed rule, we are clarifying 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 are clarifying in this 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 this proposed rule, we are proposing 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 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 this proposed rule for further discussion of this proposal.

M. Process 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 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. Beginning next year (that is, April 2018 for wage data revisions for the FY 2019 wage index), we are proposing 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.

Hospitals are given the opportunity to examine Table 2, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2018-Wage-Index-Home-Page.html.* Table 2 contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the FY 2014 data used to construct the proposed FY 2018 wage index. We note 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 plan to post the final wage index data PUFs in late April 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 are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process 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 can 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 believes 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 is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC no later than 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 must 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) will be incorporated into the final FY 2018 wage index, which will be 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 do not meet the procedural deadlines set forth above will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines set forth above (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 have access to the final wage index data PUFs by late April 2017, they have the opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 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 proposed 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. 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 this proposed rule, 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, we are proposing 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 are proposing a process similar to the existing process in which hospitals may request corrections to wage index data displayed in the January PUF. 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 believe this proposed process and timeline (as descrbed above) 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 are proposing 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 are proposing 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 are proposing 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 (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 are proposing 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, if a hospital was notified on March 20 of an adjustment to its data by CMS and does 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 did not meet the procedural deadlines set forth above 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 are proposing 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 are proposing 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 are inviting public comments on our proposals.

N. Proposed Labor Market Share for the Proposed 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 revised and rebased 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 this proposed rule, we are proposing to rebase and revise the IPPS market basket reflecting 2014 data. We also are proposing 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 this proposed rule, we are proposing this revised and rebased labor-related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. 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 this proposed rule, we are proposing 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 are proposing to use a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017.

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 are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2018 IPPS/LTCH PPS proposed rule and available via the Internet on the CMS Web site, reflect the proposed 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 proposing to apply 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 proposing to apply the wage index to a proposed labor-related share of 68.3 percent of the national standardized amount.

IV. Proposed 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. First, a base period is selected (in this proposed rule, we are proposing 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 this FY 2018 IPPS/LTCH PPS proposed rule, we are proposing to rebase the cost structure for the IPPS hospital index from FY 2010 to 2014, as discussed below.

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 this proposed rule, we are proposing to shift the base year cost structure for the IPPS hospital index from FY 2010 to 2014). We note that we are no longer referring to the market basket as a ''FY 2014-based'' market basket and instead refer to the proposed market basket as simply ''2014-based''. We are proposing 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 are proposing 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 are proposing to rebase and revise the IPPS market basket from FY 2010 to 2014. We are inviting public comments on our proposed methodology.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data

The major source of expenditure data for developing the proposed rebased and revised 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 are proposing 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. 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 are proposing 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 are proposing 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.

(1) Wages and Salaries Costs

To derive wages and salaries costs for the Medicare allowable cost centers, we are proposing to first calculate total unadjusted wages and salaries costs as reported on Worksheet S–3, part II. We are then proposing 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 are 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 are proposing to only include the proportion attributable to the Medicare allowable cost centers. We are proposing 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 are proposing 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 calculate total unadjusted employee benefits costs as the sum of Worksheet S–3, Part II, Column 4, Lines 17, 18, 20, and 22. We then exclude 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 are 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 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 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 are proposing to determine home office contract labor costs using data reported on Worksheet S–3, Part II, Column 4, line 14. Specifically, we are proposing to determine the Medicare allowable portion of these costs by multiplying them by the ratio of total Medicare allowable operating costs (as defined below in section IV.B.1.b. of the preamble to this proposed 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 below in section IV.B.1.c. of the preamble to this proposed rule.

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 address data outliers using the following steps. First, we divide 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 are proposing that total Medicare allowable operating costs are 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 are Lines 30 through 35, 50, 51, 53 through 60, 62 through 76, 90, 91, 92.01 and 93.

We then remove those providers whose derived cost weights fall in the top and bottom five percent of provider-specific cost weights to ensure the removal of outliers. After the outliers have been removed, we sum the costs for each category across all remaining providers. We then divide 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. Finally, we 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 below shows the major cost categories and their respective cost weights as derived from the Medicare cost reports for this proposed rule.

TABLE IV–01—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major cost categories	FY 2010	Proposed 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 Contract Labor *	.....	4.2
''All Other'' Residual	31.9	32.0

* Home office 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.

As we did for the FY 2010-based IPPS market basket (78 FR 50597), we are proposing 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 is 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 is 78 percent. Therefore, we are proposing 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 below 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.

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 2014-based IPPS market basket
Wages and Salaries	47.2	43.4
Employee Benefits	13.1	12.4

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 are proposing 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.[37] 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 are proposing to

[37] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

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 this 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 represents 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 represents 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 are proposing to derive 18 detailed cost categories from the proposed 2014-based IPPS market basket residual cost weight (32.0 percent). These categories are: (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 believe 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 are proposing 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 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 proposed rule). For the proposed 2014-based IPPS market basket, we also are proposing 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.

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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 is 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 believe the proposed PPIs, CPIs, and ECIs selected meet these criteria.

Below we present a detailed explanation of the price proxies that we are proposing for each cost category weight. We note that many of the proxies that we are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing to update the blended weights using 2007 Benchmark I–O data, which we also are proposing 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 has 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 below 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.

TABLE IV–03—BLENDED CHEMICAL WEIGHTS

Name	FY 2010-based IPPS weights (%)	Proposed 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 are proposing 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 are proposing to use a blended price proxy for the Medical Instruments cost category. The 2007 Benchmark Input-Output data shows an approximate 50/50 split between Surgical and Medical Instruments and Medical and Surgical Appliances and Supplies for this cost category. Therefore, we are proposing 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 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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.

Table IV–04 below sets 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 are listed.

TABLE IV–04—PROPOSED 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 2014-based IPPS market basket cost weights	Proposed 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.

TABLE IV–04—PROPOSED 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 2014-based IPPS market basket cost weights	Proposed 2014-based IPPS market basket price proxies
(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.
(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 below 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 forecasted growth rates in Table IV–05 are based on IHS Global Insight, Inc.'s (IGI) fourth quarter 2016 forecast with historical data through third quarter 2016.

TABLE IV–05.—FY 2010-BASED AND PROPOSED 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 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	1.7	1.7
Average FYs 2013–2016	1.8	1.8
Forecast:		
FY 2017	2.6	2.7
FY 2018	2.9	2.9
FY 2019	3.0	3.0
FY 2020	3.0	3.0

TABLE IV–05.—FY 2010-BASED AND PROPOSED 2014-BASED IPPS HOSPITAL OPERATING INDEX PERCENT CHANGE, FY 2013 THROUGH FY 2020—Continued

Fiscal Year (FY)	FY 2010-based IPPS market basket percent change	Proposed 2014-based IPPS market basket percent change
Average FYs 2017–2020	2.9	2.9

Source: IHS Global Insight, Inc., 4th Quarter 2016 forecast.

There is no difference between the average percent change in the FY 2010-based and the proposed 2014-based IPPS market basket over the FY 2013 through FY 2016 time period. For FY 2018, the increase is 2.9 percent for both the FY 2010-based and proposed 2014-based IPPS market baskets.

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 are proposing 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 we did in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50594). As noted in section IV.B.1.c. of the preamble of this proposed rule, for the proposed 2014-based IPPS market basket, we are proposing 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 are proposing 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 are proposing 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 received no comments (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 are proposing 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 are proposing to use the same methodology and survey results to separate the professional fees costs for the 2014-based IPPS market basket into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. 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 are proposing to apportion 3.1 percentage points of the 4.9 percentage point figure into the Professional Fees: Labor-Related share cost category and designating the remaining 1.8 percentage point into the Professional Fees: Nonlabor-Related cost category.

In addition to the professional services listed earlier, we also classify a proportion of the home office expenses 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 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 this proposed rule, for the 2014-based IPPS market basket, we are proposing to obtain these data from the Medicare cost reports. We believe that many of the home office costs 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 are proposing to include in the labor-related share only a proportion of the home office 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 compensation as reported in Worksheet S–3, Part II. Using this methodology, we determined that 62 percent of hospitals' home office 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 determined the proportion of costs that should be allocated to the labor-related share based on the percent of total hospital home office compensation costs 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.

Similar to the FY 2010-based IPPS market basket, we determined the proportion of costs that should be allocated to the labor-related share based on the percent of hospital home office compensation as reported in Worksheet S–3, Part II. Using this methodology, we determined that 60 percent of hospitals' home office compensation costs were for home offices located in their respective local labor markets. Therefore, we are proposing to allocate 60 percent of home office expenses to the labor-related share.

In the proposed 2014-based IPPS market basket, home office 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 above, we are apportioning 2.5 percentage points of the 4.2 percentage points figure into the Professional Fees: Labor-Related cost category and designating the remaining 1.7 percentage points into the Professional Fees: Nonlabor-Related cost category. In summary, based on the two allocations mentioned above, we apportioned 5.6 percentage points of the professional fees and home office cost weights into the Professional Fees: Labor-Related cost category. This amount is 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.

Below is a table comparing 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 this proposed rule, the Wages and Salaries and Employee Benefits cost weights reflect contract labor costs.

TABLE IV–06—COMPARISION OF THE FY 2010-BASED LABOR-RELATED SHARE AND THE PROPOSED 2014-BASED LABOR-RELATED SHARE

	FY 2010-based IPPS market basket cost weights	Proposed 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 are proposing 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 Pub. L. 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.

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 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 are proposing 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 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.

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, we are proposing 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 are now proposing 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 this proposed rule, for the 2014-based IPPS operating market basket, we are proposing 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 are proposing 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 are proposing 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 are able to group capital costs into the following categories: Depreciation, Interest, Lease, and Other. For each of these categories, we are proposing 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 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.

We also are proposing to allocate lease costs across each of the remaining capital cost categories as was done in the FY 2010-based CIPI. This would result 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 are proposing 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 are proposing 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 are assuming that approximately 1.2 percent (11.8 percent x 0.1) of total capital costs represent lease costs attributable to overhead, and we are proposing to add this 1.2 percent to the 5.5 percent Other cost category weight. We are then proposing 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 are shown in the right column of Table IV–07.

TABLE IV–07—PROPOSED ALLOCATION OF LEASE EXPENSES FOR THE PROPOSED 2014-BASED CIPI

Cost categories	Proposed cost shares obtained from medicare cost reports (percent of total capital costs)	Proposed 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 are proposing to further divide the Depreciation and Interest cost categories. We are proposing to separate the Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also are proposing 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 are proposing 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 are proposing 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 provides a comparison of the FY 2010-based CIPI cost weights and the proposed 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 are proposing 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. We also are proposing 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 are proposing 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 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 2014-BASED CIPI COST WEIGHTS AND PRICE PROXIES WITH FY 2010-BASED CIPI COST WEIGHTS INCLUDED FOR COMPARISION

Cost categories	FY 2010 cost weights	Proposed 2014 cost weights	Proposed 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. 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 provided earlier in this proposed rule. For the interest vintage weights, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 are presented in Table IV–09 below.

TABLE IV–09—PROPOSED 2014-BASED CIPI AND FY 2010-BASED CIPI VINTAGE WEIGHTS

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	Proposed 2014-based 27 years	FY 2010-based 26 years	Proposed 2014-based 12 years	FY 2010-based 12 years	Proposed 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
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 proposed 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, etc.

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.''

Table IV–10 below compares both the historical and forecasted percent changes in the FY 2010-based CIPI and the proposed 2014-based CIPI.

TABLE IV–10—COMPARISON OF FY 2010-BASED AND PROPOSED 2014-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2013 THROUGH FY 2020

Fiscal year	CIPI, FY 2010-based	Proposed 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	1.1	1.0
FY 2018	1.3	1.2
FY 2019	1.5	1.4
FY 2020	1.5	1.5
Average FYs 2017–2020	1.4	1.3

Source: IHS Global Insight, Inc., 4th quarter 2016 forecast.

IHS Global Insight, Inc. forecasts a 1.2 percent increase in the proposed 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 are included in Table IV–11.

TABLE IV–11—PROPOSED 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	1.0	1.6	−2.7
FY 2018	1.2	1.6	−1.6
FY 2019	1.4	1.6	−0.6
FY 2020	1.5	1.6	0.1

Source: IHS Global Insight, Inc., 4th quarter 2016 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 1.3 percent to 1.2 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 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, for FY 2018, vintage-weighted price growth is projected to be positive for the Depreciation cost category and negative for Interest cost category.

V. Other Decisions and Proposed Changes to the IPPS for Operating System

A. Proposed Changes to MS–DRGs Subject to the Postacute Care Transfer and MS–DRG Special Payment 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. Proposed Changes for FY 2018

Based on our annual review of MS–DRGs, we have identified three MS–DRGs that we are proposing to be included on the list of MS–DRGs subject to the special payment transfer policy. As we discuss in section II.F. of the preamble of this proposed rule, in response to public comments and based on our analysis of FY 2016 MedPAR claims data, we are proposing to make changes to MS–DRGs, effective for FY 2018.

As discussed in section II.F.14.b. of the preamble of this proposed rule, we are proposing 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 these 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. 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 are not proposing to change the postacute care transfer policy status for MS–DRGs 987, 988, and 989.

LIST OF PROPOSED REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2018

Proposed revised MS–DRG	MS–DRG title	Total cases	Postacute care transfers (55th percentile: 1,419)	Short-stay postacute care transfers	Percent of short-stay postacute care transfers to all cases (55th percentile: 8.01068%)	Postacute care transfer policy status
987	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC.	8,131	4,210	1,355	16.66462	YES.
988	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with CC.	8,239	3,416	706	8.56900	YES.
989	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis without MCC/CC.	2,216	* 499	47	* 2.12094	** 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.

We also have 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 are proposing that these three proposed revised MS–DRGs would be subject to

the MS–DRG special payment methodology, effective FY 2018.

LIST OF PROPOSED REVISED MS–DRGS SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2018

Proposed 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.	8.1	$36,526	$53,449	* YES.
988	Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with CC.	8.6	35,629	29,119	YES.
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 proposed postacute care transfer policy status and special payment policy status of these MS–DRGs are reflected in Table 5 associated with this proposed rule, which is listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site.

B. Proposed Changes in the Inpatient Hospital Update for FY 2018 (§ 412.64(d))

1. Proposed 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.'' 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 this proposed rule, we are proposing to replace the FY 2010-based IPPS operating and capital market baskets with the revised and rebased 2014-based IPPS operating and capital market baskets for FY 2018.

We are proposing to base the proposed FY 2018 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Insight, 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 is estimated to be 2.9 percent. We are proposing that if more recent data subsequently become 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 the final rule.

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.

For FY 2018, we are proposing 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 with historical data through third quarter 2016 to compute the proposed MFP adjustment. We are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2018 market basket update and MFP adjustment for the final rule.

Based on these data, for this proposed rule, we have determined four proposed applicable percentage increases to the standardized amount for FY 2018, as specified in the following table:

PROPOSED 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
Proposed Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.725	−0.725
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.175	0.0	−2.175
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.75	−0.425	1.025	−1.15

We are proposing 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 are proposing 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.

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 this proposed 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.

For FY 2018, we are proposing the following updates to the hospital-specific rates applicable to SCHs: A proposed update of 1.75 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 1.025 percent for a hospital that fails to submit quality data and is a meaningful EHR user; a proposed update of −0.425 percent for a hospital that submits quality data and is not a meaningful EHR user; and a proposed update of −1.15 percent for a hospital that fails to submit quality data and is not a meaningful EHR user. As mentioned previously, for this FY 2018 proposed rule, we are using IGI's fourth quarter 2016 forecast of the proposed 2014-based IPPS market basket update with historical data through third quarter 2016. Similarly, we are using IGI's fourth quarter 2016 forecast of the MFP adjustment. We are proposing that if more recent data subsequently become 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.

2. Proposed 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 propose 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 proposed rule. Accordingly, for FY 2018, we are proposing an applicable percentage increase of 1.75 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. Proposed Change to Volume Decrease Adjustment for Sole Community Hospitals (SCHs) and Medicare-Dependent, Small Rural Hospitals (MDHs) (§ 412.92)

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. Proposed 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 § 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 are not proposing specific amendments to the regulations at § 412.108(d) for MDHs. However, we are proposing 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 following 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 the PRM 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 the 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 Provider Reimbursement Manual, Part 1 (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); and *Fairbanks Memorial Hospital* v. *Wisconsin Physician Services/ BlueCross BlueShield Association,* 2015 WL 5852432 (CMS Administrator, August 5, 2015). 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. Under the current calculation methodology, the MACs calculate the volume decrease adjustment by subtracting 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. 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, we are proposing 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 are proposing 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 are proposing 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 renders 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 are proposing to remove the cap calculation from the volume decrease adjustment calculation methodology in future periods.

We are proposing 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. If these proposed changes are adopted, we also intend 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, the current calculation methodology will continue. In addition, we are 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.

The following example illustrates the calculation of the volume decrease adjustment by the MAC under our proposed change.

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 $1,360,000 of Hospital A's costs as fixed and $240,000 as variable. Hospital A's fixed cost ratio is therefore .85 = $1,360,000/$1,600,000. The MAC applies this ratio to the total MS–DRG revenue of $1,400,000 to estimate the hospital's fixed MS–DRG revenue to be $1,190,000. The volume decrease adjustment payment is then calculated by comparing the fixed MS–DRG revenue of $1,190,000 to the 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 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 fixed costs exceeded its total MS–DRG revenue if those fixed costs exceeded the previous year's costs updated for inflation.

We also are proposing 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 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 are proposing 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 are proposing that these changes would be effective for cost reporting periods beginning on or after October 1, 2017.

In summary, we are proposing to prospectively require 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 and that the cap will no longer be applied to the volume decrease adjustment calculation methodology. We are proposing to revise the regulations at § 412.92(e)(3) to reflect our proposed changes. We also are proposing 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. We are proposing that these changes be effective for cost reporting periods beginning on or after October 1, 2017. As we noted earlier, we are proposing 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 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).

D. Rural Referral Centers (RRCs): Proposed Annual Updates to Case-Mix Index and Discharge Criteria (§ 412.98)

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 proposed national median CMI value for FY 2018 is based on the CMI values of all urban hospitals nationwide, and the proposed 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 proposed values are based on discharges occurring during FY 2016 (October 1, 2015 through September 30, 2016), and include bills posted to CMS' records through December 2016.

In this proposed rule, we are proposing that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 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 are set forth in the following table.

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.4186
2. Middle Atlantic (PA, NJ, NY)	1.5126
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.5393
4. East North Central (IL, IN, MI, OH, WI)	1.5921
5. East South Central (AL, KY, MS, TN)	1.5179
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.6346
7. West South Central (AR, LA, OK, TX)	1.6949
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7614
9. Pacific (AK, CA, HI, OR, WA)	1.6466

We intend 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.

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 this proposed rule, for FY 2018, we are proposing 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 are the latest cost report data available at the time this proposed rule was developed. Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 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 as reflected in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	7,991
2. Middle Atlantic (PA, NJ, NY)	10,268
3. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,503
4. East North Central (IL, IN, MI, OH, WI)	8,202
5. East South Central (AL, KY, MS, TN)	8,697
6. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,532
7. West South Central (AR, LA, OK, TX)	5,189
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,887
9. Pacific (AK, CA, HI, OR, WA)	8,856

We intend to update these numbers in the FY 2018 final rule based on the latest available cost report data.

We note that the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges. Therefore, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

E. Proposed 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 proposed payment policies for FY 2018 in section V.E.3. of the preamble of this proposed 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. Proposed 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).

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, we are proposing 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 are further proposing 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 note 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).

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.

For this reason, we are not proposing 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. However, we are proposing that if these temporary changes to the low-volume hospital payment policy were to be extended by law, similar to extensions provided through FY 2013, by the American Taxpayer Relief Act of 2012 (ATRA), Public Law 112–240; through March 31, 2014, by the Pathway for SGR Reform Act of 2013, Public Law 113–167; through March 31, 2015, by the Protecting Access to Medicare Act of 2014 (PAMA), Public Law 113–93; and most recently through FY 2017, by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Public Law 114–10, we would make conforming changes to the regulations at § 412.101(b) through (d), as appropriate, to reflect any such extension.

These conforming changes would only be made if the temporary changes to the low-volume hospital payment adjustment policy were to be extended by statute beyond the current expiration date of September 30, 2017. If these temporary changes were to be extended by statute, for FY 2018, consistent with our historical policy and our implementation of the prior extensions, qualifying low-volume hospitals and their payment adjustment would be determined using the most recently available Medicare discharge data available at the time of the final rule, which we expect would be from the March 2017 update of the FY 2016 MedPAR file. Consistent with past practice, if these temporary changes were to be extended for FY 2018 before the development of the final rule, we would list the subsection (d) hospitals with fewer than 1,600 Medicare discharges based on the claims data from the March 2017 update of the FY 2016 MedPAR file and their potential low-volume hospital payment adjustment for FY 2018 in Table 14 listed in the Addendum of the final rule. In such an event, hospitals would still submit requests or verification to the MAC, as outlined earlier, but updated as needed to reflect the applicable discharge and mileage criteria in accordance with any such extension for FY 2018.

4. Proposed 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), CMS considers IHS and Tribal hospitals to be subsection (d) hospitals. However, 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 non-IHS hospitals and Tribal hospitals that are located less than the specified mileage from one another. Specifically, we are proposing 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 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 believe it would be appropriate to not consider non-IHS hospitals when evaluating whether an IHS or Tribal hospital meet 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 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, we are proposing 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 are proposing 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).

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, 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.

G. Proposed 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 proposed 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 each fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FYs 2014 through 2017, 1 minus the percent change in the percent of individuals under the age of 65 who are uninsured, determined by comparing the percent of such individuals who 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: *http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/113xx/doc11379/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 proposed 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 Episde 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 proposed rule for a full discussion of the provisions of section 15003 of Public Law 114–255 and our proposals for implementation.) As of the time of development of this proposed 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 policies for FY 2018.

a. Proposed 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 this FY 2018 IPPS/LTCH PPS proposed rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2018, we are proposing to continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194) of determining Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under 1886(r)(1) of the Act. 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 this 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 this FY 2018 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's January 2017 Medicare DSH estimates, which are 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 this proposed rule, 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. 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 this proposed rule, using the data sources discussed above, 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 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 2018, without regard to the application of section 1886(r)(1) of the Act, is approximately $16.003 billion. This estimate excludes 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 2018, with the application of section 1886(r)(1) of the Act, is approximately $4.001 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 proposed rule, we are proposing that Factor 1 for

FY 2018 is $12,001,915,095.04, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2018 ($16,002,553,460.05 minus $4,000,638,365.01).

The Office of the Actuary's estimates for FY 2018 for this proposed rule began with a baseline of $12.405 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	Discharge	Case-mix	Other	Total	Estimated DSH payment (in billions) *
2015	1.014	1.0068	1.005	1.0493	1.076581	$13.355
2016	1.009	0.9757	1.027	1.0689	1.080724	14.433
2017	1.0015	1.0058	1.005	1.0535	1.066506	15.393
2018	1.022088	1.0188	1.005	0.9934	1.039603	16.003

* Rounded.

In this table, the discharge column shows the increase in the number of Medicare fee-for-service (FFS) inpatient hospital discharges. The figures for FY 2015 are based on Medicare claims data that have been adjusted by a completion factor. The discharge figure for FY 2016 is based on preliminary data for 2016. The discharge figures for FYs 2017 and 2018 are assumptions 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 are based on actual data adjusted by a completion factor. The FY 2016 increase is based on preliminary data adjusted by a completion factor. The FYs 2017 and 2018 increases are based on the recommendation of the 2010–2011 Medicare Technical Review Panel. The ''Other'' column shows the increase in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges, 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. In the past, commenters have contended that the ''Other'' column understates the effect of the Medicaid expansion. 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 individual 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	2.9	−0.75	−0.4	0.4588	2.2088

Note: All numbers are based on FY 2018 President's Budget projections.

We are inviting public comments on our proposed calculation of Factor 1 for FY 2018.

b. Proposed 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.

$1 - \sqrt{((0.10–0.18)/0.18)} = 1 - 0.4444 = 0.5555$ (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) Proposed 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.

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). 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.

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, 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.*

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 do not believe this is a significant policy issue and are proposing 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 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 or 58.01 percent

0.5801 = Factor 2

Therefore, the proposed Factor 2 for FY 2018 is 58.01 percent.

The proposed FY 2018 uncompensated care amount is: $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 are inviting public comments on our proposed methodology for calculation of Factor 2 for FY 2018.

c. Calculation of Proposed 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. 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) Proposed 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. As discussed in the FY 2017 IPPS/LTCH PPS proposed rule, the purpose of this 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.

In the updated analysis performed for this year's 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 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.

We have 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. 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 non-expansion 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. We note that, while 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.

We also note 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 proposed rule, MedPAC again recommended we start using the Worksheet S–10 data with a phase-in (81 FR 56962).

In summary, 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 discuss below our proposed methodology for how we would begin to incorporate Worksheet S–10 data for FY 2014 into the calculation of Factor 3 of the uncompensated care payment methodology.

(3) Proposed 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).

For FY 2018, we are proposing to continue to use the methodology finalized in FY 2017 and to compute Factor 3 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 are proposing to advance the time period of the data used in the calculation of Factor 3 forward by one year and using data from FY 2012, FY 2013, and FY 2014 cost reports. For the reasons we described earlier, we believe 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 believe it would be appropriate to continue to use low-income insured days. Accordingly, with a time period that includes three cost reporting years consisting of FY 2014, FY 2013, and FY 2012, we are proposing to use Worksheet S–10 data for the FY 2014 cost reporting period and the low-income insured day 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 for FY 2018 is the December 2016 update of HCRIS for the proposed rule and the March 2017 update of HCRIS for the final rule. Accordingly, for FY 2018, in addition to the Worksheet S–10 data for FY 2014, we are proposing to use Medicaid days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI ratios. We also would continue to use FY 2012 cost report data submitted to CMS by IHS and Tribal hospitals to determine Medicaid days for those hospitals. (We note that cost report data from IHS and Tribal hospitals are included in HCRIS beginning in FY 2013 and are no longer submitted separately.) We also are proposing to continue the policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50020) to address several specific issues concerning the process and data to be employed in determining Factor 3 in the case of hospital mergers 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 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 one 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, we acknowledge 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 the 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 believe that 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 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 believe that 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, we are proposing 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 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 as we are not making any proposals with respect to the calculation of Factor 3 for FY 2019 at this time, we will 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 are proposing 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 are proposing 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 are inviting public comments on our proposed methodology for calculating Factor 3 for FY 2018.

We note that if this proposed methodology is 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 are not making any proposals with respect to the calculation of Factor 3 for FY 2019 at this time.

For new hospitals that do not have data for any of the three cost reporting periods used in the proposed 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 would be considered new and subject to this policy.

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with both the FY 2018 IPPS/LTCH PPS proposed rule and final rule, we will publish on the CMS Web site a table listing Factor 3 for all hospitals that we estimate would receive empirically justified Medicare DSH payments in FY 2018 (that is, those hospitals that would receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving a 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. We note that, as of this proposed rule, the FY 2015 SSI ratios are not yet available. Accordingly, for modeling purposes, we computed Factor 3 using the most recent available data regarding SSI days from the FY 2013 and FY 2014 SSI ratios. However, we expect that the FY 2015 SSI ratios will be available to calculate Factor 3 for the FY 2018 IPPS/LTCH PPS final rule.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of this FY 2018 IPPS/LTCH PPS proposed rule to review the table and supplemental data file published on the CMS Web site in conjunction with the proposed rule and to notify CMS in writing of any inaccuracies. Comments can be submitted to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We will 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 the FY 2018 IPPS/LTCH PPS final rule. After the publication of the 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 the 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.

(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), 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 this 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 are proposing to annualize Medicaid data if a hospital's cost report does not equal 12 months of data. We are not proposing 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 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 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 are proposing 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 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 are inviting 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 three cost reporting years is 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 costs reports used to calculate the Factor 3 for FY 2018 would also mitigate fluctuations in the amount of uncompensated care payments from year to year, we also are seeking 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 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 this proposed rule. However, instead of reflecting our proposed approach of calculating Factor 3 using a time period that includes three 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.

• *Scaling Factor.* Under the methodology adopted in the FY 2017 IPPS/LTCH PPS final rule and that we are proposing to apply in FY 2018, if the hospital does not have data for one or more of the three cost reporting periods, we will compute Factor 3 for the periods available and average those. In other words, we will 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 would have an average Factor 3 of 0.000050807 if averaged by 2 but an average Factor 3 of only 0.000033871 if averaged 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 estimate published in section V.G.4.b.(2) of the preamble of this proposed rule.

Accordingly, to address the effects of averaging Factor 3s calculated for three separate fiscal years, we are proposing 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. Under this proposal, we would first compute the Factor 3 and uncompensated care payments for all hospitals that we anticipate qualifying for Medicare DSH payments in FY 2018. We would then divide 1 (the *expected* sum of all eligible hospitals' Factor 3) 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 in section V.G.4.b.(2) of the preamble of this proposed rule. 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 note 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 are inviting public comments on our proposal to apply a scaling factor to all 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 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, we are again proposing 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 are inviting public comments on this proposal.

- *Trims to apply to CCRs on Line 1 of Worksheet S–10.* As we noted in the FY 2017 IPPS/LTCH proposed and final rules (81 FR 25093; 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 have 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 final rule (81 FR 56971 through 56973), for FY 2018, we are proposing 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, this trim would remove 9 hospitals that have CCRs above the calculated ceiling of 0.937.

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 all-inclusive rate providers, and providers that did not report a CCR on Worksheet S–10, Line 1. The statewide average CCR would therefore be applied to 140 hospitals, of which 14 did not report a CCR on Worksheet S–10, Line 1, 9 had a CCR that exceeded the calculated ceiling of 0.937, and 117 are all-inclusive rate providers.

After applying the applicable trims to a hospital's CCR as appropriate, we are proposing 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 are inviting public comments on our proposed trim methodology for FY 2018.

• *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, we 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 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 can be downloaded from 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 expect 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 do not anticipate making any further modifications to the Worksheet S–10 instructions at this time so that hospitals can begin to review and conform to the current instructions in Transmittal 10. Predictability is an important part of the process for reporting data on Worksheet S–10. As a result, we believe it is reasonable to wait until the Worksheet S–10 data have been submitted, the audits have been performed, and the data are available for review before we consider making any further revisions to the Worksheet S–10 instructions.

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 this proposed 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 are not proposing 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 are proposing to revise the general payment rules under § 412.90 to reflect the expiration of the MDH program. However, we are proposing that if the MDH program were to be extended by law, similar to how it was extended through FY 2013, by the ATRA (Pub. L. 112–240); through March 31, 2014, by the Pathway for SGR Reform Act of 2013 (Pub. L. 113–167); through March 31, 2015, by the PAMA (Pub. L. 113–93); and 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. These conforming changes would only be made if the MDH program were to be extended by statute beyond September 30, 2017.

I. Hospital Readmissions Reduction Program: Proposed Updates and Changes (§§ 412.150 Through 412.154)

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 3025 of the Affordable Care Act, as amended by section 10309 of the Affordable Care Act, added 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 that law 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. The 21st Century Cures Act also directs the Medicare Payment Advisory Commission (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.

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.'' 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 of 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.

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. Proposed Policies for the Hospital Readmissions Reduction Program

In this proposed rule, we are proposing 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 the 21st Century Cures Act 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. Proposed 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 this proposed rule, for FY 2018, consistent with the definition specified at § 412.152, we are proposing 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 are proposing that the excess readmissions ratios and the payment adjustment (including aggregate payments for excess readmissions and aggregate payments for all discharges) for FY 2018 would be calculated using data from the 3-year time period of July 1, 2013 through June 30, 2016.

We are inviting public comment on this proposal.

6. Proposed 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.

For FY 2018, we are proposing 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 this proposed rule, for FY 2018, we are proposing to determine aggregate payments for excess readmissions and

aggregate payments for all discharges using data from MedPAR claims with discharge dates that are on or after July 1, 2013, and no later than June 30, 2016. However, we note that, for the purpose of modeling the proposed FY 2018 readmissions payment adjustment factors for this 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 this proposed rule, for FY 2018, we are proposing to use MedPAR data from July 1, 2013 through June 30, 2016. Specifically, for this proposed rule, we are using 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 are proposing 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 are proposing 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 this proposed rule, for FY 2018, we are proposing 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 fee-for-service (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, 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 are proposing 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 this 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 are proposing 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 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:

- 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).

A detailed list of the condition-specific and procedure-specific reports detailing the ICD–10–CM and ICD–10–PCS code sets we are proposing to use to identify the applicable conditions for the period from October 1, 2015 to June 30, 2016 is not yet publicly available. However, we anticipate the 2017 AMI, HF, Pneumonia, COPD, Stroke, THA/TKA, and CABG Readmission Measures Updates and Specifications Report, will be available by mid-April and can be accessed at: *http://www.QualityNet.org* > Hospital-Inpatient > Claims-Based Measures > Readmission Measures > Measure Methodology. We are currently making a list of the ICD–10–CM and ICD–10–PCS code sets used to identify the applicable conditions for this proposed rule, titled ICD–10–CM Codes for Inclusion in the Hospital Readmissions Reduction Program Applicable Conditions for FY 2018 Proposed Rule, available on the Hospital Readmissions Reduction Program page on the CMS Web site at: *https://*

www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html.

In summary, for FY 2018, we are proposing 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 are not proposing 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 are proposing to calculate the base operating DRG payment amounts for all claims in the 3-year applicable period for each applicable condition (AMI, HF, PN, COPD, 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 are proposing 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 are proposing to then multiply the amount for each condition by the respective excess readmissions ratio minus 1 when that excess readmissions ratio is greater than 1, which indicates that a hospital has performed, with respect to readmissions for that applicable condition, worse than the average hospital with similar patients. Each product in this computation represents the payments for excess readmissions for that condition. We are proposing to then sum the resulting products which represent a hospital's proposed ''aggregate payments for excess readmissions'' (the numerator of the ratio). Because this calculation is performed separately for each of the 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 are not proposing 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 are inviting public comment on these proposals.

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 Proposed Payment Adjustment Methodology for FY 2019: Proposed 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).[38] 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

[38] 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.

report submitted to Congress in June 2013 relating to readmissions.

b. Proposed Data Sources Used To Determine Dual Eligibility

In this proposed rule, we are proposing 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 are inviting public comment on this proposal.

For this 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 are proposing 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 eligibles, calculated among Medicare FFS and managed care patients, Hospital A was assigned to the top quintile of proportion of dual eligibles 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 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 are including an alternative to define the proportion of full-benefit dual eligible beneficiaries as only Medicare FFS stays. Under both approaches, we are proposing 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 is 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 are inviting 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 are inviting public comment on our preferred proposals and alternative considerations.

c. Proposed Data Period Used To Define Dual Eligibility

Consistent with the requirement of the statute, we are proposing to group or stratify hospitals based on the proportion of full-benefit dual eligible patients determined under the proposals discussed above and are proposing 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. For this proposed rule, 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 are inviting public comment on our preferred proposal and alternative considerations.

9. Provisions for the Proposed Payment Adjustment Methodology for FY 2019: Proposed Methodology for Assigning Hospitals to Peer Groups

For this proposed rule, 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 are also seeking public comment on stratifying hospitals into two and 10 peer groups.

To understand the impact on payment adjustments of stratifying hospitals into different number of peer groups, we conducted an analysis that estimated payment adjustments when stratifying hospitals into two, five (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 two 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 two 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 eligibles, 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, so 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 (DSH) payments, 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 are proposing to stratify hospitals into quintiles (five peer groups) because it creates peer groups that accurately reflect the relationship between the proportion of dual eligibles in the hospital's population without the disadvantage of establishing a larger number of peer groups.

We are inviting public comment on our preferred proposal and alternative considerations.

10. Provisions for the Proposed Payment Adjustment Methodology for FY 2019: Proposed 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).

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

$$1 - \min\{.03, \sum_{dx} \frac{Payment(dx) * \max\{(\mathrm{ERR(dx)} - 1.0000), 0\})}{All\ payments}\}$$ [39]

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 this proposed rule, we are discussing 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

In this 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:

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM_M * Payment(dx) * \max\{(\mathrm{ERR(dx)} - \text{Median peer group ERR(dx)}), 0\})}{All\ payments}\}$$

[39] ''Payment'' refers to the base operating DRG payment.

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:

$$\mathrm{P} = 1 - \min\{.03, \sum_{\mathrm{dx}} \frac{K_\mu * \mathrm{Payment(dx)} * \max\{(\mathrm{ERR(dx)} - \mathrm{Mean\ peer\ group\ ERR(dx)}), 0\}}{\mathrm{All\ payments}}\}.$$

(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 $S_p(dx)$ and $\mu_p(dx)$ are the standard deviation and mean of the current ERR distribution for a condition (dx), and $S_p(dx)$ and $\mu_p(dx)$ 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 are proposing 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 fee-for-service 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. Since 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, since 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] (percent)	Total Medicare savings	Payment adjustment as a proportion of all DRG payments (percent)
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
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, through 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 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 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 (percent)	Median Plus neutrality modifier (neutrality modifier = 0.9546) (percent)	Mean plus neutrality modifier (neutrality modifier = 1.0135) (percent)	Budget neutralizing ERR (percent)	Standardized ERR plus neutrality modifier (neutrality modifier = 0.9710) (percent)
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
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

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 (percent)	Median Plus neutrality modifier (neutrality modifier = 0.9546) (percent)	Mean plus neutrality modifier (neutrality modifier = 1.0135) (percent)	Budget neutralizing ERR (percent)	Standardized ERR plus neutrality modifier (neutrality modifier = 0.9710) (percent)
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 are inviting public comment on our preferred proposal and alternative considerations.

11. Accounting for Social Risk Factors in the Hospital Readmissions 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) [40] 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 Readmissions Reduction Program.[41] 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.[42]

As noted in the FY 2017 IPPS/LTCH PPS final rule, the NQF has undertaken 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 can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

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 Hospital Readmissions 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: 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, we are seeking 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, we are also seeking public comment on which social risk factors might be most appropriate for stratifying measure scores and/or potential risk adjustment of a particular

[40] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[41] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[42] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

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 are seeking 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), so we also welcome 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.

12. Extraordinary Circumstance Exception (ECE) Policy

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, Ambulatory Surgical Center Quality Reporting (ASCQR), 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 are proposing 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), Hospital OQR Program (77 FR 68489 and 81 FR 79795), as well as other quality reporting programs. We are proposing 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 are proposing 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 are proposing 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 are proposing to communicate this decision through routine communication channels.

We are inviting public comment on these proposed modifications to the Extraordinary Circumstance Exception policy.

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: Proposed 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 December 2016 update of the FY 2016 MedPAR file. We intend to update this estimate for the FY 2018 IPPS/LTCH PPS final rule using 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 are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this 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 slope of the linear exchange function used to calculate those proxy value-based incentive payment adjustment factors is 3.0692781725. This slope, along with the estimated amount available for value-based incentive payments, is also published in Table 16.

We intend to update this table as Table 16A in the final rule (which will be available on the CMS Web site) to reflect changes based on the March 2017 update to the FY 2016 MedPAR file. We also intend to update the slope of the linear exchange function used to calculate those updated proxy value-based incentive payment adjustment factors. The updated proxy value-based incentive payment adjustment factors for FY 2018 will continue to be based on historic FY 2017 program year TPSs because hospitals will not have been given the opportunity to review and correct their actual TPSs for the FY 2018 program year until after the FY 2018 IPPS/LTCH PPS final rule is published.

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.

2. 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)[43] 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.[44] 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.[45]

[43] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[44] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[45] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

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.[46] We note that the MSPB measure is currently undergoing endorsement review for NQF, as part of the 2-year socioeconomic trial period described below.[47] 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 has undertaken 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 can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

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 proposing 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 proposed 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 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 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, we are seeking 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, we are also seeking 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 are seeking 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 VBP 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), we also welcome 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.

[46] 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*.

[47] 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*.

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. We are not proposing any changes to this policy.

b. Proposed 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 [48] 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 [49] 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 QI 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. We are now proposing in this FY 2018 IPPS/LTCH PPS proposed rule to remove the current PSI 90 measure from the Hospital VBP Program beginning with the FY 2019 program year.

We are inviting public comment on this proposal. We also refer readers to section V.J.4.b. of the preamble of this proposed rule where we are proposing to adopt the modified version of the PSI 90 measure for the Hospital VBP Program beginning with the FY 2023 program year.

c. Summary of Previously Adopted Measures and Proposed 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 and are proposing to remove the current PSI 90 measure, as indicated:

PREVIOUSLY ADOPTED MEASURES AND PROPOSED 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
PSI 90 ***	Patient Safety for Selected Indicators (Composite Measure)	0531
PC–01	Elective Delivery	0469

[48] The ''current'' PSI 90 measure refers to the version of the PSI 90 measure previously finalized for use in the Hospital VBP Program in the FY 2013 IPPS/LTCH PPS final rule (78 FR 50694).

[49] The AHRQ QI 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.*

PREVIOUSLY ADOPTED MEASURES AND PROPOSED MEASURE FOR REMOVAL FOR THE FY 2019 AND FY 2020 PROGRAM YEARS—Continued

Measure short name	Domain/measure name	NQF #
	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.

*** Proposed for removal beginning with the FY 2019 program year as discussed in section V.J.3.b. of the preamble of this proposed rule.

4. Proposed 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. Proposed 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, and pneumonia patients incur roughly $10 billion in aggregate health care costs.[50] 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.[51] 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,[52] thereby

[50] 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.

[51] 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*.

[52] 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

Continued

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 are proposing 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 proposed rule where we are proposing 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.[53] 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 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 proposed 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.[54] 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 are inviting public comment on this proposal.

(2) Proposed Scoring Methodology for the PN Payment Measure

We are proposing to calculate the PN Payment measure using the same

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).

[53] ''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*.

[54] Ryan AM, Tompkins CP. Efficiency and Value in Healthcare: Linking Cost and Quality Measures. Washington, DC: NQF; 2014.

methodology we use to score the MSPB measure and, as finalized in the FY 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are inviting public comment on the proposed scoring methodology for the proposed PN Payment measure.

b. Proposed 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.[55] Due to statutory requirements in the Hospital VBP Program,[56] 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 proposed rule, we are proposing 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, we are now proposing 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),[57] beginning with the FY 2018 payment determination, and we intend to publicly report initial measure data on the measure on *Hospital Compare* on or around July 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;[58]
- PSI 09 Perioperative Hemorrhage or Hematoma Rate;*
- PSI 10 Postoperative Acute Kidney Injury Requiring Dialysis Rate;*[59]
- 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.[60] [61]

(* Denotes new component for the Patient Safety and Adverse Events (Composite) measure)

[55] 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).

[56] 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.

[57] 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).

[58] Previously titled ''Postoperative Hip Fracture'' prior to v6.0.

[59] Previously titled ''Postoperative Physiologic and Metabolic Derangement'' prior to v6.0.

[60] Previously titled ''Accidental Puncture or Laceration Rate'' prior to v6.0.

[61] Available at: *http://www.qualityforum.org/QPS/0531*.

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.[62]

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 due to concerns with the underlying component indicators and their composite weights. In its final report, the NQF Patient Safety Committee deferred their final decision for the PSI 90 measure until the following measure evaluation cycle.[63] 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.[64] For more information on the proposed Patient Safety and Adverse Events (Composite) measure and component indicators, we refer readers to the Quality Indicators Empirical Methods 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 central line-associated blood stream infections, catheter-associated urinary tract infections, 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.[65]

We are proposing 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 are proposing that the measure would be added to the Safety domain, like the previously adopted PSI 90 measure that we are proposing to remove in section V.J.3.b. of the preamble of this 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'' [66] and received support from the MAP, which noted the importance of safety measures for the Hospital VBP Program.[67] Therefore, we are proposing to add the Patient Safety and Adverse Events (Composite) measure to the Safety domain for the FY 2023 program year and subsequent years.

We are inviting public comment on this proposal.

5. Previously Adopted and Proposed 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

[62] 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*.

[63] 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*.

[64] 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*.

[65] 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*.

[66] ''List of Measures Under Consideration for December 1, 2015.'' Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[67] 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*.

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.

We are not proposing 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).

We are not proposing 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). We are not proposing 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). We are not proposing 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 conclude 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, for the FY 2023 program year and subsequent years, we are proposing 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 are proposing 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 are inviting public comment on these proposals.

(3) Proposed PN Payment Measure in the FY 2022 Program Year

As discussed in section V.J.4.a. of the preamble of this proposed rule, we are proposing to adopt the PN Payment measure beginning with the FY 2022 program year. In order to adopt this measure as early as feasible into the Hospital VBP Program, we are proposing to adopt a 36-month baseline period and a 23-month performance period. We are proposing 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 are proposing 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.[68] 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)[69] 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.[70]

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

[68] Shrout P, Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. *Psychol. Bull.* Mar 1979;86(2):420–428.

[69] Shrout P, Fleiss J. Intraclass Correlations: Uses in Assessing Rater Reliability. *Psychol. Bull.* Mar 1979;86(2):420–428.

[70] Landis J, Joch G. The Measurement of Observer Agreement for Categorical Data. *Biometrics.* Mar 1997;33(1):159–174.

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 are inviting public comment on these proposals.

(4) Proposed 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, we are proposing 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 are inviting public comment on these proposals.

(5) Proposed 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, for the FY 2024 program year and subsequent years, we are proposing to adopt a 36-month baseline period and a 36-month performance period for the proposed PN Payment measure. Specifically, we are proposing 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 are inviting public comment on these proposals.

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).

We are not proposing any changes to these policies.

(2) Proposed 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 proposed rule, we are proposing 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 proposed rule, we are proposing 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 are proposing to adopt a 21-month baseline period and 24-month performance period for the measure for the FY 2023 program year. Specifically, we are proposing 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 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 are now proposing, found it to be reliable using 12 months of data.[71]

We are inviting public comment on these proposals.

(3) Proposed 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, we are proposing 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 are proposing to adopt a performance period that runs from July 1, 4 years prior to the applicable fiscal program year, to June 30, 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 are inviting public comment on these proposals.

[71] "Patient Safety 2015 Final Report" is available at: *http://www.qualityforum.org/Publications/2016/02/Patient_Safety_2015_Final_Report.aspx.*

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).[72] 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. We are now proposing 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 are inviting public comment on these proposals.

(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. We are not proposing 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, we are now proposing 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 are inviting public comment on these proposals.

f. Summary of Previously Adopted and Proposed 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 proposing to adopt in this proposed 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).		
• THA/TKA	• July 1, 2009–June 30, 2012	• July 1, 2014–June 30, 2017.
	• 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:		
• MSPB	• January 1, 2015–December 31, 2015	• January 1, 2017–December 31, 2017.

* As discussed in section V.J.3.b. of the preamble of this proposed rule, we are proposing to remove 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.

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.

[72] 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 2020 PROGRAM YEAR—Continued

Domain	Baseline period	Performance period
Efficiency and Cost Reduction:		
• MSPB	• January 1, 2016–December 31, 2016	• January 1, 2018–December 31, 2018.

* As discussed in section V.J.3.b. of the preamble of this proposed rule, we are proposing to remove 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.

PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2021 PROGRAM YEAR

Domain	Baseline period	Performance period
Person and Community Engagement:		
• HCAHPS Survey	• January 1, 2017–December 31, 2017	• January 1, 2019–December 31, 2019.
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.

* As discussed in section V.J.3.b. of the preamble of this proposed rule, we are proposing to remove 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.

PREVIOUSLY ADOPTED AND PROPOSED 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.
• PN Payment **	• July 1, 2013–June 30, 2016	• August 1, 2018–June 30, 2020.

* As discussed in section V.J.3.b. of the preamble of this proposed rule, we are proposing to remove 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.

** As discussed in section V.J.4.a. of the preamble of this proposed rule, we are proposing to adopt the PN Payment measure beginning with the FY 2022 program year.

PREVIOUSLY ADOPTED AND PROPOSED 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:		

PREVIOUSLY ADOPTED AND PROPOSED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2023 PROGRAM YEAR—Continued

Domain	Baseline period	Performance period
• 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.

*As discussed in section V.J.4.b. of the preamble of this proposed rule, we are proposing to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year.

**As discussed in section V.J.4.a. of the preamble of this proposed rule, we are proposing to adopt the PN Payment measure beginning with the FY 2022 program year.

6. Proposed Performance Standards for the Hospital VBP Program

a. Background

Section 1886(o)(3)(A) of the Act requires the Secretary to establish performance standards for the measures selected under the Hospital VBP Program for a performance period for the applicable fiscal year. The performance standards must include levels of achievement and improvement, as required by section 1886(o)(3)(B) of the Act, and must be established 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 and AMI Payment measures;
- The proposed PN Payment measure; and
- The proposed Patient Safety and Adverse Events (Composite) measure.

This distinction is made in contrast to other measures for which higher values indicate better performance.[73] 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 Proposed 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)), we are proposing to adopt additional performance standards for the FY 2020 program year. We note that the numerical values for the performance standards displayed in this proposed rule, below, represented estimates based on the most recently available data, and we intend to update the numerical values in the FY 2018 IPPS/LTCH PPS final rule. We note 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. These previously adopted and newly proposed performance standards for the measures in the FY 2020 program year are set out in the tables below.

PREVIOUSLY ADOPTED AND PROPOSED 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 *†	0.806	0.000.
CLABSI *†	0.797	0.000.
CDI *†	0.876	0.090.
MRSA Bacteremia *†	0.794	0.000.
Colon and Abdominal Hysterectomy SSI *†	• 0.784	• 0.000.
	• 0.775	• 0.000.
PC–01 *	0.005952	0.000000.
Clinical Care Domain		
MORT–30–AMI ±	0.853715	0.875869.

[73] 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.

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR THE FY 2020 PROGRAM YEAR: SAFETY, CLINICAL CARE, AND EFFICIENCY AND COST REDUCTION DOMAINS #—Continued

Measure short name	Achievement threshold	Benchmark
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.

As discussed in section V.J.3.b. of the preamble of this proposed rule, we are proposing to remove 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 were calculated using one quarter (Q4) CY 2015 data and three quarters (Q1, Q2, and Q3) CY 2016 data. We will update this table's performance standards using four quarters of CY 2016 data in the final rule.

† In section III.F.2.e. of preamble of the FY 2016 IPPS/LTCH PPS final rule (80 FR 49544 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.

PROPOSED 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	49.26	78.99	87.17
Communication with Doctors	46.91	80.31	88.56
Responsiveness of Hospital Staff	35.92	65.16	80.05
Communication about Medicines	23.44	63.41	73.94
Hospital Cleanliness & Quietness	37.21	65.81	79.29
Discharge Information	65.60	87.36	92.04
Care Transition	21.20	51.12	62.56
Overall Rating of Hospital	35.46	71.35	85.01

* 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 one quarter (Q4) CY 2015 data and three quarters (Q1, Q2, and Q3) CY 2016 data. We will update this table's performance standards using four quarters of CY 2016 data in the final rule.

We are inviting public comments on these proposed performance standards for the FY 2020 program year.

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 Proposed 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 this proposed rule, we are proposing 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. The previously adopted and newly proposed performance standards for these measures are set out in the table below.

PREVIOUSLY ADOPTED AND PROPOSED 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.

PREVIOUSLY ADOPTED AND PROPOSED PERFORMANCE STANDARDS FOR THE FY 2022 PROGRAM YEAR—Continued

Measure short name	Achievement threshold	Benchmark
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 proposed rule.

We are inviting public comment on the proposed PN Payment measure performance standards for the FY 2022 program year.

e. Proposed 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. We are proposing 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 proposing 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.

PROPOSED 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.

PROPOSED PERFORMANCE STANDARDS FOR THE FY 2023 PROGRAM YEAR—Continued

Measure short name	Achievement threshold	Benchmark
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 proposed rule.

We are inviting public comments on these proposed performance standards for the FY 2023 program year.

7. Scoring Methodology and Data Requirements for the FY 2019 Program Year and Subsequent Years

a. Proposed 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 4 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. We are not proposing 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 are proposing to retain this same domain weighting for hospitals receiving a score on all four domains. The previously adopted and newly proposed 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 are inviting public comment on this proposal.

b. Proposed 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). We are not proposing 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.

We are proposing two changes to our domain scoring policies for the FY 2019 program year and subsequent years. We are proposing 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 are proposing 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 is 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 are proposing to reduce the minimum number of required measure scores within the Safety domain from three measures to two.

In addition, we note that we are not proposing 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 in section V.J.4.a. of the preamble of this proposed rule we are proposing to adopt one additional condition-specific payment measure, the PN Payment measure. We are therefore proposing 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 are inviting public comment on these proposals.

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.

We are not proposing 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).

We are not proposing 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.[74]

Beginning with the FY 2023 program year, we are proposing 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 are inviting public comment on our proposal regarding the minimum number of cases for 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),

[74] 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.

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 proposed rule, we are proposing 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 and HF Payment measures, as well as the proposed PN Payment measure, if finalized), we are proposing 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 are inviting public comment on our proposal regarding the minimum number of cases for the AMI, HF, and PN Payment measures.

(6) Summary of Previously Adopted and Proposed Minimum Numbers of Cases for the FY 2019 Program Year and Subsequent Years

These previously adopted and newly proposed minimum numbers of cases for these measures are set forth in the table below.

PREVIOUSLY ADOPTED AND PROPOSED 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.

As discussed in section V.J.3.b. of the preamble of this proposed rule, we are proposing to remove the current PSI 90 measure beginning with the FY 2019 program year. As discussed in section V.J.4.b. of the preamble of this proposed rule, we are proposing to adopt the Patient Safety and Adverse Events (Composite) measure beginning with the FY 2023 program year.

* As discussed in section V.J.4.a. of the preamble of this proposed rule, we are proposing 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 proposed rule, we are proposing 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, we are proposing 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 are proposing 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 are inviting public comment on these proposals.

K. Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program

1. Background

We refer readers to section V.I.1.a. of the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program. 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) measures for use in the FY 2018 program and subsequent years for Domain 1. 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.[75] 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.

In this proposed rule, for the HAC Reduction Program, we are: (1) Proposing to specify the dates of the time period used to calculate hospital performance for the FY 2020 HAC Reduction Program; (2) requesting comments on additional measures for potential future adoption; (3) requesting comments on social risk factors; (4) requesting comments on accounting for disability and medical complexity in the CDC NHSN measures in Domain 2; and (5) proposing 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. Proposed 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 2-year time 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 2-year data collection period for calculating the Total HAC Score for the FY 2018 and FY 2019 HAC Reduction Programs, in order 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.

For the FY 2020 program, we are proposing to return to a two-year time period for the calculation of HAC Reduction Program measure results. We believe that using 2 years of data for both domains balances the needs of the program and allows for sufficient time to process the claims data and calculate the measure results. The 2-year time 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 are proposing 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 are proposing to use data from CYs 2017 and 2018, that is January 1, 2017—December 31, 2018, for the FY 2020 program.

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 that focus 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 diagnosis, 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]

[75] Available at: *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetBasic&cid=1228773343598.*

[76] The National Quality Forum. *NQF: MAP hospital Workgroup—materials.* October 18, 2016 *http://www.qualityforum.org/ProjectMaterials.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

Continued

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 and effective prevention strategies for VAP include early removal of invasive devices and strict infection control and prevention efforts should target these high-risk groups.[85]

Our overarching purpose is to support the National Quality Strategy's three-part aim of better health care for individuals, better health for populations, and lower costs for health care.[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 take into account widely accepted criteria established in medical literature.

We welcome public comments and suggestions on these measure areas, as well as additional outcome-based patient-safety measures that will help achieve the program goals.

5. 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' 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 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 has undertaken 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 can be assessed to determine whether risk adjustment for selected social risk factors is appropriate for these measures. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on 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. 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 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, while we sought input on this topic previously, we

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*.

[87] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs*.

[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.

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 proposed 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. While we consider whether and to what extent we currently have statutory authority to implement one or more of the above-described methods, we are seeking 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 HAC Reduction Program.

In addition, we are also seeking 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 are seeking 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 data calculations, among others), so we also welcome 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.

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, we are requesting stakeholder feedback on risk-adjusting the CDC NHSN measures for disability or medical complexity. Although we are not proposing any specific changes to the measures at this time, we will consider all comments as a guide to potential future action.

7. 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. We are not proposing any changes to this policy at this time.

[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.

8. 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) 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 proposed rule, we are proposing 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.

We are proposing 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 are proposing 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 are proposing 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 are proposing to communicate this decision through routine communication channels.

We are inviting public comment on these proposed modifications to the HAC Reduction Program's ECE policy.

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 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 proposed 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 and our proposals for implementation; and our proposals for budget neutrality, including a discussion of the budget neutrality methodology used in previous final rules, the proposed budget neutrality methodology for the extension period authorized by section 15003 of Public Law 114–255, and the proposed 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 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) (and thereby (b)(1)(A)) of Public Law 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. Proposed 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. 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. For the reasons discussed below, we believe that it would be reasonable and consistent with the statute 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 are proposing 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 are proposing 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. An additional reason for our proposal that the second 5-year period of performance start no earlier than October 1, 2017 for any of the hospitals (previously participating or newly selected) is to align the start of the periods of performance with FY 2018 for purposes of estimating the costs of the demonstration and thus determining the budget neutrality offset amount for the demonstration (discussed later in this section) for FY 2018. (The FY 2018 IPPS/LTCH PPS final rule is effective October 1, 2017.)

We believe the approach we are proposing above is consistent with section 410A of Public Law 108–173, as amended by Public Law 114–255. As discussed earlier, the statutory language does not specifically address how the 10-year extension period is to be implemented in the event of a gap between the end of the first 5-year extension of the demonstration for a participating hospital and the enactment of Public Law 114–255 authorizing the second 5-year extension of the demonstration. Furthermore, we believe that the payment methodology set forth in section 410A(b)(1)(A) and (g)(4) of Public Law 108–173, as amended by section 15003 of Public Law 114–255, contemplates that the first 5 years and the second 5 years of the 10-year extension period be treated as separate periods, in that, as discussed above, it provides for payment of reasonable costs 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.'' We believe that our proposed approach, which provides for a gap in participation between the end of the first 5 years and the start of the second 5 years of the 10-year extension period, is reasonable, given that most of the hospitals that participated in the first 5-year extension under the Affordable Care Act had already ended their participation under the demonstration when Public Law 114–255 was enacted, and that all hospitals now have been

paid under other payment methodologies outside the demonstration for a significant period of time (anywhere from 3 months to more than 2 years as of the publication of this proposed rule).

In addition, we note that certain types of administrative actions are generally required in order to implement a demonstration program that administers Medicare payment according to a methodology that differs from the methodology that would otherwise apply under the statute. These include development of participation agreements, formulating direction to MACs, and the procurement of audit and evaluation contracts. We believe that implementing the second 5-year extension for each participating hospital beginning with the start of its first cost reporting period on or after October 1, 2017, following upon the announcement of the selection of the additional hospitals for the demonstration, gives us the time necessary to implement such administrative actions.

Furthermore, we believe that it is reasonable and preferable to provide, to the extent possible, for alignment of the periods of participation of the previously participating hospitals with any newly selected hospitals during the second 5 years of the 10-year extension period. Under our proposed implementation approach, all previously participating hospitals would begin their periods of performance under the 5-year extension in FY 2018 on the same basis as the newly selected hospitals (the start of the first cost reporting period beginning on or after October 1, 2017, following upon the announcement of the selection of the new hospitals). We believe that aligning the participation periods for all hospitals in this manner would be more conducive to testing the feasibility and advisability of the payment methodology required by section 410A of Public Law 108–173 because, for all hospitals, the demonstration payment methodology would be applicable and its effect evaluated for similar time periods. In addition, we believe our proposed approach would allow for streamlined and administratively feasible budget neutrality calculations for the second 5-year extension period because the costs of the demonstration would be estimated for periods of performance beginning in the same fiscal year.

We are inviting public comments on the proposed approach discussed above 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 are inviting 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.

One potential alternative approach that we considered is for each previously participating hospital to 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 this proposed rule. Although we believe 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, for the reasons discussed below, we believe that our proposed approach outlined above would be more appropriate. First, we note that applying the extension in this alternative manner would result in hospitals being paid under the cost-based payment methodology provided for under section 410A of Public Law 108–173 (as amended) for a period of time during which the hospitals were not actively participating in the demonstration. We believe that it would be more appropriate to conduct both the implementation and evaluation of the demonstration for a period of time for which the hospitals have actively agreed to participate.

Furthermore, we note that applying the demonstration payment methodology starting at the end of each previously participating hospital's participation in the first 5-year extension period under the Affordable Care Act (as far back as cost reporting years beginning in FY 2015), in addition to implementing a new selection of hospitals, is likely to create a situation whereby the periods of participation for demonstration hospitals under the new extension period would be starting across 4 different fiscal years, because hospitals could have periods of performance that start as early as January 1, 2015, and as late as July 1, 2018. We believe that such a structure for the demonstration would not be as conducive to the goal of testing the feasibility and advisability of the cost-based payment methodology under section 410A of Public Law 108–173, as amended. Implementing a payment methodology that is different from that which would otherwise apply under the statute requires coordination among MACs and audit, quality monitoring, and evaluation contractors. Administering the second 5-year extension period so that the extension begins over a span of time to include several years would add substantial complexity to these contractual arrangements. In addition, methodologies for evaluating the effects of a payment methodology enacted under a demonstration program often involve examination of the experience of nonparticipating providers. Conducting such an analysis over different time periods might reduce the usefulness of such an evaluation approach because metrics assessed in relation to participating hospitals and nonparticipating hospitals, respectively, would not apply to uniform time periods.

Nevertheless, we are seeking 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 this proposed rule.

c. Solicitation for Additional Participants

As required under section 15003 of Public Law 114–255, we will issue a solicitation for additional hospitals to participate in the demonstration. We expect that this solicitation will be released in April 2017, and eligible hospitals will have 30 days to submit applications. Among other things, the solicitation will ask 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 provides that, in determining which rural community hospitals that submitted an application pursuant to the solicitation under subparagraph (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 are using 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.

We note that the table in this compendium presenting information on State population density includes separate sets of statistics for 2010 and 2013. Both of the 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 are choosing 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 note 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. As a result, we will consider the population density of the State in which the hospital is located. We believe that this consideration is reasonable given that 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 the date of enactment of this paragraph. 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.

Our goal is 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 (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 will confirm the start dates for the periods of performance for these newly selected hospitals. In accordance with our proposed implementation approach discussed in section V.L.3.b. of the preamble of this proposed rule, if the selection is announced by June 2017, we 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 final rule. As previously discussed, under our proposal, the periods of performance for the hospitals (Cohorts 1, 2, and 3) would not start earlier than October 1, 2017.

If final selection of the Cohort 3 hospitals does not 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 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 are selected. Therefore, if the announcement of the final selection of the Cohort 3 hospitals does not 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 final rule. As a result, if the announcement of the final selection of the Cohort 3 hospitals does not 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 is announced in accordance with our proposal. We are proposing that if the selection of the Cohort 3 hospitals is 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.

According to our proposal, regardless of whether the final selection of the Cohort 3 hospitals occurs by June 2017, no period of performance in the second 5 years of the 10-year extension period for any of the hospitals (Cohorts 1, 2, and 3) would start earlier than October 1, 2017. Our goal is, to the greatest extent possible, to align the start of the periods of performance with FY 2018 for purposes of estimating the costs of the demonstration and thus determining the budget neutrality offset amount for FY 2018. (We refer readers to section V.L.4. of the preamble of this proposed rule for our proposed 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 viable under the usual form of budget neutrality—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 become available.

c. Proposed Budget Neutrality Methodology for Extension Period Authorized by the 21st Century Cures Act (Pub. L. 114–255)

For the implementation approach that we are proposing in section V.L.3.b. of the preamble of this proposed rule, we are proposing 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 would implement this adjustment through the corresponding proposed and final IPPS rules. In addition, 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 earlier, we are proposing 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) is 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 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 does not occur 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. In that situation, we are proposing 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.

As described earlier, if the selection of the newly participating hospitals authorized by section 410A(g)(6) of Public Law 108–173 (as added by section 15003 of Pub. L. 114–255) is announced by June 2017, we are proposing that the periods of performance under the second 5 years of the 10-year extension period for each of the participating hospitals (Cohorts 1, 2, and 3) would start with the hospital's first cost report year on or after October 1, 2017. Thus, the start dates for the periods of performance for the entire set of participating hospitals would occur during FY 2018.

If the selection of the new hospitals is announced by June 2017, under our proposed implementation approach as described in section V.L.3.b. of the preamble of this proposed rule, 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 note that the same general methodology would be used if the announcement of the selection of additional hospitals does 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.)

Consistent with the approach adopted in the FY 2016 IPPS/LTCH PPS final rule, we are proposing 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 are proposing 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 are proposing 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 expect that for most of the hospitals these ''as submitted'' cost reports will be those with cost report period end dates in CY 2015. In the solicitation for additional participants, we will be requesting applicants to submit cost report information from the most recent year available. For the selected additional hospitals (that is, Cohort 3), we would be using the submitted information for the calculation of the budget neutrality offset amount for FY 2018.) We believe 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 are proposing 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 are proposing to use the most recently available ''as submitted'' cost reports for this calculation.

For each hospital, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 would apply only the FY 2017 and final FY 2018 market basket percentage increases. We recognize 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 lessen the precision of the estimate. However, we believe that the potential margin of error in estimating the total costs for the demonstration hospitals inherent in using a uniform set of update factors is justifiable for purposes of streamlining and applying a consistent calculation method for all participating hospitals. In addition, we note that, as in previous years, we are proposing 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 this proposed rule, 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 this proposed rule. We also are proposing to then multiply the product of the unadjusted general 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 are proposing 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 general total reasonable cost amount described above to model the estimated FY 2018 reasonable cost amount under the demonstration. We are proposing to use the IPPS market basket percentage increases because we believe that these update factors appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved. The 3-percent annual volume adjustment was stipulated by the CMS Office of the Actuary and is being proposed because it is intended to accurately reflect the tendency of hospitals' inpatient caseloads to increase. We acknowledge the possibility that inpatient caseloads for small hospitals may fluctuate, and thus are proposing to incorporate into the estimate of demonstration costs a factor to allow for a potential increase in inpatient hospital services.

Step 2: For each of the participating hospitals, we are proposing 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 are proposing 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 are proposing to multiply this sum for each participating hospital by the hospital-specific prorating factor. We are then proposing 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 are proposing 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 are proposing to apply the market basket percentage increases to the sum of the hospitals' applicable general total estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments would constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates. 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 are proposing 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 are proposing to subtract the amount derived in Step 2 (representing the sum of estimated amounts that generally would otherwise be paid to the participating hospitals for covered inpatient hospital services for FY 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 are proposing 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 are proposing 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 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 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 are inviting public comments on the budget neutrality calculation methodology proposed above. In addition, we are inviting 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.

d. Alternative Budget Neutrality Approach Considered

In section V.L.3.b. of the preamble of this proposed rule, 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 decides 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.

Under this alternative approach that we considered, depending on which among the Cohorts 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 would 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 alternative approach, any additional amounts associated with the cost-based payment methodology for this period would need to be paid to the hospitals.

Although we considered this alternative implementation approach and budget neutrality methodology, for the reasons discussed in section V.L.3.b. of the preamble to this proposed rule, we are instead proposing the implementation approach (according to which the periods of performance for previously participating hospitals for the second 5-year extension period would begin with the hospital's first cost reporting period on or after October 1, 2017, following the announcement of the selection of additional hospitals) and budget neutrality methodology described in sections V.L.3.b. and V.L.4.c. of the preamble of this proposed rule. Nevertheless, we are inviting public comments on the budget neutrality methodology that we describe below for the alternative approach.

In general, the methodology that we considered for calculating a budget neutrality offset under this alternative 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 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 this proposed rule, under the alternative methodology we considered, we would seek to 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). (The methodology for estimating the costs for FY 2018 for this alternative implementation approach that we considered is described below.)

Thus, under the alternative approach we considered, 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 alternative approach that we considered, 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 note 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 believe 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 note that, for hospitals (either Cohort 1 or 2) with an October 1 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 alternative approach that we considered, 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 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 this proposed rule for estimating the costs of the demonstration for FY 2018, the alternative methodology we considered for estimating the costs of

the demonstration for FY 2018 would follow 3 steps:

Step 1: 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. These calculations would be identical to those described for our proposed methodology in section V.L.4.c. of the preamble of this 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 this alternative methodology that we considered, for hospitals with a cost report start date other than October 1, 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. (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 would then follow the same calculations as in our proposed budget neutrality calculation described in section V.L.4.c. of the preamble of this proposed rule, including application of the same update factors to reflect increases in cost and volume.

Step 2: 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 this 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 the alternative methodology.

Step 3: 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 would follow the identical methodology for estimating the costs of the demonstration for FY 2018 as described for the proposed budget neutrality methodology under the proposed implementation approach. Similar to the description above for the proposed approach, if the selection of additional participants under the solicitation authorized by Public Law 114–255 is announced by June 2017, we would be able to incorporate the estimates of the costs of the demonstration for the Cohort 3 hospitals for FY 2018 within a budget neutrality offset adjustment to be included in the FY 2018 IPPS/LTCH PPS final rule. However, we note that if this selection is not announced by that time, 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. 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 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 above), and include that difference either as a positive or negative adjustment in the upcoming year's final rule.
- For future years, 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 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 note that, under the alternative approach we considered, 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. However, we note the overall complexity of the methodology for budget neutrality under this alternative implementation methodology, involving various differing methods for either determining or estimating the costs of the demonstration over several different fiscal years, potentially to be applied to budget neutrality offset adjustment amounts for IPPS final rules for different fiscal years. We believe our proposed implementation approach and budget neutrality calculation (described in sections V.L.3.b. and V.L.4.c. of the preamble of this proposed rule) are more reasonable and appropriate for the reasons discussed previously, and because of the complexity inherent in meeting the budget neutrality requirement, and the administrative burden involved in tracking payments and associated calculations over multiple years under the alternative methodology.

Nevertheless, we are inviting public comments on the alternative budget neutrality calculation methodology we considered, as discussed above.

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, we are proposing 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. 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, 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 are proposing 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 lessening the possibility of both positive and negative adjustments to be applied in consecutive years, and enhancing administrative feasibility. Specifically, we are proposing 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 expect that this would occur in FY 2019. We also are proposing 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 plan to provide an update in a future final rule regarding the year that we would expect that this analysis would occur.

We are inviting public comments on this proposal.

M. Payment for Services in Inpatient and Outpatient Hospital Settings

1. 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 this FY 2018 IPPS/LTCH PPS proposed 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, as explained in detail in section II. of the Addendum to this proposed rule.

We note 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.

2. Eliminating Inappropriate Medicare Payment Differentials for Similar Services in the Inpatient and Outpatient Settings

CMS is committed to eliminating inappropriate Medicare payment differentials for similar services in the inpatient and outpatient settings in order to execute our responsibility to taxpayers to prudently pay for high quality care. As MedPAC has previously noted, ''The high profitability of one-day stays under the inpatient prospective payment system (IPPS) and the generally lower payment rates for similar care under the outpatient prospective payment system (OPPS) have heightened concern about the appropriateness of inpatient one-day stays'' (Medicare and the Health Care Delivery System Report to Congress, June 2015).

In the past, CMS has requested public comment on potential payment policy options to address the issue of payment differentials between services provided in the inpatient and outpatient settings. However, our most recent solicitation occurred in the CY 2016 OPPS/ASC final rulemaking (80 FR 70549). Since that time, both hospitals and CMS have had the opportunity to gain experience under the various policy changes that have occurred with respect to short inpatient hospital stays. In this context, we believe it is an appropriate time to seek public comment on transparent ways to identify and eliminate inappropriate payment differentials for similar services provided in the inpatient and outpatient settings.

N. Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations

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, we are proposing 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 are proposing 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 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. We are not proposing 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 welcome public comments on our proposals.

O. Request for Information Regarding Physician-Owned Hospitals

We are seeking public comments on the appropriate role of physician-owned hospitals in the delivery system. We are also seeking public comments on how the current scope of and restrictions on physician-owned hospitals affects healthcare delivery. In particular, we are interested in comments on the impact on Medicare beneficiaries.

VI. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. 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. Proposed Annual Update for FY 2018

The proposed 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 proposed 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, 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 proposed rule.)

In section II.D. of the preamble of this proposed rule, we present a discussion of the MS–DRG documentation and coding adjustment, including previously finalized policies and historical adjustments, as well as the adjustment to the standardized amount under section 1886(d) of the Act that we are proposing 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 proposing a similar adjustment to the national capital Federal rate (or to the hospital-specific rates).

VII. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed 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 applies as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) 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 this proposed rule, we are proposing to revise and rebase the IPPS operating market basket to a 2014 base year. Therefore, we are proposing 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 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. Based on IHS Global Insight, Inc.'s 2016 fourth quarter forecast, for this proposed rule, we estimate 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 are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2018.

In addition, as discussed in section VIII.J. of the preamble of this proposed 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, we are proposing 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 are now referring 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 proposed changes to § 412.23 to implement the provisions of section 15008 of Public Law 114–255, we refer readers to section VIII.J. of the preamble of this proposed 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, we are proposing 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 this proposed rule, is 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 this proposed rule, the proposed update to a long-term care neoplastic disease hospital's target amount for FY 2018 is 2.9 percent, which is based on IHS Global Insight, Inc.'s 2016 fourth quarter forecast. Furthermore, we are proposing that if more recent data become available for the final rule, we would use that updated data to calculate the IPPS operating market basket update for FY 2018.

B. Proposed Changes to 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 proposals to make several changes to our HwH regulations.

In this proposed rule, we are proposing 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. This proposal 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. 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 are proposing 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 are proposing to revise the introductory language of § 412.22(e) to reflect this 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 are not proposing changes to our HwH regulations for co-located IPPS and IPPS-excluded hospitals, we are seeking 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 this proposed rule, we also are proposing 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 are proposing 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 are proposing 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 do 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 do not believe, at this 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 welcome public comment on these proposals.

C. 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.

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 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

Based on feedback from stakeholders, we have reviewed the CAH 96-hour certification requirement to determine if there are ways to reduce its burden on providers. 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 policy. In order to minimize the burden of documentation submission requirements for CAHs with respect to the 96-hour certification requirement, in this proposed rule, we are providing 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. This means that, absent concerns of probable fraud, waste, or abuse with respect to the 96-hour certification requirement, these contractors will not conduct medical record reviews. 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.

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 are providing 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. 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.

Under the revised instructions to contractors, CAHs will not receive any medical record requests from MACs, RACs, QIO, or SMRCs related to the 96-hour certification 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, QIO, or SMRCs 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.

VIII. Proposed 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 (long-term Care neoplastic disease 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 proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, 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 proposed 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 related to high-cost

outlier payments in section V.D. of the Addendum of this proposed rule. The provisions of section 15006 of Public Law 114–255 extended various moratoria on the implementation of the 25-percent payment adjustment threshold policy. We discuss our proposals related to the provisions of section 15006 in section VIII.G. of the preamble of this proposed 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 related to the provisions of section 15007 in section VIII.I. of the preamble of this proposed rule. The provisions of section 15008 of Public Law 114–255 changed the classification of certain hospitals. We discuss our proposals related to the provisions of section 15008 in section VIII.J. of the preamble of this proposed 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 hospitals. We discuss our proposals related to the provisions of section 15009 in section VIII.E. of the preamble of this proposed rule. The provisions of section 15010 of Public Law 114–255 contain a temporary exception to the site neural payment rate for certain wound care discharges from certain LTCHs. We discuss our proposals related to the provisions of section 15010 in section VIII.F. of the preamble of this proposed rule. In addition, we are proposing to amend 42 CFR 412.500 to include Public Law 114–255 as one of the bases and scope of subpart O of part 412.

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). 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 are proposing to add a sunset date to subclause (II) LTCHs (which have become a new category of IPPS-excluded hospitals known as long-term care neoplastic disease hospitals). Long-term care neoplastic disease hospitals are discussed in greater detail in section VIII.J. of the preamble of this proposed rule. In addition, in section VIII.I. of the preamble of this proposed rule, we discuss the proposed changes to the calculation of the greater than 25-day average length-of-stay requirement provided by the provisions of section 15008 of Pub. L. 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 proposed 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. Proposed 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 would be 754 MS–DRG groupings based on the proposed changes discussed in section II.F. of the preamble of this FY 2018 IPPS/LTCH PPS proposed rule. Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. We then assign an appropriate weight to the MS–LTC–DRGs to account for the difference in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCHs.

In this section of the proposed rule, we provide a general summary of our existing methodology for determining the proposed FY 2018 MS–LTC–DRG relative weights under the LTCH PPS.

In this proposed rule, in general, for FY 2018, we are proposing to continue 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 proposed rule). As we established when we implemented the dual rate LTCH PPS payment structure codified under § 412.522, which began in FY 2016, we are again proposing that the annual recalibration of the MS–LTC–DRG relative weights would be determined: (1) Using only data from available LTCH PPS claims that would have qualified for payment under the new LTCH PPS standard Federal payment rate if that rate 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 would 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 proposed rule). In addition, for FY 2018, we are proposing to continue to exclude the data from all-inclusive rate providers and LTCHs paid in accordance with demonstration projects, as well as any Medicare Advantage claims from the MS–LTC–DRG relative weight calculations for the reasons discussed in section VIII.B.3.c. of the preamble of this proposed rule.

Furthermore, for FY 2018, in using data from applicable LTCH cases to establish MS–LTC–DRG relative weights, we are proposing to continue to establish low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases) using our quintile methodology in determining the MS–LTC–DRG relative weights because LTCHs do not typically treat the full range of diagnoses as do acute care hospitals. Therefore, for purposes of determining the relative weights for the large number of low-volume MS–LTC–DRGs, we group all of the low-volume MS–LTC–DRGs into five quintiles based on average charges per discharge. Then, under our existing methodology, we account for adjustments made to LTCH PPS standard Federal 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 proposed rule.)

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted 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 proposed 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. Proposed 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, we are proposing 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 this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2018 presented in this proposed rule are the same as the proposed MS–DRGs that are being proposed for use under the IPPS for FY 2018. In addition, because the proposed MS–LTC–DRGs for FY 2018 are the same as the proposed MS–DRGs for FY 2018, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 35 as discussed in section II.F. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, also would be applicable under the LTCH PPS for FY 2018.

3. Development of the Proposed 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 Proposed 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 this FY 2018 IPPS/LTCH PPS proposed rule, we are proposing to continue to use our current methodology to determine the proposed 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 proposed MS–LTC–DRGs, proposed low-volume and no-volume MS–LTC–DRGs, proposed adjustments for nonmonotonicity, the steps for calculating the proposed MS–LTC–DRG relative weights with a proposed 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 proposed application of our existing methodology for determining the proposed MS–LTC–DRG relative weights for FY 2018, and we discuss the effects of our proposals concerning the data used to determine the proposed FY 2018 MS–LTC–DRG relative weights on the various components of our existing methodology in the discussion that follows.

c. Data

For this proposed rule, consistent with our proposals regarding the calculation of the proposed MS–LTC–DRG relative weights for FY 2018, we obtained total charges from FY 2016 Medicare LTCH claims data from the December 2016 update of the FY 2016 MedPAR file, which are the best available data at this time, and we are proposing to use proposed Version 35 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if more recent data become available, we would use those data and the finalized Version 35 of the GROUPER in establishing the FY 2018 MS–LTC–DRG relative weights in the final rule. To calculate the proposed FY 2018 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue 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 December 2016 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 proposed 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 Pub. L. 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 proposed 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 Pub. L. 114–255, had the exception been in effect at the time of the discharge.

Furthermore, consistent with our historical methodology, 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 Pub. L. 90–248 or section 222(a) of Pub. L. 92–603. In addition, consistent with our historical practice and our proposals, 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 proposed MS–LTC–DRG relative weights for FY 2018.

In summary, in general, we identified the claims data used in the development of the proposed FY 2018 MS–LTC–DRG relative weights in this proposed rule, as we are proposing, 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 December 2016 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 December 2016

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 are proposing to use the remaining data (that is, the applicable LTCH data) to calculate the proposed 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 this FY 2017 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the proposed MS–LTC–DRG relative weights for FY 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 are proposing to reduce the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for 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, 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 proposed rule) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. SSO cases are cases with a length of stay that is less than or equal to five-sixths the average length of stay of the MS–LTC–DRG (§ 412.529 and § 412.503). The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The resulting ratio is multiplied by that LTCH's case-mix index to determine the standardized charge for the case.

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 Proposed MS–LTC–DRG Relative Weights

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section of the proposed 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 are proposing 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 proposed FY 2018 MS–LTC–DRG relative weights, when necessary, as is our longstanding practice, we are proposing to 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 proposed rule. We refer readers to the discussion in the FY 2010 IPPS/RY 2010 LTCH PPS final rule for our rationale for including an adjustment for nonmonotonicity (74 FR 43953 through 43954).

f. Proposed Low-Volume MS–LTC–DRGs

In order to account for proposed MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for proposed low-volume MS–LTC–DRGs, such that we group the proposed ''low-volume MS–LTC–DRGs'' (that is, proposed MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)). In cases where the initial assignment of a proposed low-volume MS–LTC–DRG to a quintile results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume proposed MS–LTC–DRGs to preserve monotonicity, as discussed in detail in section VIII.B.3.g. (Step 6) of the preamble of this proposed rule.

In this proposed rule, based on the best available data (that is, the December 2016 update of the FY 2016 MedPAR files), we identified 261 proposed MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of proposed MS–LTC–DRGs was then divided into one of the proposed 5 low-volume quintiles, each containing at least 52 proposed MS–LTC–DRGs (261/5 = 52 with a remainder of 1). We assigned the proposed low-volume MS–LTC–DRGs to specific proposed low-volume quintiles by sorting the proposed low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the

data available for the proposed rule, the number of proposed MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5 and, therefore, we are proposing to employ our historical methodology for determining which of the proposed low-volume quintiles contain the additional proposed low-volume MS–LTC–DRG. Therefore, we are proposing to use our historical methodology for determining which of the low-volume quintiles should contain the additional proposed low-volume MS–LTC–DRG. Specifically for this proposed rule, after organizing the proposed MS–LTC–DRGs by ascending order by average charge, we would assign the first 52 (1st through 52nd) of proposed low-volume MS–LTC–DRGs (with the lowest average charge) into Quintile 1. The 52 proposed MS–LTC–DRGs with the highest average charge cases would be assigned into Quintile 5. Because the average charge of the 105th proposed low-volume MS–LTC–DRG in the sorted list was closer to the average charge of the 104th proposed low-volume MS–LTC–DRG (assigned to Quintile 2) than to the average charge of the 106th proposed low-volume MS–LTC–DRG (assigned to Quintile 3), we assigned it to Quintile 2 (such that Quintile 2 contains 53 proposed low-volume MS–LTC–DRGs before any adjustments for nonmonotonicity, as discussed below). This results in 4 of the 5 proposed low-volume quintiles containing 52 proposed MS–LTC–DRGs (Quintiles 1, 3, 4, and 5) and 1 proposed low-volume quintile containing 53 proposed MS–LTC–DRGs (Quintile 2). Table 13A, listed in section VI. of the Addendum to this proposed rule and available via the Internet, lists the composition of the proposed low-volume quintiles for MS–LTC–DRGs for FY 2018.

In order to determine the proposed FY 2018 relative weights for the proposed low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles described previously. We determined a proposed relative weight and (geometric) average length of stay for each of the five proposed low-volume quintiles using the proposed methodology described in section VIII.B.3.g. of the preamble of this proposed rule. We are proposing to assign the same proposed relative weight and average length of stay to each of the proposed low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases will vary in the future. Furthermore, we note that we 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 proposed low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

g. Steps for Determining the Proposed FY 2018 MS–LTC–DRG Relative Weights

In this proposed rule, we are proposing to continue to use our current methodology to determine the proposed FY 2018 MS–LTC–DRG relative weights.

In summary, to determine the proposed FY 2018 MS–LTC–DRG relative weights, we are proposing to group applicable LTCH cases to the appropriate proposed MS–LTC–DRG, while taking into account the proposed low-volume quintiles (as described above) and cross-walked proposed no-volume MS–LTC–DRGs (as described later in this section). After establishing the appropriate proposed MS–LTC–DRG (or proposed low-volume quintile), we are proposing to calculate 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 are proposing to adjust the number of applicable LTCH cases in each proposed MS–LTC–DRG (or proposed low-volume quintile) for the effect of SSO cases (Step 3 below). After removing 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 are proposing to calculate proposed ''relative adjusted weights'' for each proposed 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 proposed calculation of the proposed 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 proposed 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, in determining the proposed FY 2018 MS–LTC–DRG relative weights, we are proposing to remove 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 proposed calculation of the proposed 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, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the proposed relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the proposed relative weights 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 proposed 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 proposed 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 proposed calculation of the proposed FY 2018 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust 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 are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay for the MS–LTC–DRG for non-SSO cases. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2018 MS–LTC–DRG relative weights would lower the proposed 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, we are proposing to continue 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 proposed FY 2018 MS–LTC–DRG relative weights on an iterative basis.

Consistent with our historical relative weight methodology, we are proposing to calculate the proposed 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 proposed MS–LTC–DRG, we calculated the proposed FY 2018 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the proposed 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 proposed MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value from above divided by the sum of equivalent applicable LTCH cases from Step 3 for each proposed 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 proposed 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 proposed FY 2018 relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the proposed MS–LTC–DRGs for which there were no claims in the December 2016 update of the FY 2016 MedPAR file and, therefore, for which no charge data was available for these proposed MS–LTC–DRGs. Because patients with a number of the diagnoses under these proposed MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we are generally proposing to assign a proposed relative weight to each of the proposed no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' proposed MS–LTC–DRGs, ''error'' proposed MS–LTC–DRGs, and proposed MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this proposed rule). (For additional information on this step of the proposed relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

We are proposing to cross-walk each proposed no-volume MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a proposed relative weight (determined in accordance with the methodology described above). Then, the ''no-volume'' proposed MS–LTC–DRG was assigned the same proposed relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this proposed rule).

Of the 754 proposed MS–LTC–DRGs for FY 2018, we identified 351 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 are proposing to assign proposed relative weights to each of the 351 no-volume proposed MS–LTC–DRGs that contained trimmed applicable LTCH cases based on clinical similarity and relative costliness to 1 of the remaining 403 (754 − 351 = 403) proposed MS–LTC–DRGs for which we calculated proposed 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'' proposed MS–LTC–DRGs as the proposed MS–LTC–DRGs to which we cross-walked 1 of the 351 ''no volume'' proposed MS–LTC–DRGs.) Then, we are generally proposing to assign the 351 no-volume proposed MS–LTC–DRGs the proposed relative weight of the cross-walked proposed MS–LTC–DRG. (As explained below in Step 6, when necessary, we made adjustments to account for nonmonotonicity.)

We cross-walked the no-volume proposed MS–LTC–DRG to a proposed MS–LTC–DRG for which we calculated proposed relative weights based on the December 2016 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 proposed relative weight of the cross-walked proposed MS–LTC–DRG as the proposed relative weight for the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight (and average length of stay) for FY 2018. We note that, if the proposed cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its proposed relative weight (calculated using the methodology described in Steps 1 through 4 above) is assigned to the no-volume proposed MS–LTC–DRG as well. Similarly, if the proposed MS–LTC–DRG to which the no-volume proposed MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, is designated to 1 of the proposed low-volume quintiles for purposes of determining the proposed relative weights, we assigned the proposed relative weight of the applicable proposed low-volume quintile to the no-volume proposed MS–LTC–DRG such that both of these proposed MS–LTC–DRGs (that is, the no-volume proposed MS–LTC–DRG and the cross-walked proposed MS–LTC–DRG) have the same proposed relative weight for FY 2018. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume proposed MS–LTC–DRG resulted, additional adjustments as described in Step 6 are required in order to maintain monotonically increasing proposed relative weights.)

For this proposed rule, a list of the no-volume proposed MS–LTC–DRGs and the proposed MS–LTC–DRGs to which each was cross-walked (that is, the proposed cross-walked MS–LTC–DRGs) for FY 2018 is shown in Table 13B, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site.

To illustrate this methodology for determining the proposed 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 proposing to use for this proposed rule for proposed MS–LTC–DRG 061 (Acute Ischemic Stroke with Use of Thrombolytic Agent with MCC). We determined that proposed MS–LTC–DRG 070 (Nonspecific Cerebrovascular Disorders with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 061. Therefore, we assigned the same proposed relative weight (and average length of stay) of proposed MS–LTC–DRG 70 of 0.8890 for FY 2018 to proposed MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet 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 are proposing to use the most recent available claims data to identify the trimmed applicable LTCH cases from which we determined the proposed relative weights in this proposed rule.

For FY 2018, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 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 proposed MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

In this proposed rule, consistent with our practice in FYs 2016 and 2017, we are proposing to establish a proposed relative weight for FY 2018 equal to the respective FY 2015 relative weight of the MS–LTC–DRGs for the following ''psychiatric or rehabilitation'' proposed MS–LTC–DRGs: proposed MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); proposed MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); proposed MS–LTC–DRG 881 (Depressive Neuroses); proposed MS–LTC–DRG 882 (Neuroses Except Depressive); proposed MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); proposed MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); proposed MS–LTC–DRG 885 (Psychoses); proposed MS–LTC–DRG 886 (Behavioral & Developmental Disorders); proposed MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); proposed MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); proposed MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); proposed MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); proposed MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); proposed MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and proposed 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'' proposed 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 proposed relative weight for the ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs. In other words, any LTCH PPS discharges grouped to any of the 15 ''psychiatric and rehabilitation'' proposed MS–LTC–DRGs would always be paid at the site neutral payment rate, and, therefore, those proposed MS–LTC–DRGs would never include any LTCH cases that meet the criteria for exclusion from the site

neutral payment rate. However, section 1886(m)(6)(B) of the Act establishes a transitional payment method for cases that 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'' proposed MS–LTC–DRGs in FY 2018, we assigned a proposed relative weight to these proposed 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'' proposed 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 proposed MS–LTC–DRGs for which we were able to determine proposed relative weights based on applicable LTCH cases in 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 proposed MS–LTC–DRG relative weight calculation to use the LTCH discharges in the MedPAR file data to calculate a proposed relative weight for those 15 ''psychiatric and rehabilitation'' proposed 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 proposing to establish a proposed relative weight (and average length of stay thresholds) equal to the respective FY 2015 relative weight of the proposed MS–LTC–DRGs for the 15 ''psychiatric or rehabilitation'' proposed MS–LTC–DRGs listed previously (that is, proposed 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 proposed rule and is available via the Internet on the CMS Web site, reflects this proposed policy.

Step 6—Adjust the proposed 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 proposed FY 2018 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue 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 proposed FY 2018 MS–LTC–DRG relative weights in this proposed rule by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site.

Step 7—Calculate the proposed 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, we are proposing to 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 proposed FY 2018 MS–LTC–DRG relative weights.

In this FY 2018 IPPS/LTCH PPS proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology.

To calculate the proposed normalization factor for FY 2018, we grouped applicable LTCH cases using the proposed FY 2018 Version 35 GROUPER, and the recalibrated proposed 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 proposed for FY 2018. That ratio is the proposed normalization factor. Because the calculation of the proposed normalization factor involves the proposed relative weights for the proposed MS–LTC–DRGs that contained applicable LTCH cases to calculate the average CMIs, any low-volume proposed MS–LTC–DRGs are included in the calculation (and the proposed MS–LTC–DRGs with no applicable LTCH cases are not included in the calculation).

To calculate the proposed budget neutrality adjustment factor, we simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed FY 2018 normalized relative weights and proposed 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 the proposed budget neutrality adjustment factor. The calculation of the proposed budget neutrality factor involves the proposed relative weights for the LTCH cases used in the payment simulation, which includes any cases grouped to low-volume proposed MS–LTC–DRGs or to proposed MS–LTC–DRGs with no applicable LTCH cases, and generally does not include payments for cases grouped to a proposed 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 proposed relative weight calculation in step 2) that are grouped to a proposed MS–LTC–DRG with no applicable LTCH cases are included in the payment simulations used to calculate the proposed budget neutrality factor. However, the number and payment amount of such cases have a negligible impact on the proposed budget neutrality factor calculation).

In this proposed rule, to ensure budget neutrality in the update to the MS–LTC–DRG classifications and relative weights under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in this proposed rule, in the first step of our proposed MS–LTC–DRG budget neutrality methodology, for FY 2018, we are proposing to calculate and apply a proposed normalization factor to the recalibrated proposed 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 proposed changes to the classification system. That is, the proposed normalization adjustment is intended to ensure that the recalibration of the proposed MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2018 (the first step of our proposed 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 proposed FY 2018 GROUPER (that is, proposed Version 35 for FY 2018) and the recalibrated proposed 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 proposed MS–LTC–DRG relative weights for FY 2018, each recalibrated proposed MS–LTC–DRG relative weight is multiplied by the proposed normalization factor of 1.28875 (determined in Step 1.c.) in the first step of the proposed budget neutrality methodology, which produced ''normalized relative weights.''

In the second step of our proposed MS–LTC–DRG budget neutrality methodology, we calculate a second proposed budget neutrality factor consisting of the ratio of estimated aggregate FY 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 proposed rule, for FY 2018, under the second step of the proposed budget neutrality methodology, we are proposing to determine the proposed budget neutrality adjustment factor using the following three steps: (2.a.) simulated estimated total FY 2018 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed normalized relative weights for FY 2018 and proposed 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 proposed FY 2018 MS–LTC–DRG relative weights, each normalized proposed relative weight is then multiplied by a budget neutrality factor of 0.9866449 (the value determined in Step 2.c.) in the second step of the proposed budget neutrality methodology to achieve the budget neutrality requirement at § 412.517(b).

Accordingly, in determining the proposed FY 2018 MS–LTC–DRG relative weights in this proposed rule, consistent with our existing methodology, we are proposing to apply a normalization factor of 1.28875 and a budget neutrality factor of 0.9866449. Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the Internet on the CMS Web site, lists the proposed MS–

LTC–DRGs and their respective proposed 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. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed 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 412.536. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 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 this FY 2018 IPPS/LTCH PPS proposed rule, we present 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 proposed update to the LTCH PPS standard Federal payment rate for FY 2018 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2018 are discussed below, including the statutory 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 proposed rule). In addition, we are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level adjustment for FY 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 proposed rule), a proposed budget neutrality adjustment stemming from our proposed change to the SSO payment methodology (as discussed in VIII.D. of the preamble of this proposed rule).

2. Proposed 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 proposed rule.) We note that because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed 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) 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) 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. Proposed 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)). We discuss the application of the 2.0 percentage point reduction under § 412.523(c)(4)(i) in our discussion of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2018 in section VIII.C.2.c. of the preamble of this proposed rule. (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C.2.c. of the preamble of this proposed rule.)

d. Proposed 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, we are proposing 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), we are proposing to further reduce the proposed annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points in accordance with section 1886(m)(5) of the Act. As such, the proposed 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 will be the proposed 1-percent annual rate increase for FY 2018 reduced by 2.0 percentage points. For this proposed rule, we are proposing to establish a proposed 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 proposed FY 2018 LTCH PPS standard Federal payment rate, we are also applying a proposed area wage level budget neutrality factor in accordance with § 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule) and a proposed budget neutrality adjustment stemming from our proposed change to the SSO payment methodology (as discussed in VIII.D. of the preamble of this proposed rule).

Absent the special provisions for FY 2018 required by section 1886(m)(3)(C) of the Act, we note the proposed annual market basket update would have been based on the FY 2018 full market basket increase of 2.8 percent (based on IGI's fourth quarter 2016 forecast of the 2013-based LTCH market basket) reduced by the proposed FY 2018 MFP adjustment of 0.4 percentage point (also based on IGI's fourth quarter 2016 forecast). Following application of the productivity adjustment, the adjusted proposed market basket update of 2.4 percent (2.8 percent minus 0.4 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 a proposed annual market basket update under to the LTCH PPS standard Federal payment rate for FY 2018 of 1.65 percent (that is, 2.8 percent, less the proposed MFP adjustment of 0.4 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. Proposed 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 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 this proposed rule, we are proposing 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, the proposed changes to our SSO policy presented in this section 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 would remain 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 are proposing 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 a LTCH PPS standard Federal payment rate 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.

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 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 believe that this proposed 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 are proposing to codify the change to the SSO policy described above by revising § 412.529 of the regulation. Specifically, we are proposing 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.

The goal of this proposed revision to the SSO policy is to remove the incentive to delay patient discharges for payment reasons. 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, we expect this proposed SSO payment adjustment methodology would result in increased payments to SSO cases. Based on data and FY 2018 payment estimates used for this proposed rule, we estimate that, under this proposal, Medicare payments to SSO cases would 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 would 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 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 the proposed policy, these cases would not have previously been SSO cases. We believe the proposed 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, while we expect this behavior change by LTCHs would reduce Medicare expenditures, we do not believe that the decrease in expenditures from fewer delayed discharge cases would offset the estimated increase in expenditures under the proposed SSO payment adjustment methodology. As such, we project that this 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.

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 believe the appropriate policy approach is to propose to implement this proposed change to the SSO payment methodology on a budget neutral basis; that is, to implement the proposed 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 our proposed 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, 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 implementing the proposed SSO payment methodology, we are proposing to use a budget neutrality adjustment to offset the projected net increase in Medicare spending, which accounts 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 believe that our proposal to incorporate a projection of the expected decrease in spending resulting from 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 are proposing to amend § 412.523 by adding a new paragraph (d)(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, we are proposing to use the following methodology to determine the proposed budget neutrality factor that would be applied to the proposed FY 2018 LTCH PPS standard Federal payment rate using the 2016 LTCH standard Federal payment rate payment cases used for this proposed rule. These estimates are based upon the most recently available data (for example, the December 2016 update of the FY 2016 MedPAR file), and consistent with historical practice, if more recent data become available, we are proposing to use such data for the final rule.

- 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). (For the remainder of this discussion, we refer to this amount as ''estimated FY 2018 payments under the existing SSO payment

methodology''.) Under this step, our estimated FY 2018 payments under the existing SSO payment methodology is $3.177 billion.

• 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 (as discussed earlier), which is determined as follows in Step 2a through Step 2d. (A discussion and supporting details for the assumptions for expected changes in LTCHs' discharge behavior used in this step are provided after Step 2c. For the remainder of this discussion, we refer to this amount as the ''estimated FY 2018 payments under the proposed SSO payment methodology''.)

• 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. (For the remainder of this discussion, we refer to this amount as the ''estimated unadjusted FY 2018 payments under the proposed SSO payment methodology.'' We note that this estimate is comprised of estimated unadjusted FY 2018 payments under the proposed SSO payment methodology for non-SSO cases and for SSO cases.) This estimate represents the proposed change in the SSO payment methodology alone in the absence of any behavioral assumptions. We note that, in addition to estimated unadjusted FY 2018 payments under the proposed SSO payment methodology for SSO cases, this estimate includes estimated unadjusted FY 2018 payments under the proposed SSO payment methodology for non-SSO cases (which are the same as the estimated FY 2018 payments under the existing SSO payment methodology in Step 1 for non-SSO cases because there would be no change in which cases would be subject to an SSO payment adjustment under our proposal). Based on data used for this proposed rule (which is described in section I.J.1. of the Regulatory Impact Analysis in Appendix A to this proposed rule), we estimate that, in the absence of any behavioral assumptions, under our SSO policy proposal, FY 2018 Medicare payments to SSO cases would increase approximately 4.6 percent, or approximately $145 million. This amount reflects the first of the two different impacts on Medicare LTCH spending that we would expect under the proposed change to the SSO policy (as discussed earlier), which would, without incorporating the second impact discussed above, increase Medicare spending under the LTCH PPS to $3.322 billion.

• 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 proposed changes to the SSO policy. Under this step, we use the estimated unadjusted FY 2018 payments under the proposed SSO payment methodology for non-SSO cases (simulated in Step 2a) and our actuarial projection (described in detail below) of a 10-percent decrease in non-SSO cases under the proposed change to the SSO policy. Therefore, under this step, we would subtract an amount equal to 10 percent of our estimated unadjusted FY 2018 payments under the proposed SSO payment methodology for non-SSO cases from the amount determined in Step 2a. (In other words, after applying Step 2b, under our actuarial assumptions, estimated FY 2018 unadjusted payments under the proposed SSO payment methodology for non-SSO cases are projected to be 90 percent of the corresponding estimate for such cases from Step 2a to reflect the expected decrease in non-SSO cases under the proposed changes to the SSO policy.) Based on data used for this proposed rule, we estimate that 10 percent of our estimated unadjusted FY 2018 payments under the proposed SSO payment methodology for non-SSO cases is approximately $272 million. (In Step 2d below, this estimated $272 million is subtracted from our estimated FY 2018 unadjusted payments under the proposed SSO payment methodology to account for the projected decrease in non-SSO cases under the proposed 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. Under our actuarial assumptions (used in Step 2b above and described in detail below), we project SSO cases under the proposed change to the SSO policy to increase at the same level as the projected decrease in non-SSO cases (that is, by 10 percent of the non-SSO cases). That is, under the proposed change to the SSO policy, our actuaries estimate that there would be a 10-percent shift in LTCH cases from non-SSO cases to SSO cases and, therefore, we project a resulting aggregate increase in payments to SSO cases. (In Step 2d below, this estimated increase is added to our estimated FY 2018 unadjusted payments under the proposed SSO payment methodology to account for the projected increase in SSO cases under the proposed changes to the SSO policy.)

To incorporate our actuarial estimate of this case shifting in our estimated FY 2018 payments under the proposed SSO payment methodology, we again determined the estimated unadjusted FY 2018 payments for all non-SSO cases but now paid as if all such cases were SSO cases under our proposed SSO policy. (For readability, we use the term ''aggregate SSO comparable amount'' below to refer to this amount.) In other words, we estimate payments for non-SSO cases as if all factors of each case remained the same, but the length of stay decreased to less than the SSO threshold. (The basis for the decrease in the length of stay is discussed in greater detail below.) This 10 percent of the ''aggregate SSO comparable amount'' represents our estimate of the aggregate increase in SSO payments under our proposed SSO policy for those cases that are expected to shift to SSO cases from non-SSO cases because we are projecting that 10 percent of non-SSO cases would become SSO cases as a result of our proposal.

Therefore, under this step, we would add an amount equal to 10 percent of the ''aggregate SSO comparable amount'' to the amount determined in Step 2a. (In other words, under our actuarial assumptions and after applying Step 2c, our estimated unadjusted FY 2018 payments under the proposed SSO payment methodology would be increased to reflect the expected increase in SSO cases.)

To estimate proposed SSO payments based on non-SSO cases under this step, because our proposed payment adjustment for SSO cases depends on the length of stay, these estimated payments depend on where, relative to the SSO threshold, the shifts from non-SSO cases to SSO cases occur. As we discuss in greater detail below, our actuaries estimate the majority of the increase in SSO cases resulting from this proposed policy would occur within 1 to 3 days prior to the SSO threshold. As such, we based our estimated payment amount in this step on our actuarial assumption (discussed in greater detail below) that the length of stay shifts would occur only between 1 and 3 days prior to the SSO threshold. We then performed three payment simulations to estimate proposed SSO payments if all of the non-SSO cases would have a length of stay of 1 day, 2 days, and 3 days prior to the SSO threshold. To determine the estimated SSO payments for the non-SSO cases,

we took an average of those three aggregate estimates: payments where non-SSO cases moved 1 day prior to the SSO threshold; payments where non-SSO cases moved 2 days prior to the SSO threshold; and payments where non-SSO cases moved 3 days prior to the SSO threshold. This amount is the ''aggregate SSO comparable amount'' described above. Then we took 10 percent of the ''aggregate SSO comparable amount'' as the estimated increase in aggregate SSO payments expected to result from the expected increase in SSO cases under our proposal.

Based on data used for this proposed rule, using the calculation described above, we estimate that 10 percent of the ''aggregate SSO comparable amount'' is approximately $229 million. (In Step 2d below, this estimated $229 million is added to our estimated FY 2018 unadjusted payments under the proposed SSO payment methodology to account for 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 ($272 million 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 $229 million from Step 2c). The resulting amount is the estimated FY 2018 payments under the proposed SSO payment methodology (which is used in Step 3 below). As such, we estimate FY 2018 payments under the proposed SSO payment methodology is $3.279 billion (that is, $3.322 billion from Step 2a minus the $272 million from Step 2b plus the $229 million from Step 2c.) Therefore, we estimate 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 minus the $3.279 billion as calculated here in Step 2).

Actuarial Assumptions for Shifts in Cases Used under Steps 2b and 2c: 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 this 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 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, our actuaries estimate that the elimination of the payment cliff would result in a 10-percent reduction in non-SSO cases, resulting in an increase in SSO cases by 10 percent of our non-SSO cases. For these non-SSO cases that shift, 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.

As stated above, the net result of the amounts determined in Steps 2b and 2c of an approximately $43 million decrease (approximately −$272 million from Step 2b plus approximately $229 million from Step 2c) reflects the second of the two different impacts on Medicare LTCH spending we would expect under the proposed change to the SSO policy (as discussed earlier), which would decrease Medicare spending under the LTCH PPS.

- 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). This ratio is calculated by dividing the estimated FY 2018 payments under the existing SSO payment methodology ($3.177 billion as calculated in Step 1) by the estimated FY 2018 payments under the proposed SSO payment methodology ($3.279 billion as calculated in Step 2). We note that, under this step, an iterative process is used 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 because the portion of estimated FY 2018 payments under the proposed SSO payment methodology that is not based on LTCH PPS standard Federal payment rate (that is, the IPPS comparable amount portion under the proposed SSO payment methodology) is not affected by the application of this budget neutrality factor.

We also note that, under this step, the proposed budget neutrality factor for the proposed change in the SSO payment methodology is applied to the proposed FY 2018 LTCH PPS standard Federal payment rate after the application of the proposed FY 2018 annual update and the proposed FY 2018 area wage level adjustment budget neutrality factor (discussed in section V. of the Addendum to this proposed rule).

Based on the claims data used for this proposed rule, we estimate 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 minus the $3.279 billion as calculated in Step 2) which reflects 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 this proposed rule, using the steps in the proposed methodology described earlier, we have determined a proposed budget neutrality factor for the proposed change to the SSO payment methodology of 0.9672. (We are proposing, consistent with historical practice, that if more recent data become available and if finalized, we would use such data to determine a budget neutrality factor for the proposed change to the SSO payment methodology in the final rule.) Accordingly, in section V.A. of the Addendum to this proposed rule, to determine the proposed FY 2018 LTCH PPS standard Federal payment rate, we are proposing to apply a one-time, permanent budget neutrality factor of 0.9672 for the proposed change in the SSO payment methodology. The proposed FY 2018 LTCH PPS standard Federal payment rate shown in Table 1E in section VI. of the Addendum to this proposed rule reflects this proposed adjustment.

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, we plan to provide further details regarding the implementation of the significant out-of-state admissions criterion through subregulatory guidance. However, in this proposed rule, we are proposing 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 are proposing 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 are seeking public comments on this proposal. Based on information currently available, we believe that two hospitals may qualify for this exception.

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 concurrently in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57070). Therefore, to the extent applicable, we are implementing this provision in an identical manner to our implementation of the amendments made by section 231 of the Consolidated Appropriations Act, 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).'' We are proposing 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 meets 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 are proposing 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 are proposing 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.

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 are proposing 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 are proposing 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.

G. Moratorium and Proposed 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 proposed 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 section § 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, we are proposing 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 are proposing 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.)

In addition, we are proposing to adopt a 1-year regulatory moratorium on the implementation of the 25-percent threshold policy; that is, we are proposing to impose a regulatory moratorium on our implementation of § 412.538 until October 1, 2018. This proposal is 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 is appropriate at this 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. 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 this 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 this time we only have 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. 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 this proposed rule, we are proposing 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 are proposing that if, in response to public comments, we do 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 are seeking public comments on our proposals.

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, we are proposing 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 are discussed in section V.D. of the Addendum to this proposed rule.) We are seeking public comments on this proposal.

I. Proposed 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 had 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, we are proposing 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 are seeking public comments on our proposal.

J. Change in Medicare Classification for Certain Hospitals (§ 412.23)

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 512.526, including § 412.526(c)(3) and § 412.526(c)(4), since January 1, 2015.)

In order to implement these requirements, we are proposing 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 are proposing to add a new paragraph (j) to § 412.23 that would establish a new classification of IPPS-excluded hospital (''long-term care neoplastic disease hospitals'') 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 are not proposing to make changes to Subpart O by removing references to ''subclause (II) LTCHs'' due to the proposed sunset date we are adding to § 412.23(e)(2)(ii).) We are seeking public comments on our proposal.

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 2018 PQRS will be replaced by the Quality Payment Program (QPP);
- 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; 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.

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. Our goal for the future is to align the clinical quality measure requirements of the Hospital IQR Program with various other Medicare and Medicaid programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so the reporting burden on providers will be reduced. As appropriate, we will consider the adoption of clinical quality measures with electronic specifications so the electronic collection of performance information is a seamless component of care delivery. Establishing such a system will require interoperability between electronic health records (EHR) and CMS data collection systems, additional infrastructure development on the part of hospitals and CMS, and adoption of standards for capturing, formatting, and transmitting the data elements that make up the measures. However, once these activities are accomplished, adoption of measures which rely on data obtained directly from EHRs will enable us to expand the Hospital IQR Program measure set with less cost and reporting burden to hospitals. We believe that, in the near future, collection and reporting of data elements through EHRs will greatly simplify and streamline reporting for various CMS quality reporting programs, and hospitals will have decreased burden as they are able to switch primarily to EHR-based data reporting for many measures that are currently manually chart-abstracted and submitted to CMS for the Hospital IQR Program.

We also have implemented a Hospital VBP Program under section 1886(o) of the Act, described in the 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 (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 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 this proposed rule, we are proposing 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 this proposed rule, we are proposing 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 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.

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 Web site 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 subregulatory process to incorporate nonsubstantive updates to the measure specifications for measures we have adopted for the Hospital IQR Program so that these measures remain up-to-date. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505) and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203) for our policy for using a subregulatory process to make nonsubstantive 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 subregulatory 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 this proposed rule, we are not proposing any changes to our policies on the measures maintenance process, including the maintenance of nonsubstantive 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*.

In this proposed rule, we are not proposing any changes to these policies.

d. 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) [98] 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 of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[99] 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.[100]

As noted in the FY 2017 IPPS/LTCH PPS final rule, 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 entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review its findings.

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 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, we are also seeking 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 are seeking 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 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 proposed 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 are seeking 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.

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,

[98] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[99] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[100] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

availability of data, statistical considerations relating to reliability of data calculations, among others), so we also welcome 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.

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 this proposed rule, we are not proposing 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 this proposed rule, we are not proposing 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 this FY 2018 IPPS/LTCH PPS proposed rule, we are not proposing 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
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

HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2019 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
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
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 this proposed rule, we are not proposing 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 this proposed rule, we are proposing refinements to two measures. First, we are proposing 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 are proposing 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 are proposing 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 are proposing 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/ASC final rule (71 FR 68201), 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 32 questions about their recent hospital stay. 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.[101] 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:

[101] ''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.

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 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, for the FY 2020 payment determination and subsequent years, we are proposing 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 will be used to form the composite measure ''Communication about Pain.'' The ''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/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 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.[102]

We plan to resubmit the ''Communication About Pain'' composite measure to the MAP at the next opportunity. As we discuss in more detail below, the 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 will be posted on the official HCAHPS On-Line Web site, *www.HCAHPSonline.org*. 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 Communication About Pain questions in a large-scale experiment that involved patients from 50 hospitals across the nation. Our analyses suggest the 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).[103] These properties of the individual questions used in the proposed 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 standard, providing further evidence of reliability.[104]

As stated above, the MAP recommended the proposed Communication About Pain composite measure be submitted to the NQF for review and endorsement once testing has been completed.[105] The proposed 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 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 Communication About Pain composite measure because communicating with patients about their pain is an integral part of delivering high quality, person-centered care.[106] In developing the proposed

[102] ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS'' available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452*.

[103] 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.

[104] Cronbach, L.J. (1984). *Essentials of psychological testing* (4th ed.). New York: Harper.

[105] ''2017 Considerations for Implementing Measures Hospitals—Final Report,'' available at: *http://www.qualityforum.org/map/*.

[106] ''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://*

Continued

Communication About Pain composite measure, we followed our standard survey development processes,[107] which included drafting alternative questions, cognitive interviews, focus group evaluation, field testing, statistical analysis, and stakeholder input. We believe the 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. We note that if our proposal to revise the current Pain Management measure questions with those in the proposed Communication About Pain composite measure is not finalized, we would continue to use the Pain Management questions as previously finalized.

The Communication About Pain composite measure is discussed below. We are proposing 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 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 *Hospital Compare* 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 *Hospital Compare* in October 2018. 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 items 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 will create scores for the Communication About Pain composite measure.

We will 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/2019 payment determination will be the last period for which we have four quarters of the original Pain Management measure data which, as stated above, will be publicly reported on *Hospital Compare* in October 2018. We will be unable to publicly report either the original or new Communication About Pain composite measure on *Hospital Compare* in December 2018, April 2019, or July 2019 because there will be fewer than 4 quarters of data for both the original and the new measure. The CY 2018 reporting period/FY 2020 payment determination will be the first period for which we have four quarters of the new Communication About Pain composite measure. Therefore, the Communication About Pain composite measure would be publicly reported for the first time on *Hospital Compare* in October 2019. From this point forward, the new Communication About Pain composite measure could be used for payment determinations.

(2) Overview of Measure

The refined questions that comprise the proposed 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:

www.annemergmed.com/article/S0196-0644(16)30367-5/fulltext.

[107] ''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 be applicable to all patients who experienced pain during their hospital stay.

(3) Data Collection

The revised 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 new 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 new 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 are inviting 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 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.

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

For the FY 2023 payment determination and subsequent years, we are proposing 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,[108] [109] [110] and is part of the national guidelines on stroke care.[111]

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 [112] in the risk-adjustment model as a measure of stroke severity. These refinements result in a modestly higher c-statistic compared with the risk-adjustment model in the current Stroke 30-Day Mortality Rate, which means that the updated measure model better differentiates the risk of mortality among patients.

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.[113] [114] 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.[115] [116] [117] [118]

We are proposing 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.[119] 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.[120]

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.[121]

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.[122] 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 that the measure might be misleading, limited, or inaccurate without adjustment for stroke severity, and four comments suggested risk

[108] 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.

[109] 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.

[110] 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.

[111] 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.

[112] NIH Stroke Scale. Available at: *http://www.nihstrokescale.org/*.

[113] 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.

[114] 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.

[115] 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.

[116] 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.

[117] 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.

[118] 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.

[119] NIH Stroke Scale. Available at: *http://www.nihstrokescale.org/*.

[120] 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.

[121] ICD–10–CM Official Guidelines for Coding and Reporting. Available at: *https://www.cdc.gov/nchs/data/icd/10cmguidelines_2017_final.pdf*.

[122] 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.

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 different risk 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.[123] The MAP also noted that 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 that 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, and 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.[124] 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 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-Stroke Registry, the Committee noted that 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 that the primary reason for upholding the Committee's decision was based on the lack of testing 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 that the measure met the NQF's evidence criterion, 19 members voted that the measure met the high or moderate standard for the Performance Gap, 18 members voted that the measure met high or moderate standard for reliability, 19 members voted that the measure met the high or moderate standard for feasibility, and 18 members voted that the measure met the moderate standard for Use and Usability.[125] We tested and validated the measure using NIH Stroke Scale data derived from medical record review done by the Get With The Guidelines (GWTG)-Stroke registry data supplied by AHA/ASA. The NQF committee ultimately determined that the validity testing was not sufficient for endorsement.[126]

However, we believe that 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,[127] compared with 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.[128]

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 that the measure accurately risk adjusts for different hospital populations without unfairly penalizing high-performance providers, and that the NIH Stroke Scale is well validated, highly reliable, widely used, 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

[123] 2016 Spreadsheet of Final Recommendations to HHS & CMS Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367*.

[124] The memo regarding the CSAC's decision is available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=83217*.

[125] The memo regarding the CSAC's decision is available at: *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=83217*.

[126] 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.

[127] 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.

[128] 2017 Condition-Specific Mortality Measures Updates and Specifications Report. Available at: *www.qualitynet.org > Hospitals-Inpatient > Claims-Based Measures > Mortality Measures > Measure Methodology.*

not available for hospitals to use in their claims until October 2016. Therefore, we are proposing this measure now to inform hospitals that 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 reevaluation 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 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.

However, we are proposing this measure now because we believe that 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 require to plan and begin to alter 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 are proposing that 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.

(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).[129]

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.[130] 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 then 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

[129] Bernheim S WC, Want Y, et al. *Hospital 30-Day Mortality Following Acute Ischemic Stroke Hospitalization Measure Methodology Report.* 2010.

[130] 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.

a modestly higher c-statistic with fewer risk variables, meaning that 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.[131] 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 1, 2020, to calculate measure results for the dry-run anticipated in CY 2021. The data in the confidential hospital-specific feedback reports would not be publicly reported.

We are inviting 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.

c. Summary of Previously Adopted 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 proposed refinements from this proposed rule) for the FY 2020 payment determination and subsequent years. The proposed, 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

[131] ICD–10–CM Official Guidelines for Coding and Reporting. Available at: *https://www.cdc.gov/nchs/data/icd/10cmguidelines_2017_final.pdf.*

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
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	+

PREVIOUSLY ADOPTED HOSPITAL IQR PROGRAM MEASURES FOR THE FY 2020 PAYMENT DETERMINATION AND SUBSEQUENT YEARS—Continued

Short name	Measure name	NQF #
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 listed twice, as both chart-abstracted and electronic clinical quality measure.
** Proposed 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 proposed rule.
*** Proposed 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 proposed rule.
+ NQF endorsement has been removed.

7. Proposed 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 that 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) had not been endorsed when the MAP considered the measure, it encouraged further development (80 FR 49698),[132] 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,

[132] 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.

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.[133] 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.[134] [135] [136] In addition, inclusion of clinical information from patient EHRs is responsive to stakeholders who find it preferable to 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. Proposal for Voluntary Reporting of Electronic Health Record Data for the Hybrid HWR Measure (NQF #2879)

In accordance with, and to the extent permitted by, the HIPAA Privacy Rule and other applicable law, we are proposing 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 is being proposed for voluntary data collection in this 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 this proposal 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

[133] 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.

[134] 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*.

[135] 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*.

[136] 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*.

believe up to approximately 100 hospitals would voluntarily submit data for the Hybrid HWR measure. Details about the measure and our proposal for voluntary reporting certain data elements for this measure are discussed below.

c. Data Sources

We are proposing 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 Fee-For-Service 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. 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).[137] This algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital.[138] The algorithm was most recently refined in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50211 through 50216) for the previously adopted, claims-based measure. That same algorithm is used for this proposed voluntary Hybrid HWR measure.[139] 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.[140] 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.[141] 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)[142] surgical procedure category. Admissions with an eligible surgical procedure category are assigned

[137] 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.*

[138] *Ibid.*

[139] 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.*

[140] 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.*

[141] 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.*

[142] Clinical Classifications Software (CCS) for ICD–9–CM Fact Sheet. Accessed at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp.*

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
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

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.[143] The proposed voluntary Hybrid HWR measure specialty cohort groups are further defined in section IX.A.7.e. of the preamble of this proposed 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.[144] 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 that 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 differ 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.

[143] 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.*

[144] 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.*

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 are proposing that hospitals use QRDA I files for each Medicare Fee-For-Service 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 proposed rule for additional proposals related to data submission and reporting requirements for the Hybrid HWR measure.

We also are proposing 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 percent of these patients discharged over the same time period. Data reporting 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 CY 2021 reporting period/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. We would propose to require reporting on this measure in future rulemaking after we collect and analyze information from voluntary reporting.

We are inviting 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.

8. Proposed 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 this proposed rule, we are proposing 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 are proposing 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 are made in conjunction with our proposals discussed in sections IX.E.2.b. of the preamble of this proposed 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 were 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; and
- 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 still reporting CY 2016 data.

In response to these issues, we are proposing 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. Proposed Modifications to the eCQM Reporting Requirements for the Hospital IQR Program for the CY 2017 Reporting Period/FY 2019 Payment Determination

For the CY 2017 reporting period/FY 2019 payment determination, we are proposing to modify our policies to require hospitals to: (1) report on at least six of the available eCQMs, instead of eight as previously finalized, and (2) submit two self-selected quarters of data, instead of one full calendar year of data as previously finalized. We believe that reducing the number of eCQMs required to be reported from eight to six and reducing the quarters of data to be reported from four quarters to any two quarters will ease the burden on data submitters, allowing them to shift resources to support system upgrades, data mapping, and staff training related to eCQMs. We also believe that the reduction in the number of required eCQMs will lessen the burden of identifying measures to report on and vendor coding of new measures; under the modified policy, hospitals will only be required to identify two additional measures between CY 2016 and CY 2017, as opposed to four additional measures. Further, 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.

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, giving hospitals ample time to adjust to these proposed modified policies. Any hospital that was prepared to submit one full calendar year of data for eight eCQMs in accordance with the previously finalized CY 2017 reporting requirements should be able to submit two self-selected quarters of data for six eCQMs in accordance with the proposed modifications to the CY 2017 reporting requirements. Reducing the number of data reporting periods to two quarters, rather than four, and allowing hospitals to select which two quarters of CY 2017 to report also will offer greater reporting flexibility and allow 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 that we are making similar proposals in the EHR Incentive Program and refer readers to section IX.E.2.b. of the preamble of this proposed rule. Our proposals to modify the CY 2017 reporting period eCQM requirements in the Hospital IQR Program would continue to be fully aligned with the requirements of the CQM electronic reporting option in the Medicare EHR Incentive Program for eligible hospitals and CAHs to reduce confusion and reporting burden. In addition, we are not proposing 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 are inviting 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.

c. Proposed 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 are proposing similar modifications for the CY 2018 reporting period/FY 2020 payment determination. Specifically, we are proposing 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 are proposing 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 note 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 are being made in conjunction with proposals discussed in section IX.E.3. of the preamble of this 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 note 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 are inviting 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.

The proposed modifications to the CY 2017 reporting period/FY 2019 payment determination and CY 2018 reporting period/FY 2020 payment determination requirements, if finalized as proposed, 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 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 proposed rule where we discuss our proposal to modify those requirements in order to align the eCQM validation process with these proposals.

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 [145] and the CMS Strategic Plan.[146]

In keeping with these considerations, we are inviting 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.

[145] HHS Strategic Plan, available at: *https://www.hhs.gov/about/strategic-plan/*.

[146] CMS Strategy: The Road Forward 2013–2017, available at: *https://www.cms.gov/About-CMS/Agency-Information/CMS-Strategy/Downloads/CMS-Strategy.pdf*.

- 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.[147 148 149 150 151 152 153]

Despite their importance, and our regulations in the Conditions for Participation Guidelines,[154] 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 that 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.

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 fundamental step for advancing patient-centered decision making.[155 156 157 158 159 160] 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,

[147] 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.

[148] Zuckerman MJ, Shen B, Harrison ME, et al. Informed consent for GI endoscopy. Gastrointestinal endoscopy. 2007;66(2):213–218.

[149] 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.

[150] 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.

[151] 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.

[152] 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.

[153] Lorenzen B, Melby CE, Earles B. Using principles of health literacy to enhance the informed consent process. AORN journal. 2008;88(1):23–29.

[154] § 482.24, § 482.51, § 482.90, § 482.98, § 482.102.

[155] 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.

[156] 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.

[157] Robb WJ, Carroll C, Kuo C. Orthopaedic Surgical Consent: The First Step in Safety. *American Academy of Orthopaedic Surgeons (AAOS) Now.* 2015;9(9).

[158] 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.

[159] 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.

[160] Krumholz HM. Informed consent to promote patient-centered care. *JAMA.* 2010;303(12):1190–1191.

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 interrater 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 better quality. 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 are inviting 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 Accreditation Program (HAP),[161] 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.[162] The Joint Commission offers additional guidance for best practices.[163] 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/*

[161] 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.

[162] 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.

[163] *https://www.jointcommission.org/assets/1/23/Quick_Safety_Issue_Twenty-One_February_2016.pdf.*

Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html.

(6) Inclusion and Exclusion Criteria

Qualifying electively-performed procedures were identified using the AHRQ Clinical Classification Software (CCS) codes [164] 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/HospitalQualityInits/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 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

[164] Clinical Classifications Software (CCS) for ICD–9–CM Fact Sheet. Accessed at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccsfactsheet.jsp.*

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 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 that 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.[165] 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.[166] 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 that the measure be submitted to NQF for review and endorsement.[167]

We are inviting public comment on multiple aspects of the measure. Specifically, we are seeking 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 are seeking 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 are seeking 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 results more often than less frequent reporting. Finally, we are seeking input on a potential validation process for the Quality of Informed Consent Documents measure.

[165] ''2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *http://www.qualityforum.org/map/*.

[166] ''2017 Considerations for Implementing Measures Hospitals—Final Report,'' available at: *http://www.qualityforum.org/map/*.

[167] *Ibid.*

b. Potential Inclusion of Four End-of-Life (EOL) Measures for Cancer Patients

(1) Background

The quality of palliative and end-of-life care has been identified as a measurement gap in the Hospital IQR Program.[168] 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.'' [169] 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.[170] 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,'' [171] 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.[172] 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

[168] 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*.

[169] *Ibid.*

[170] *Ibid.*

[171] 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.

[172] *Ibid.*

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 Merit Based Incentive Payment Program (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).[173] 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.[174] 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.

We believe that these measures would 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 proposed in section IX.B.4.b.of the preamble of this proposed 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 are inviting public comment on the possible future inclusion 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

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 care.[175] Studies have shown there is a link between 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.[176] 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.[177] Further, more recent literature has demonstrated that nursing skill mix (licensure level) and increased RN nursing hours are associated with decreased rates of patient falls, pressure ulcers, urinary tract infections, and bloodstream infections.[178] [179] [180]

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 are seeking 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.[181] 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

[173] 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, Available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[174] ''2017 Considerations for Implementing Measures Hospitals-Final Report,'' available at: *http://www.qualityforum.org/map/.*

[175] Institute of Medicine. (2011). The future of nursing: Leading change, advancing health. Washington, DC: National Academies Press.

[176] 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.

[177] 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).

[178] 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.*

[179] 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. Availab le at: *http://doi.org/10.1002/jhrm.20092.*

[180] 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.*

[181] Spreadsheet of MAP 2015 Final Recommendations, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

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.[182] The final recommendation from that review was to conditionally support the inclusion of these measures, contingent upon review and endorsement from the NQF. We note that these measures initially obtained NQF endorsement on August 5, 2009, and after subsequent review by NQF for aggregation at the hospital level, the measures retained their endorsement as of December 10, 2015.[183] Further, we note that approximately half of hospitals are already reporting this information to the NDNQI®,[184] founded by the American Nurses Association (ANA).[185] NDNQI® data are not publicly reported.

(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

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 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.[186]

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.[187] 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 that 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 are seeking 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 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 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 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.

[182] MAP 2014–2015 Preliminary Recommendations, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[183] NQF Measures Database, ''Quality Positioning System,'' available at: *http://www.qualityforum.org/QPS/204* and *http://www.qualityforum.org/QPS/0205.*

[184] 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.

[185] Press Ganey Nursing Quality (NDNQI), available at: *http://www.pressganey.com/solutions/clinical-quality/nursing-quality.*

[186] 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.

[187] NHSN Patient Safety Component Manual *https://www.cdc.gov/nhsn/about-nhsn/index.html* [under ''Related Links''].

(d) Cohort

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 are inviting 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 are seeking 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.

(3) Nursing Hours per Patient Day Measure (NQF #0205)

(a) Overview of Measure

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 that 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 are seeking 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, 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 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. 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 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 are inviting public comment on the possible future inclusion of the Nursing Hours per Patient Day measure for the Hospital IQR Program. Specifically, we are seeking 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.

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 keeping with this goal, we are soliciting 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 make strides with 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 proposed 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 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 are seeking 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

(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.[188] 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.[189] [190] 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.[191] [192] [193] In addition, an analysis

[188] 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.*

[189] 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.*

[190] 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.*

[191] 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/.*

[192] 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/.*

Continued

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.[194]

(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.[195] 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.[196]

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 are inviting public comment on the possible future inclusion of this opioid prescribing 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.[197] [198] 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 undernutrition risk and high undernutrition risk experience increased costs by 28.8 percent and 21.1 percent, respectively, when compared to non-malnourished patients.[199] 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.[200] 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.[201] 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.[202] Thus, there is an 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

[193] 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.*

[194] 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.*

[195] 2016 Measures Under Consideration List (PDF), available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[196] ''2017 Considerations for Implementing Measures Hospitals-Final Report,'' available at: *http://www.qualityforum.org/map/.*

[197] 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.

[198] 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.

[199] 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.

[200] 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.

[201] 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.

[202] 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.

researchers, using validated screening tools, indicate a significantly higher prevalence of undiagnosed malnutrition in the hospital, ranging from 33 to 54 percent.[203] 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.[204] 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.[205] 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 are inviting public comment on the possible future inclusion of one or more of these malnutrition measures in the Hospital IQR Program. In addition, we are inviting 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.

(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.[206] 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.[207] 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.[208] 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.[209] [210] [211] [212] 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.[213]

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.[214] 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 [215] 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);

[203] 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.

[204] ''2017 Considerations for Implementing Measures Hospitals-Final Report,'' available at: *http://www.qualityforum.org/map/*.

[205] *Ibid.*

[206] 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*.

[207] 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*.

[208] *Ibid.*

[209] 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.

[210] 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.

[211] Lightwood JM. The economics of smoking and cardiovascular disease. Prog Cardiovasc Dis. 2003 Jul-Aug;46(1):39–78.

[212] 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*.

[213] *Ibid.*

[214] Joint Commission Quality Check Data, available at: *https://www.qualitycheck.org/*. (Data download.)

[215] Joint Commission Quality Check Data available at: *https://www.qualitycheck.org/*.

• 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.[216] 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 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 that 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.[217] 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.[218] 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 are inviting 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 are inviting 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.

(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.[219] 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.[220] 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 use disorder.[221] 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

[216] The Joint Commission, Substance Use Measures overview, available at: *https://www.jointcommission.org/core_measure_sets.aspx*.

[217] 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *http://www.qualityforum.org/map/*.

[218] *Ibid.*

[219] 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*.

[220] 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*.

[221] 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*.

disease.[222] 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.[223] Similar benefits have been observed for individuals with substance use disorders who are identified and referred to treatment.[224] [225] 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.[226] 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,[227] 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.'' [228] 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 (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.[229]

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

[222] 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.*

[223] 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.

[224] 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.

[225] 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.

[226] Joint Commission Quality Check Data, available at: *https://www.qualitycheck.org/.* (Data download.)

[227] 2016 Measures Under Consideration Spreadsheet, available at: *http://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

[228] 2016–2017 Spreadsheet of Final Recommendations to HHS and CMS, available at: *http://www.qualityforum.org/map/.*

[229] ''2017 Considerations for Implementing Measures Hospitals—Final Report,'' available at: *http://www.qualityforum.org/map/.*

process and these measures received NQF endorsement. Sufficient evidence exists linking the measures to improved patient outcomes [230] [231] in the inpatient setting.[232] 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.[233] 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 are inviting 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 are inviting 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.

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). We are not proposing 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. We are not proposing any changes to the data submission requirements for chart-abstracted measures.

d. Proposed Changes to the Reporting and Submission Requirements for eCQMs

In this proposed rule, we are proposing 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 eight self-selected eCQMs from the available eCQMs in the Hospital IQR Program for the FY 2019 and FY 2020 payment determinations. However, in this proposed rule, we are proposing to modify: (1) The CY 2017 reporting period/FY 2019 payment determination eCQM reporting requirements so that hospitals would be required to report on six eCQMs and submit two, self-selected, calendar quarters of CY 2017 data; and (2) for the CY 2018 reporting period/FY 2020 payment determination eCQM reporting requirements so that hospitals would be required to report on six eCQMs and to submit the first three calendar quarters of CY 2018 data. We refer readers to section IX.A.8. of the preamble of this proposed rule for more detail on these proposals. In order to fully align the Hospital IQR Program with the requirements for the CQM electronic reporting option in the Medicare EHR Incentive Program for the CY 2017 reporting period/FY 2019 payment determination and the CY 2018 reporting period/FY 2020 payment determination, we are proposing similar policies for the Medicare EHR Incentive Program for eligible hospitals and CAHs. We are proposing these changes to assist hospitals in their efforts to transition towards reporting more eCQMs and towards reporting four full

[230] 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.

[231] 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.

[232] 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).

[233] The Joint Commission, Substance Use Measures overview, available at: *https://www.jointcommission.org/core_measure_sets.aspx*.

quarters of eCQM data. We refer readers to section IX.E.3. of the preamble of this proposed rule, where we are proposing aligned policies for the CQM electronic reporting option in the Medicare EHR Incentive Program for eligible hospitals and CAHs.

(2) Proposed Changes to the Reporting and Submission Requirements for eCQMs for the FY 2019 Payment Determination and Subsequent Years

In this proposed rule, we are not proposing any changes to our file format requirements or reporting deadlines. However, we are proposing 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). 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 those of the Medicare EHR Incentive Program for eligible hospitals and CAHs (81 FR 57255 through 57257). We are not proposing any changes to these requirements in this proposed rule.

(b) Proposed Changes to the Certification Requirements for eCQM Reporting

(i) Background

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 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 proposed 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. Furthermore, we believe that there are many benefits for 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. 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 of CEHRT. One possibility is the flexibility to use technology certified to the 2014 Edition or the 2015 Edition in CY 2018. Another option 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 invite public comment on these options for offering flexibility in CY 2018 with regard to EHR certification requirements.

In this proposed rule, we are proposing two changes related to certification requirements with regard to eCQM reporting: (1) To require EHR technology certified to all eCQMs that are available to report; and (2) to note that 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) Proposal To Require 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 that their CEHRT products were recertified to the most recent version of the electronic specifications for the clinical quality measures. In this proposed rule, we are proposing new policies regarding the Hospital IQR Program eCQM specification requirements to align with the Medicare EHR Incentive Program 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 finalized that in the event an eligible hospital or CAH has EHR technology that is certified to the 2014 Edition and not certified to all of the eCQMs that are available to electronically report for the CY 2017 reporting period/FY 2019 payment determination, we require that a hospital needs 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/FY 2019 payment determination, eligible hospitals and CAHs 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 with the Medicare EHR Incentive Program requirements for eligible hospitals and CAHs, in this proposed rule, we are proposing 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 for the CY 2017 reporting period/FY 2019 payment determination in order to meet the eCQM reporting requirements for the CY 2017 reporting period/FY 2019

payment determination. We further propose 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 are proposing to continue our policy regarding the reporting of eCQMs, which would require the use of the most recent version of the eCQM specifications for each eCQM to which the EHR is certified. For the CY 2018 eCQM reporting period, 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 page *https://ecqi.healthit.gov/*. In addition, we are proposing to require that a hospital would need to have its 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. As described in the 2015 EHR Incentive Programs final rule (80 FR 62767) and as previously finalized for the Hospital IQR Program's eCQM reporting requirements, starting with the CY 2018 reporting period, hospitals are required to use EHR technology certified to the 2015 Edition. Furthermore, we are proposing 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 are proposing 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 proposed rule.

We are inviting public comment on these proposals.

(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. We are not proposing any changes to the eCQM submission deadlines for the FY 2020 payment determination or subsequent years.

(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 vendors to submit QRDA I files early, and to use one of the pre-submission testing tools for electronic reporting, such as the CMS Pre-Submission Validation Application (PSVA), to allow additional time for testing and to make sure all required data files are successfully submitted by the deadline. The PSVA 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 this FY 2018 IPPS/LTCH PPS proposed rule, for the CY 2017 reporting period/FY 2019 payment determination, we are proposing for the Hospital IQR Program that: (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, we are proposing for the Hospital IQR Program that: (1) A hospital using EHR technology certified to the 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. Further, we are proposing that: (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). eCQM specifications are available on the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*.

We are inviting public comment on our proposals related to the reporting and submission requirements of eCQM data for the Hospital IQR Program. We refer readers to section IX.E.3.c. of the preamble of this proposed rule, where similar policies are described for the Medicare EHR Incentive Program for eligible hospitals and CAHs.

e. Proposed Submission Form and Method for the Proposed 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 this proposed rule, we are proposing 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 that 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) Proposed Certification and File Format Requirements for Core Clinical Data Element Submissions

We are proposing that hospitals that voluntary report data for the Hybrid Hospital-Wide Readmission measure use EHR technology certified to the 2015 Edition. We also refer readers to our discussion of EHR certification requirements for eCQM reporting above and in section IX.G.4. of the preamble of this proposed rule where the same proposed requirements are discussed in detail for the Medicare EHR Incentive Program for eligible hospitals and CAHs. In addition, we are proposing 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 that 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 proposed rule, participating hospitals are expected to successfully submit data values for vital signs and six linking variables required to merge with the CMS claims data on more than 95 percent of all Medicare FFS patients who are 65 years and older 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 are inviting 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.

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 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. We are not proposing 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 proposed rule for details on our proposal to refine the three questions of the Pain Management measure in the HCAHPS Survey. While we are proposing to refine the survey with respect to the questions about pain management in section IX.A.6.a. of the preamble of this proposed rule, we are not proposing 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. We are not proposing 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/*. We are not proposing any changes to data submission and reporting requirements for HAI measures reported via the NHSN.

11. Proposed 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 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 this proposed rule, we are proposing to modify policies for eCQM validation for the FY 2020 payment determination and subsequent years. First, for hospitals selected to participate in validation of eCQMs, we are proposing that we will select eight cases per quarter for the CY 2017 reporting period/FY 2020 payment determination and subsequent years. We note that this proposal is 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 proposed rule, are finalized as proposed. Second, we are proposing to add additional exclusion criteria to our hospital and case selection process for eCQM validation for the CY 2017 reporting period/FY 2020 payment determination and subsequent years. Third, we are proposing 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 finalized policy.

For validation of chart-abstracted measures data, we are proposing to update our educational review process for the FY 2020 payment determination and subsequent years. These proposals are discussed in more detail below.

b. Proposed 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 validation (81 FR 57178). In this proposed rule, we are proposing to modify that requirement and are proposing that 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, instead of 32 cases, over all four quarters, as previously finalized. This proposal is being made in conjunction with our proposals to modify the number of quarters required for eCQM data submission from: (1) Four to two quarters for CY 2017 (with validation of these data affecting the FY 2020 payment determination); and (2) four to three quarters for CY 2018 (with validation of these data affecting the FY 2021 payment determination) as discussed in section IX.A.8. of the preamble of this proposed rule. If all of these proposals are finalized as proposed, hospitals participating in eCQM 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 are inviting public comment on these proposals as discussed above.

(2) Selection of Hospitals and Cases

In this proposed rule, for the CY 2017 reporting period/FY 2020 payment determination and subsequent years, we are proposing changes to our policies related to the selection of hospitals and cases for eCQM 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 57174–57178), 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 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 this proposed rule, we are proposing to expand the types of hospitals that could be excluded. For the FY 2020 payment determination and subsequent years, we are proposing 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 are proposing that the three exclusions described above would be applied before the random selection of 200 hospitals for eCQM 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 are inviting 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 validation; 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) as discussed above.

(b) Selection of Cases

We have not previously specified processes for the selection of cases for eCQM validation. For the FY 2020 payment determination and subsequent years, we are proposing to exclude the following cases from validation for those hospitals selected to participate in eCQM validation:

- Episodes of care that are longer than 120 days; and
- Cases with a zero denominator for each measure.

We believe that excluding episodes of care that are longer than 120 days will reduce the reporting burden on hospitals selected for eCQM validation, as the volume of data reported for longer cases is greater. Further, we believe that excluding cases with zero denominators for each measure would ensure that we perform validation on cases with applicable measure data. We note that 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 are inviting 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 validation for the FY 2020 payment determination and subsequent years as discussed above.

(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

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 the FY 2020 payment determination only, that for hospitals selected for eCQM validation, that: (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 this proposed rule, we are not making any changes related to these operational procedures. However, we are proposing to continue these policies for the FY 2021 payment determination and subsequent years.

In this proposed rule, we are proposing to extend to the FY 2021 payment determination and subsequent years our previously finalized medical record submission policy for eCQM 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 are proposing to extend to the FY 2021 payment determination our previously finalized medical record submission policy for eCQM 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 if our proposals in section IX.A.8. of the preamble of this proposed rule to require 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), are finalized as proposed, and hospitals selected for eCQM 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 this proposed rule; and (3) that hospitals selected for eCQM validation are required to submit complete information for 75 percent of requested cases are 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, we are proposing 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 are inviting public comment on our proposal as discussed above.

(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 this proposed rule, we are proposing 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 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 validation procedures will be posted on the QualityNet Web site at: *http://www.QualityNet.org/*.

We are inviting public comment on this proposal as discussed above.

c. Proposed 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.[234] 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 this proposed rule, we are proposing: (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 are proposing 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

[234] QualityNet: Validation- Educational Review. *https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228775419006*.

during the annual reconsideration process, both for hospitals and CMS.

(2) Proposed 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 this proposed rule, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 are proposing 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 proposed rule for a discussion about our 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 are inviting 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.

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. We are not proposing 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 this proposed rule, we are not proposing any changes to public display requirements. However, we are soliciting public comment on potential options for confidential and public reporting 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). In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57167 through 57168), 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 this proposed rule, we are seeking 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.

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 this proposed rule, we discuss 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 note in section IX.A.1.d. of the preamble of this 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, to be associated with poor health outcomes and some of this disparity is related to the quality of health care.[235] One of our core objectives is to improve health outcomes for all beneficiaries, and 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.[236] 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.[237]

As part of this effort, we are soliciting feedback on which social risk factors provide information that is most valuable to stakeholders. We also are seeking 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 compared to non-dual eligible).

The goal 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 [238] and the ASPE report [239] 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 *Hospital Compare,* 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.[240] As discussed in sections V.I.7. through V.I.10. of the preamble of this proposed rule, the Hospital Readmissions Reduction Program, as required by the statute, is proposing 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.[241]

The *Hospital Compare* Web site currently displays readmission rates for each hospital's patients together, but does not specifically highlight hospitals' quality of care for vulnerable populations. We believe stratifying data by social risk factors would supplement the current reporting of the Pneumonia Readmission and Pneumonia Mortality measures by highlighting disparities, that is, differences in outcomes, within hospitals that are not simply due to differences in illness level, 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

[235] 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.

[236] 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.*

[237] *http://www.qualityforum.org/SES_Trial_Period.aspx.*

[238] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/cms-quality-strategy.html.*

[239] 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.*

[240] *Ibid.*

[241] *Ibid.*

on the subgroup of dual eligible patients.

We previously sought public comment on the potential public reporting of quality measures 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, empower consumers to make informed decisions about health care, and 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 were concerned 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 *Hospital Compare.*

Our goal in producing stratified results is to provide information about disparities in patient 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 are inviting 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 and the Pneumonia Mortality (MORT–30–PN) measure; (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 *Hospital Compare.* These are discussed in more detail below.

(2) Hospital Specific Confidential Preview Reports Prior to Publicly Reporting Stratified Data

We are seeking public comment on the possibility of providing hospitals specific confidential 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 *Hospital Compare* 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 and non-dual eligible patients because dual eligibility is an important social risk factor among the Medicare Fee-for-Service population and is feasible to measure.[242] In order to provide information about differences in readmission outcomes for dual eligible 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 would build on the methodology used to calculate the currently implemented RSRRs.[243] 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.[244]

[242] 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.*

[243] *http://www.qualitynet.org/dcs/ContentServer?cid=1219069855841&pagename=QnetPublic%2FPage%2FQnetTier4&c=Page.*

[244] 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=121906*

(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 the preceding section IX.A.13.b.(3)(a) of the preamble of this proposed 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 [245] (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 dual eligible 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. For ease of interpretation, 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 rate 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. Therefore, this approach would allow quantification of the difference in readmissions between dual 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 much 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 in rates, 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). There is a trade-off; 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 or non-dual beneficiaries within hospitals and also provide information for hospitals and consumers on the relative disparities across hospitals. We are soliciting 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 hospital specific confidential preview reports containing data stratified by patient dual eligibility would be modelled after current hospital specific confidential preview reports and include patient-level data for hospitalizations included in the measure. The current hospital specific confidential 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 are inviting 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

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[245] 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.

hospitals, accounting for differences in comorbidities, age, and other risk factors between dual eligible and non-dual eligible patients.

(4) Data Sources

To provide an example of the statistical approach we could apply, below 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 proposed rule, above. 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 [246] (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) [247] and determined that there is a total of 3,851 hospitals that have a 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 reported 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 not 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 welcome 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 [248] 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 are inviting public comment on the potential future public reporting of certain outcomes measures, such as the Pneumonia Readmission (NQF #0506) and Pneumonia Mortality measures (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 hospital specific confidential preview reports prior to the public reporting of any information.

We are inviting 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.

(6) Summary

To summarize, we are inviting 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 and the Pneumonia Mortality measure; (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 *Hospital Compare* as discussed above.

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. We are not proposing any changes to the reconsideration and appeals procedures in this proposed rule.

15. Proposed 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

[246] *https://www.cms.gov/research-statistics-data-and-systems/files-for-order/limiteddatasets/denominatorlds.html*.

[247] 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.

[248] 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*.

QualityNet Web site at: *http://www.QualityNet.org/* for our current requirements for submission of a request for an extension or exemption. In this proposed rule, we are making one proposal and a clarification in order to align the ECE policy across CMS quality programs. We are also proposing updates to 42 CFR 412.140(c)(2) to reflect our ECE policy.

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 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 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 this proposed rule, we are proposing 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 are proposing 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 are inviting public comment on this proposal as discussed above.

(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 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.

(3) Updates to CFR

In this proposed rule, we are proposing 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 are proposing 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 are inviting public comments on these proposals as discussed above.

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. 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.

We are not proposing any changes to these policies in this proposed rule.

3. Retention and Proposed 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), FY 2019 program year, 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 proposed rule for more information regarding these previously finalized measures.

b. Proposed Removal of Measures From the PCHQR Program Beginning With the FY 2020 Program Year

Based on a review of the above criteria, we are proposing 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 extraction 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 are inviting public comment on our proposal to remove these three measures from the PCHQR Program beginning with the FY 2020 program year.

4. Proposed 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 this proposed rule, we are not proposing 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 are proposing four new measures, described below.

b. Proposed New Quality Measures Beginning With the FY 2020 Program Year

For the FY 2020 PCHQR program year, we are proposing 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 generally 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,'' [249] 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.[250] 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).'' [251] 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.[252] 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,'' [253] and may include palliative care. Palliative care is generally defined as multi-faceted, holistic care that anticipates, prevents, and alleviates suffering.[254] 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.[255] 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.'' [256] 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.[257]

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 costs.[258] 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.[259]

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 proposed rule, we are inviting public comment on the future inclusion of these measures in the Hospital IQR Program. These four measures are described in more detail below.

(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.[260] 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).[261] 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.[262] 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.[263] 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.[264] While the impetus for continuing treatment may vary from case to case,[265] the available evidence indicates continuing to receive chemotherapy—for palliation

[249] 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.*

[250] 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.*

[251] 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.*

[252] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[253] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[254] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[255] National Quality Forum, Technical Report. Palliative and End-of-Life Care 2015–2016. (December 23, 2016).

[256] 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.

[257] 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.

[258] NQF. Final Report, National Voluntary Consensus Standards: Palliative Care and End-of-Life Care—A Consensus Report. 2012.

[259] 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.

[260] 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.

[261] 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.

[262] 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.

[263] 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.

[264] 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.

[265] 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.

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.[266] 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.[267] 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.[268] 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.[269] 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.[270] In particular, clinically meaningful improvements in quality of life and mood were noted.[271]

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 are proposing, 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 are inviting 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.

(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.[272] 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.[273] 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.[274] 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.[275] 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.'' [276] 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.[277]

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.[278] Researchers have theorized that while patients who die at home are able to have care that focuses on symptom management and

[266] 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.

[267] 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.

[268] 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).

[269] Temel JC et al. Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer. NEJM. 2010; 363:733–742.

[270] Temel JC et al. Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer. NEJM. 2010; 363:733–742.

[271] Temel JC et al. Early Palliative Care for Patients with Metastatic Non-Small-Cell Lung Cancer. NEJM. 2010; 363:733–742.

[272] 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.

[273] 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.

[274] 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.

[275] 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.

[276] 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.

[277] Wright AA et al., Family Perspectives on Aggressive Cancer Care Near the End of Life, JAMA (2016)315:3;284–292.

[278] 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.

comfort; hospitals and ICUs focus instead on keeping the patient alive.[279]

ICU admission at the end of life is also costly,[280] with ICU admissions identified as one of the ''key drivers of resource use and expenditures.'' [281] 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.[282]

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 proposed 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 are inviting 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.

(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.[283] Such aggressive care has been identified to include the underutilization of hospice,[284] which is either lack of referral or late referral to hospice services.[285] 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.[286]

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.[287] 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.[288] 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.'' [289]

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 in section IX.B.4.b.(5) of the preamble of this proposed 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

[279] 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.

[280] 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.

[281] 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.

[282] 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.

[283] 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.

[284] 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.

[285] 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.

[286] 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.

[287] 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.

[288] 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.

[289] 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.

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 are inviting 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.

(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.[290] 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.[291]

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.[292] 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.[293] 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 improving the 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 proposed 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 who 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 are inviting 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.

c. Summary of Previously Finalized and Newly Proposed PCHQR Program Measures for the FY 2020 Program Year and Subsequent Years

In summary, the previously finalized and newly proposed measures for the PCHQR Program for the FY 2020 program year and subsequent years are listed in the table below.

PREVIOUSLY FINALIZED AND NEWLY PROPOSED PCHQR MEASURES FOR THE FY 2020 PROGRAM YEAR AND SUBSEQUENT YEARS

Short name	NQF No.	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.

[290] 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.

[291] 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.

[292] Wright AA et al., Family Perspectives on Aggressive Cancer Care Near the End of Life, JAMA (2016)315:3;284–292.

[293] Wright AA et al., Family Perspectives on Aggressive Cancer Care Near the End of Life, JAMA (2016)315:3;284–292.

PREVIOUSLY FINALIZED AND NEWLY PROPOSED PCHQR MEASURES FOR THE FY 2020 PROGRAM YEAR AND SUBSEQUENT YEARS—Continued

Short name	NQF No.	Measure name
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.[y]
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer Not Admitted to Hospice.[y]
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.[y]
EOL–3DH	0216	Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days.[y]
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 proposed for removal in this proposed 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.

* Finalized update in FY 2019 program year.

** Finalized for FY 2019 program year.

*** This measure was previously titled ''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 Hormones Receptor Negative Breast Cancer.'' This name change, which we used in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191), is consistent with NQF updates to the measure name and reflects an update in the AJCC staging, does not reflect a change in the measure inclusion criteria, and is not considered substantive.

[y] This measure is proposed for adoption for the FY 2020 program year.

5. 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) [294] 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 of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[295] 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

[294] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[295] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

for social risk factors, including stratified public reporting.[296]

As noted in the FY 2017 IPPS/LTCH PPS final rule, 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 entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review their findings.

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, we are also seeking 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 are seeking 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 PCHQR 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), so we also welcome 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.

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. We welcome 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.

We are also seeking 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.[297]

These measures were included on the publicly available document entitled ''List of Measures under Consideration for December 1, 2016'' [298] 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_*

[296] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

[297] CMS Quality Strategy 2016. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/qualityinitiativesgeninfo/downloads/cms-quality-strategy.pdf.*

[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.*

Guide.html#MUC16-375PCHQ. We are requesting public comment on the possible inclusion of these measures in future years of the 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 are requesting public comment on the possible inclusion of this measure in future years of the 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. We are not proposing any changes to this policy in this proposed rule.

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

Measures	Public reporting
Summary of Previously Finalized Public Display Requirements	
• 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)*.	
• 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)	2016 and subsequent years.
• CLABSI (NQF #0139)**.	
• CAUTI (NQF #0138)**	Deferred.
• 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 proposed for removal beginning the FY 2020 program year.

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. We are not proposing any changes to this policy in this proposed rule.

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 this proposed rule, we are not proposing any changes to previously finalized data submission requirements.

b. Proposed Reporting Requirements for the Proposed New Measures

As further described above, we are proposing 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 data submission requirements for PCHs related to these measures. As these measures use Medicare administrative claims data, we are proposing to calculate these measures on a yearly basis. Specifically, we are proposing that the data collection period will be from July 1 from the year 3 years prior to the program year to June 30 from 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 are inviting public comment on this proposal.

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)[299] 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. Proposed Modifications to the ECE Policy

We are proposing 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 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 are proposing to modify their policies to achieve alignment. We are proposing 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) Proposal To Extend the ECE Request 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.

[299] 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).

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 are inviting public comments on this proposal.

(2) Proposal To Grant 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 affects facilities' abilities to submit data. In these circumstances, we are proposing 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 are proposing to communicate this decision through routine communication channels.

We are inviting public comment on this proposal.

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).

Please note that term ''FY [year] LTCH QRP'' refers 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, entitled ''Standardized Post-Acute Care (PAC) Assessment Data for Quality, Payment and Discharge Planning,'' that enacts new data reporting requirements for certain post-acute care (PAC) providers, including LTCHs. Specifically, new 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 each of their 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 toat least three domains. Section 1899B(a)(1)(A)(i) of the Act further requires each of these PAC providers to report under their 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. All of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act must be standardized and interoperable so as 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,[300] which incorporates the three broad aims of the National Quality Strategy.[301]

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, it means 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 an Application of Percent of Residents Experiencing One or More Falls With Major Injury (Long Stay) (NQF #0674), which is 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.''

b. Accounting for Social Risk Factors in the LTCH QRP

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

[300] *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

[301] *http://www.ahrq.gov/workingforquality/nqs/nqs2011annlrpt.htm.*

(ASPE) [302] 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 of Medicare beneficiaries on quality measures and measures of resource use used in one or more of nine Medicare value-based purchasing programs.[303] 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.[304]

As discussed in the FY 2017 IPPS/LTCH PPS final rule, 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. Measures from the LTCH QRP are being addressed in this trial. This trial entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, 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 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 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, we are also seeking 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 are seeking 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 welcome 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.

3. Proposed Collection of Standardized Patient Assessment Data Under the LTCH QRP

a. Proposed Definition of Standardized Patient Assessment Data

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. 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 this proposed rule, we are proposing 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

[302] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[303] *https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs.*

[304] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

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 are proposing 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 and to inform payment models that take into account patient characteristics rather than setting, as described in the IMPACT Act.

We are inviting public comment on this proposed definition.

b. General Considerations Used for the Selection of Proposed 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 Post-Acute Care-Payment Reform Demonstration (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 Proposal To Apply 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). We are proposing to apply this policy to the standardized patient assessment data that we adopt for the LTCH QRP.

We are inviting public comment on our proposal.

5. Policy for Adopting Changes to LTCH QRP Measures and Proposal To Apply That Policy 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. Substantive changes will be proposed and finalized through rulemaking. For further information on what constitutes a substantive versus a nonsubstantive change and the subregulatory process for nonsubstantive changes, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53615 through 53616). We are proposing to apply this policy to the standardized patient assessment data that we adopt for the LTCH QRP.

We are inviting public comment on our proposal.

6. Quality Measures Previously Finalized for the LTCH QRP

The LTCH QRP currently has 17 finalized measures as outlined in the table below:

QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP

Short name	Measure name and 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).
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).*

QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP—Continued

Short name	Measure name and data source
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.

7. LTCH QRP Quality Measures Proposed Beginning With the FY 2020 LTCH QRP

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 proposed rule, we are proposing 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 are also proposing 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. Proposal 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 this proposed rule, we are proposing 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 are 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 are proposing 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.[305 306 307 308 309 310] Studies 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.[311] Furthermore, some studies indicate that DTIs, if managed using appropriate care, can be resolved without deteriorating into a worsened pressure ulcer.[312 313]

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. 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. 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.[314]

[305] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 19(10): 20–24.

[306] Gorzoni, M. L. and S. L. Pires (2011). ''Deaths in nursing homes.'' Rev Assoc Med Bras 57(3): 327–331.

[307] 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.

[308] White-Chu, E. F., et al. (2011). ''Pressure ulcers in long-term care.'' Clin Geriatr Med 27(2): 241–258.

[309] 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.

[310] Bennet, G, Dealy, C Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[311] 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.

[312] 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-patient.*

[313] Posthauer, ME, 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.*

[314] VanGilder, C, MacFarlane, GD, Harrison, P, Lachenbruch, C, Meyer, S (2010). The Demographics of Suspected Deep Tissue Injury in the United States: An Analysis of the International

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 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.

(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 proposed 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.[315] [316]

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 proposed quality measure. Other commenters did not support the inclusion of DTIs in the proposed 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, 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

Pressure Ulcer Prevalence Survey 2006–2009. Advances in Skin & Wound Care. 23(6): 254–261.

[315] 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: *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.*

[316] 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.*

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 are proposing 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 proposed 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. For more information on LTCH CARE Data Set submission using the QIES ASAP System, we refer readers to: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*.

For technical information about this proposed 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, *Proposed 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*.

We are proposing 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 are inviting 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.

b. Proposed 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. We are proposing 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 proposed 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 TCT or 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,[317] and LTCHs, where patients are frequently transferred for weaning following treatment in ICUs.[318] [319] [320] 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.[321]

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.[322] [323] [324] 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,[325] [326] [327] [328] ventilator-

[317] 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.

[318] 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.

[319] Kahn, J. M., et al. (2010). ''Long-term acute care hospital utilization after critical illness.'' *JAMA* 303(22): 2253–2259.

[320] 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.

[321] MedPAC (2016). Chapter 10. Long-term Care Hospital Services. In: Report to the Congress: Medicare Payment Policy. Washington, DC, Medicare Payment Advisory Commission.

[322] Esteban, A., et al. (2002). ''Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study.'' *JAMA* 287(3): 345–355.

[323] 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.

[324] 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.

[325] 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.

associated lung injury,[329 330 331] ventilator induced diaphragm dysfunction,[332] psychological distress [333 334 335] and post-traumatic stress disorder,[336] disability [337] and decreased functional status,[338 339] and chronic critical illness syndrome.[340] 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.[341] 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).[342]

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.[343] 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.[344 345 346]

Although there is evidence regarding the benefit of daily assessments of patient readiness for weaning from invasive mechanical ventilation,[347] as well as for the importance of adherence to weaning protocols,[348] 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,[349] because failure to assess the patient for readiness to wean may lead to undue prolonged mechanical ventilation,[350] thus exposing patients unnecessarily to adverse ventilator-associated morbidity and mortality.[351] 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.[352 353] Clinician delays in recognizing that weaning may be possible and beginning assessment of weaning readiness are two common causes of weaning delays.[354] 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.[355] Because prompt identification of patients' readiness for SBTs has been shown to reduce weaning duration without harm to patients,[356] such delays indicate less than optimal

[326] Papazian, L., et al. (1996). ''Effect of ventilator-associated pneumonia on mortality and morbidity.'' *Am J Respir Crit Care Med* 154(1): 91–97.

[327] 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.

[328] Safdar, N., et al. (2005). ''Clinical and economic consequences of ventilator-associated pneumonia: a systematic review.'' *Crit Care Med* 33(10): 2184–2193.

[329] 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.

[330] 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.

[331] 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.

[332] Levine, S., et al. (2008). ''Rapid disuse atrophy of diaphragm fibers in mechanically ventilated humans.'' *N Engl J Med* 358(13): 1327–1335.

[333] 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.

[334] 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.

[335] 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.

[336] Jubran, A., et al. (2010). ''Post-traumatic stress disorder after weaning from prolonged mechanical ventilation.'' *Intensive Care Med* 36(12): 2030–2037.

[337] Barnato, A. E., et al. (2011). ''Disability among elderly survivors of mechanical ventilation.'' *Am J Respir Crit Care Med* 183(8): 1037–1042.

[338] 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.

[339] 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.

[340] 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.

[341] 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.

[342] 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.

[343] 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.

[344] 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.

[345] 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.

[346] Sedwick, M. B., et al. (2012). ''Using evidence-based practice to prevent ventilator-associated pneumonia.'' *Crit Care Nurse* 32(4): 41–51.

[347] 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.

[348] 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.

[349] Boles, J. M., et al. (2007). ''Weaning from mechanical ventilation.'' *Eur Respir J* 29(5): 1033–1056.

[350] 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.

[351] Hess, D. R., & MacIntyre, N. R. (2011). Ventilator discontinuation: why are we still weaning? *Am J Respir Crit Care Med,* 184(4), 392–394.

[352] MacIntyre, N. R. (2013). ''The ventilator discontinuation process: an expanding evidence base.'' *Respir Care* 58(6): 1074–1086.

[353] 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.

[354] Boles, J. M., et al. (2007). ''Weaning from mechanical ventilation.'' *Eur Respir J* 29(5): 1033–1056.

[355] Cook, D., et al. (2000). Criteria for Weaning from Mechanical Ventilation. *Evidence Reports/Technology Assessments,* Agency for Healthcare Research and Quality.

[356] 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.

performance [357] 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.[358] 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 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,[359] [360] unnecessarily prolonged mechanical ventilation can be an indicator of poor care quality or of persistent illness.[361] 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,[362] that variation in quality of care exists among LTCHs,[363] and that ventilator care is an important safety priority for LTCHs.[364]

Since the MAP's review and recommendation of continued development in 2015, we have continued to refine this proposed measure in compliance 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_*

[357] 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.

[358] 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.

[359] 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.

[360] Epstein, S. K. (2009). Weaning from ventilatory support. *Curr Opin Crit Care, 15*(1), 36–43. doi: 10.1097/MCC.0b013e3283220e07.

[361] MacIntyre, N. R. (2013). ''The ventilator discontinuation process: an expanding evidence base.'' *Respir Care* 58(6): 1074–1086.

[362] ''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*.

[363] ''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*.

[364] 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*.

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 are proposing 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 are proposing that data for this ventilator weaning quality measure be collected through the LTCH CARE Data 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: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html*. We intend 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 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, *Proposed 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*.

We are inviting 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.

c. Proposed Mechanical Ventilation Outcome Quality Measure: Ventilator Liberation Rate

Invasive mechanical ventilation care was identified as an important gap in the LTCH QRP measure set,[365] 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. We are proposing 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 proposed 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 are proposing 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 proposed 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 post-discharge mortality, even among the elderly,[366 367 368 369 370] 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.[371] 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[372 373] 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

[365] Technical Expert Panel Report: Quality Measures for Long-Term Care Hospitals. Thaker, S., Gage, B., Bernard, S., and Nguyen, K. March 2011.

[366] 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.

[367] 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.

[368] 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.

[369] 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.

[370] 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.

[371] 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.

[372] 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.

[373] Jubran, ''Effect of pressure support vs unassisted breathing through a tracheostomy collar on weaning duration in patients requiring prolonged mechanical ventilation: a randomized trial.''

PMV >21 days, facility-level liberation rates ranged from 34 percent to 60 percent, with an overall weaning rate of 52 percent.[374] 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.[375] 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 [376] [377] [378] and ICUs [379] [380] 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.[381] [382] [383] Unnecessarily prolonged mechanical ventilation increases the risk of negative patient outcomes and can be an indicator of poor quality care or of persistent illness.[384] 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 [385] [386] and decreased costs.[387] 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.[388]

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). The TEP 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.*

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 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 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

[374] Scheinhorn, D. J., et al. (2001). ''Post-ICU weaning from mechanical ventilation: the role of long-term facilities.'' *Chest* 120(6 Suppl): 482S–484S.

[375] 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.*

[376] 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.

[377] Vitacca, M., et al. (2001). ''Comparison of two methods for weaning patients with chronic obstructive pulmonary disease requiring mechanical ventilation for more than 15 days.'' *Am J Respir Crit Care Med* 164(2): 225–230.

[378] 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.

[379] 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.

[380] Burns, K. E., et al. (2014). ''Noninvasive ventilation as a weaning strategy for mechanical ventilation in adults with respiratory failure: a Cochrane systematic review.'' *CMAJ* 186(3): E112–122.

[381] 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.

[382] 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.

[383] 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.

[384] MacIntyre, N. R. (2013). ''The ventilator discontinuation process: an expanding evidence base.'' *Respir Care* 58(6): 1074–1086.

[385] 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.

[386] 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.

[387] 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.

[388] Kahn, J. M., & Carson, S. S. (2013). Generating evidence on best practice in long-term acute care hospitals. *JAMA, 309*(7), 719–720.

specifications of this measure. The MAP encouraged continued development of the measure, stating that this measure has high value potential for the LTCH QRP [389] because successful weaning is important for improving quality of life and decreasing morbidity, mortality, and resource use among patients.[390] [391]

Since the MAP's review and recommendation of continued development in 2015, we have continued to refine this proposed measure in compliance 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 are proposing 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 are proposing 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: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCHTechnicalInformation.html.* We intend 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, *Proposed 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.*

We are inviting public comments on our proposal to adopt the quality measure, Ventilation Liberation Rate, beginning with the FY 2020 LTCH QRP.

8. Proposed Removal of the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge From LTCHs From the LTCH QRP

We are proposing to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512) from the 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.

We are proposing to remove the All-Cause Unplanned Readmission measure beginning with the FY 2019 LTCH QRP. We are proposing that public reporting of this measure would end by October 2018 when public reporting of the PPR

[389] ''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.*

[390] 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.*

[391] ''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.*

30-Day Post-Discharge measure begins by October 2018. We refer readers to section IX.C.17. of the preamble of this proposed 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 are inviting 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.

9. LTCH QRP Quality Measures Under Consideration for Future Years

a. LTCH QRP Quality Measures Under Consideration for Future Years

We are inviting 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.
NQS Priority: Communication and Care Coordination	
Measure	• Modification of the Discharge to Community–PAC LTCH QRP measure.

In this proposed rule, we are also soliciting 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 are inviting public comment on the possible inclusion of such measures in future years of the LTCH QRP.

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 are inviting 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.

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.

10. Proposed Standardized Patient Assessment Data Reporting for the LTCH QRP

a. Proposed 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 proposing that the current pressure ulcer measure, Percent of Residents or Patients with Pressure Ulcers That Are New or Worsened (Short Stay) (NQF #0678), be 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, with respect to the requirement that LTCHs report standardized patient assessment data for the FY 2019 LTCH QRP, we are proposing that the data elements used to calculate that measure 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.[392] [393] [394] [395] [396] [397] 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.[398] 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.[399]

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/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.*

We are inviting public comment on this proposal.

b. Proposed Standardized Patient Assessment Data Reporting Beginning With the FY 2020 LTCH QRP

We describe below 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) that would be required with respect to LTCH admissions only that occur between April 1, 2018 and December 31, 2018. The BIMS, Hearing, and Vision data elements would be assessed at admission only due to the relatively stable nature of the types of cognitive function, hearing impairment, and vision impairment, making it unlikely that these assessments would change between the start and end of the PAC stay. Assessment of the BIMS, Hearing, and Vision data elements at discharge would introduce additional burden without improving the quality or usefulness of the data, and is unnecessary. 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 below, 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,

[392] Casey, G. (2013). ''Pressure ulcers reflect quality of nursing care.'' Nurs N Z 19(10): 20–24.

[393] Gorzoni, M.L. and S.L. Pires (2011). ''Deaths in nursing homes.'' Rev Assoc Med Bras 57(3): 327–331.

[394] 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.

[395] White-Chu, E.F., et al. (2011). ''Pressure ulcers in long-term care.'' Clin Geriatr Med 27(2): 241–258.

[396] 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.

[397] Bennet, G, Dealy, C, Posnett, J (2004). The cost of pressure ulcers in the UK, *Age and Aging,* 33(3):230–235.

[398] 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.*

[399] Landis, R., & Koch, G. (1977, March). The measurement of observer agreement for categorical data. Biometrics 33(1), 159–174.

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.

Below, we discuss the proposed standardized patient assessment data by category.

(1) Functional Status Data

We are proposing 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.'' [400] 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'' [401] 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.'' [402] 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 are inviting public comment on this proposal.

(2) Cognitive Function and Mental Status Data

Cognitive function and mental status in PAC patient and resident populations can be affected by a number of underlying conditions, including dementia, stroke, traumatic brain injury, side effects of medication, metabolic and/or endocrine imbalances, delirium, and depression.[403] The assessment of cognitive function and mental status by PAC providers is important because of the high percentage of patients and residents with these conditions,[404] and the opportunity for improving the quality of care. Symptoms of dementia may improve with pharmacotherapy, occupational therapy, or physical activity,[405] [406] [407] and promising treatments for severe traumatic brain injury are currently being tested.[408] For older patients and residents diagnosed with depression, treatment options to reduce symptoms and improve quality of life include antidepressant medication and psychotherapy,[409] [410] [411] [412] and targeted services, such as therapeutic recreation, exercise, and restorative nursing, to increase opportunities for psychosocial interaction.[413]

Accurate assessment of cognitive function and mental status of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of health care resources. For example, standardized assessment of cognitive function and mental status of patients and residents in PAC will support establishing a baseline for identifying changes in cognitive function and mental status (for example, delirium), anticipating the patient or resident's ability to understand and participate in treatments during a PAC stay, ensuring patient and resident safety (for example, risk of falls), and identifying appropriate support needs at the time of discharge or transfer. Standardized assessment data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care through: Facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing cognitive impairment and mental status are needed in order to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

• Brief Interview for Mental Status (BIMS)

We are proposing that the data elements that comprise the Brief Interview for Mental Status meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of seven BIMS questions that result in a cognitive function score. For more information on the BIMS, we refer readers to the document titled, *Proposed*

[400] 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).

[401] *Ibid.*

[402] *Ibid.*

[403] National Institute on Aging. (2014). Assessing Cognitive Impairment in Older Patients. A Quick Guide for Primary Care Physicians. Retrieved from: *https://www.nia.nih.gov/alzheimers/publication/assessing-cognitive-impairment-older-patients.*

[404] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 4 of 4). Research Triangle Park, NC: RTI International.

[405] Casey D.A., Antimisiaris D., O'Brien J. (2010). Drugs for Alzheimer's Disease: Are They Effective? *Pharmacology & Therapeutics,* 35, 208–11.

[406] Graff M.J., Vernooij-Dassen M.J., Thijssen M., Dekker J., Hoefnagels W.H., Rikkert M.G.O. (2006). Community Based Occupational Therapy for Patients with Dementia and their Care Givers: Randomised Controlled Trial. BMJ, 333(7580): 1196.

[407] Bherer L., Erickson K.I., Liu-Ambrose T. (2013). A Review of the Effects of Physical Activity and Exercise on Cognitive and Brain Functions in Older Adults. Journal of Aging Research, 657508.

[408] Giacino J.T., Whyte J., Bagiella E., et al. (2012). Placebo-controlled trial of amantadine for severe traumatic brain injury. New England Journal of Medicine, 366(9), 819–826.

[409] Alexopoulos G.S., Katz I.R., Reynolds C.F. 3rd, Carpenter D., Docherty J.P., Ross R.W. (2001). Pharmacotherapy of depression in older patients: a summary of the expert consensus guidelines. *Journal of Psychiatric Practice,* 7(6), 361–376.

[410] Arean P.A., Cook B.L. (2002). Psychotherapy and combined psychotherapy/pharmacotherapy for late life depression. *Biological Psychiatry,* 52(3), 293–303.

[411] Hollon S.D., Jarrett R.B., Nierenberg A.A., Thase M.E., Trivedi M., Rush A.J. (2005). Psychotherapy and medication in the treatment of adult and geriatric depression: which monotherapy or combined treatment? *Journal of Clinical Psychiatry,* 66(4), 455–468.

[412] Wagenaar D, Colenda CC, Kreft M, Sawade J, Gardiner J, Poverejan E. (2003). Treating depression in nursing homes: practice guidelines in the real world. *J Am Osteopath Assoc.* 103(10), 465–469.

[413] Crespy SD, Van Haitsma K, Kleban M, Hann CJ. Reducing Depressive Symptoms in Nursing Home Residents: Evaluation of the Pennsylvania Depression Collaborative Quality Improvement Program. J Healthc Qual. 2016. Vol. 38, No. 6, pp. e76–e88.

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.*

Dementia and cognitive impairment are associated with long-term functional dependence and, consequently, poor quality of life and increased health care costs and mortality.[414] This makes assessment of mental status and early detection of cognitive decline or impairment critical in the PAC setting. The burden of cognitive impairment in PAC is high. The intensity of routine nursing care is higher for patients and residents with cognitive impairment than those without, and dementia is a significant variable in predicting readmission after discharge to the community from PAC providers.[415] The BIMS is a performance-based cognitive assessment that assesses repetition, recall with and without prompting, and temporal orientation. It was developed to be a brief screener to assess cognition, with a focus on learning and memory. The BIMS data elements are currently in use in two of the PAC assessments: The MDS 3.0 in SNFs and the IRF–PAI in IRFs. The BIMS was tested in the PAC PRD where it was found to have substantial to almost perfect agreement for inter-rater reliability (kappa range of 0.71 to 0.91) when tested in all four PAC settings.[416] Clinical and subject matter expert advisors working with our data element contractor agreed that the BIMS is a feasible data element for use by PAC providers. In addition, discussions during a TEP convened on April 6 and 7, 2016, demonstrated support for the BIMS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

To solicit additional feedback on the BIMS, we asked for public comment from August 12 to September 12, 2016. Many commenters expressed support for use of the BIMS, noting that it is reliable, feasible to use across settings, and will provide useful information about patients and residents. These comments noted that the data collected through the BIMS will provide a clearer picture of patient or resident complexity, help with the care planning process, and be useful during care transitions and when coordinating across providers. A full report of the comments 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.*

Therefore, we are proposing to adopt the BIMS for use in the LTCH QRP. We are proposing to add the data elements that comprise the BIMS to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions 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. The BIMS data element would be assessed at admission only due to the relatively stable nature of the types of cognitive function assessed by the BIMS, making it unlikely that a patient's score on this assessment would change between the start and end of the PAC stay. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe that it is unnecessary.

We are inviting public comment on these proposals.

- Confusion Assessment Method (CAM)

We are proposing that the data elements that comprise the Confusion Assessment Method (CAM) meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The CAM is a six-question instrument that screens for overall cognitive impairment, as well as distinguishes delirium or reversible confusion from other types of cognitive impairment. For more information on the CAM, we refer readers to the document titled, *Proposed 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.*

The CAM was developed to identify the signs and symptoms of delirium. It results in a score that suggests whether the patient or resident should be assigned a diagnosis of delirium. Because patients and residents with multiple comorbidities receive services from PAC providers, it is important to assess delirium, which is associated with a high mortality rate and prolonged duration of stay in hospitalized older adults.[417] Assessing these signs and symptoms of delirium is clinically relevant for care planning by PAC providers.

The CAM is currently in use in two of the PAC assessments: the MDS 3.0 in SNFs and the LCDS in LTCHs. The CAM was tested in the PAC PRD where it was found to have substantial agreement for inter-rater reliability for the ''Inattention and Disorganized Thinking'' questions (kappa range of 0.70 to 0.73); and moderate agreement for the ''Altered Level of Consciousness'' question (kappa of 0.58).[418]

Clinical and subject matter expert advisors working with our data element contractor agreed that the CAM is feasible for use by PAC providers, that it assesses key aspects of cognition, and that this information about patient or resident cognition would be clinically useful both within and across PAC provider types. The CAM was also supported by a TEP that discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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*. We asked for public comment on the CAM from August 12 to September 12, 2016. Many commenters expressed support for use of the CAM, noting that it would provide important information for care planning and care coordination, and therefore, contribute to quality improvement. The commenters noted it is particularly helpful in distinguishing

[414] Agüero-Torres, H., Fratiglioni, L., Guo, Z., Viitanen, M., von Strauss, E., & Winblad, B. (1998). ''Dementia is the major cause of functional dependence in the elderly: 3-year follow-up data from a population-based study.'' Am J of Public Health 88(10): 1452–1456.

[415] RTI International. Proposed Measure Specifications for Measures Proposed in the FY 2017 LTCH QRP NPRM. Research Triangle Park, NC. 2016.

[417] Fick, D. M., Steis, M. R., Waller, J. L., & Inouye, S. K. (2013). ''Delirium superimposed on dementia is associated with prolonged length of stay and poor outcomes in hospitalized older adults.'' J of Hospital Med 8(9): 500–505.

[418] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

delirium and reversible confusion from other types of cognitive impairment. A full report of the comments 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.*

As noted above, the CAM is already included on the LCDS. For purposes of reporting for 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. 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.

We are inviting public comment on these proposals.

- Behavioral Signs and Symptoms

We are proposing that the Behavioral Signs and Symptoms data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of three Behavioral Signs and Symptoms questions and result in three scores that categorize respondents as having or not having certain types of behavioral signs and symptoms. For more information on the Behavioral Signs and Symptoms data elements, we refer readers to the document titled, *Proposed 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.*

The questions included in the Behavioral Signs and Symptoms group assess whether the patient or resident has exhibited any behavioral symptoms that may indicate cognitive impairment or other mental health issues during the assessment period, including physical, verbal, and other disruptive or dangerous behavioral symptoms, but excluding patient wandering. Such behavioral disturbances can indicate unrecognized needs and care preferences and are associated most commonly with dementia and other cognitive impairment, and less commonly with adverse drug events, mood disorders, and other conditions. Assessing behavioral disturbances can lead to early intervention, patient- and resident-centered care planning, clinical decision support, and improved staff and patient or resident safety through early detection. Assessment and documentation of these disturbances can help inform care planning and patient transitions and provide important information about resource use.

Data elements that capture behavioral symptoms are currently included in two of the PAC assessments: the MDS 3.0 in SNFs and the OASIS–C2 in HHAs.[419] In the MDS, each question includes four response options ranging from ''behavior not exhibited'' (0) to behavior ''occurred daily'' (3). The OASIS–C2 includes some similar data elements which record the frequency of disruptive behaviors on a 6-point scale ranging from ''never'' (0) to ''at least daily'' (5). Data elements that mirror those used in the MDS and serve the same assessment purpose were tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, and feasible for use in each of the four PAC settings.[420]

The proposed data elements were supported by comments from the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP identified patient and resident behaviors as an important consideration for resource intensity and care planning, and affirmed the importance of the standardized assessment of patient behaviors through data elements such as those in use in the MDS. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

Because the PAC PRD version of the Behavioral Signs and Symptoms data elements were previously tested across PAC providers, we solicited additional feedback on this version of the data elements by including these data elements in a call for public comment that was open from August 12 to September 12, 2016. Consistent with the TEP discussion on the importance of patient and resident behaviors, many commenters expressed support for use of the Behavioral Signs and Symptoms data elements, noting that they would provide useful information about patient and resident behavior at both admission and discharge and contribute to care planning related to what treatment is appropriate for the patient or resident and what resources are needed. Public comment also supported the use of highly similar MDS version of the data element in order to provide continuity with existing assessment processes in SNFs. A full report of the comments 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.*

Therefore, we are proposing the MDS version of the Behavioral Signs and Symptoms data elements because they focus more closely on behavioral symptoms than the OASIS data elements, and include more detailed response categories than those used in the PAC PRD version, capturing more information about the frequency of behaviors. We are proposing to add the Behavioral Signs and Symptoms data elements to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

- Patient Health Questionnaire-2 (PHQ–2)

We are proposing that the PHQ–2 data elements meet the definition of standardized patient assessment data with respect to cognitive function and mental status under section 1899B(b)(1)(B)(ii) of the Act. The proposed data elements consist of the PHQ–2 two-item questionnaire that assesses the cardinal criteria for depression: depressed mood and anhedonia (inability to feel pleasure). For more information on the PHQ–2, we refer readers to the document titled, *Proposed 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.*

Depression is a common mental health condition often missed and under-recognized. Assessments of depression help PAC providers better understand the needs of their patients

[420] Gage B., Morley M., Smith L., et al. (2012). Post-Acute Care Payment Reform Demonstration (Final report, Volume 2 of 4). Research Triangle Park, NC: RTI International.

and residents by: Prompting further evaluation (that is, to establish a diagnosis of depression); elucidating the patient's or resident's ability to participate in therapies for conditions other than depression during their stay; and identifying appropriate ongoing treatment and support needs at the time of discharge. A PHQ–2 score beyond a predetermined threshold signals the need for additional clinical assessment in order to determine a depression diagnosis.

The proposed data elements that comprise the PHQ–2 are currently used in the OASIS–C2 for HHAs and the MDS 3.0 for SNFs (as part of the PHQ–9). The PHQ–2 data elements were tested in the PAC PRD, where they were found to have almost perfect agreement for inter-rater reliability (kappa range of 0.84 to 0.91) when tested by all four PAC providers.[421]

Clinical and subject matter expert advisors working with our data element contractor agreed that the PHQ–2 is feasible for use in PAC, that it assesses key aspects of mental status, and that this information about patient or resident mood would be clinically useful both within and across PAC provider types. We note that both the PHQ–9 and the PHQ–2 were supported by TEP members who discussed and rated candidate data elements during a meeting on April 6 and 7, 2016. They particularly noted that the brevity of the PHQ–2 made it feasible with low burden for both assessors and PAC patients or residents. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

To solicit additional feedback on the PHQ–2, we asked for public comment from August 12 to September 12, 2016. Many commenters provided feedback on using the PHQ–2 for the assessment of mood. Overall, commenters believed that collecting these data elements across PAC provider types was appropriate, given the role that depression plays in well-being. Several commenters expressed support for an approach that would use PHQ–2 as a gateway to the longer PHQ–9 and would maintain the reduced burden on most patients and residents, as well as test administrators, which is a benefit of the PHQ–2, while ensuring that the PHQ–9, which exhibits higher specificity,[422] would be administered for patients and residents who showed signs and symptoms of depression on the PHQ–2. Specific comments are described in a full report 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.*

Therefore, we are proposing to add the PHQ–2 data elements to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

(3) Special Services, Treatments, and Interventions Data

Special services, treatments, and interventions performed in PAC can have a major effect on an individual's health status, self-image, and quality of life. The assessment of these special services, treatments, and interventions in PAC is important to ensure the continuing appropriateness of care for the patients and residents receiving them, and to support care transitions from one PAC provider to another, an acute care hospital, or discharge. Accurate assessment of special services, treatments, and interventions of patients and residents served by PAC providers are expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of health care resources.

For example, standardized assessment of special services, treatments, and interventions used in PAC can promote patient and resident safety through appropriate care planning (for example, mitigating risks such as infection or pulmonary embolism associated with central intravenous access), and identifying life-sustaining treatments that must be continued, such as mechanical ventilation, dialysis, suctioning, and chemotherapy, at the time of discharge or transfer. Standardized assessment of these data elements will enable or support: Clinical decision-making and early clinical intervention; person-centered, high quality care through, for example, facilitating better care continuity and coordination; better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing special services, treatments, and interventions are needed to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

We are proposing 15 special services, treatments, and interventions as presented below grouped by cancer treatments, respiratory treatments, other treatments, and nutritional approaches. A TEP convened by the data element standardization contractor provided input on the 15 data elements for Special Services, Treatments, and Interventions. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice, and that the collection of these data by means of a list and checkbox format would conform with common workflow for PAC providers. A full report of the TEP discussion 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.*

- Cancer Treatment: Chemotherapy (IV, Oral, Other)

We are proposing that the Chemotherapy (IV, Oral, Other) data elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Chemotherapy data element and three sub-elements: IV Chemotherapy, Oral Chemotherapy, and Other. For more information on the Chemotherapy data element, we refer readers to the document titled, *Proposed Specifications for LTCH QRP Quality Measures and Standardized Data Elements,* available at: *https://*

[421] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

[422] Arroll B, Goodyear-Smith F, Crengle S, Gunn J, Kerse N, Fishman T, et al. Validation of PHQ–2 and PHQ–9 to screen for major depression in the primary care population. *Annals of family medicine.* 2010;8(4):348–53. doi: 10.1370/afm.1139 pmid:20644190; PubMed Central PMCID: PMC2906530.

www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Measures-Information.html.

Chemotherapy is a type of cancer treatment that uses drugs to destroy cancer cells. It is sometimes used when a patient has a malignancy (cancer), which is a serious, often life-threatening or life-limiting condition. Both intravenous (IV) and oral chemotherapy have serious side effects, including nausea/vomiting, extreme fatigue, risk of infection due to a suppressed immune system, anemia, and an increased risk of bleeding due to low platelet counts. Oral chemotherapy can be as potent as chemotherapy given by IV, but can be significantly more convenient and less resource-intensive to administer. Because of the toxicity of these agents, special care must be exercised in handling and transporting chemotherapy drugs. IV chemotherapy may be given by peripheral IV, but is more commonly given via an indwelling central line, which raises the risk of bloodstream infections. Given the significant burden of malignancy, the resource intensity of administering chemotherapy, and the side effects and potential complications of these highly-toxic medications, assessing the receipt of chemotherapy is important in the PAC setting for care planning and determining resource use.

The need for chemotherapy predicts resource intensity, both because of the complexity of administering these potent, toxic drug combinations under specific protocols, and because of what the need for chemotherapy signals about the patient's underlying medical condition. Furthermore, the resource intensity of IV chemotherapy is higher than for oral chemotherapy, as the protocols for administration and the care of the central line (if present) require significant resources.

The Chemotherapy (IV, Oral, Other) data elements consist of a principal data element and three sub-elements: IV chemotherapy, which is generally resource-intensive; oral chemotherapy, which is less invasive and generally less intensive with regard to administration protocols; and a third category provided to enable the capture of other less common chemotherapeutic approaches. This third category is potentially associated with higher risks and is more resource intensive due to delivery by other routes (for example, intraventricular or intrathecal).

The principal Chemotherapy data element is currently in use in the MDS 3.0. One proposed sub-element, IV Chemotherapy, was tested in the PAC PRD and found feasible for use in each of the four PAC settings. We solicited public comment on IV Chemotherapy from August 12 to September 12, 2016. Several commenters provided support for the data element and suggested it be included as standardized patient assessment data. Commenters stated that assessing the use of chemotherapy services is relevant to share across the care continuum to facilitate care coordination and care transitions and noted the validity of the data element. Commenters also noted the importance of capturing all types of chemotherapy, regardless of route, and stated that collecting data only on patients and residents who received chemotherapy by IV would limit the usefulness of this standardized data element. A full report of the comments 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*.

As a result of the comments and input received from clinical and subject matter experts, we are proposing a principal Chemotherapy data element with three sub-elements, including Oral and Other for standardization. Our data element contractor then presented the proposed data elements to the Standardized Patient Assessment Data TEP on January 5 and 6, 2017, who supported these data elements for standardization. A full report of the TEP discussion 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*.

Therefore, we are proposing that the Chemotherapy (IV, Oral, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Chemotherapy (IV, Oral, Other) data elements to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

- Cancer Treatment: Radiation

We are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Radiation data element. For more information on the Radiation data element, we refer readers to the document titled, *Proposed 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*.

Radiation is a type of cancer treatment that uses high-energy radioactivity to stop cancer by damaging cancer cell DNA, but it can also damage normal cells. Radiation is an important therapy for particular types of cancer, and the resource utilization is high, with frequent radiation sessions required, often daily for a period of several weeks. Assessing whether a patient or resident is receiving radiation therapy is important to determine resource utilization because PAC patients and residents will need to be transported to and from radiation treatments, and monitored and treated for side effects after receiving this intervention. Therefore, assessing the receipt of radiation therapy, which would compete with other care processes given the time burden, would be important for care planning and care coordination by PAC providers.

The Radiation data element is currently in use in the MDS 3.0. This data element was not tested in the PAC PRD. However, public comment and other expert input on the Radiation data element supported its importance and clinical usefulness for patients in PAC settings, due to the side effects and consequences of radiation treatment on patients that need to be considered in care planning and care transitions. To solicit additional feedback on the Radiation data element we are proposing, we asked for public comment from August 12 to September 12, 2016. Several commenters provided support for the data element, noting the relevance of this data element to facilitating care coordination and supporting care transitions, the feasibility of the item, and the potential for it to improve quality. A full report of the comments 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.

The proposed data element was presented to and supported by the TEP held by our data element contractor on January 5–6, 2017, which opined that Radiation was important corollary information about cancer treatment to collect alongside Chemotherapy (IV, Oral, Other), and that, because capturing this information is a customary part of clinical practice, the proposed data element would be feasible, reliable, and easily incorporated into existing workflow.

Therefore, we are proposing that the Radiation data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Radiation data element to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Respiratory Treatment: Oxygen Therapy (Continuous, Intermittent)

We are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Oxygen data element and two sub-elements, ''Continuous'' (whether the oxygen was delivered continuously, typically defined as >=14 hours per day), or ''Intermittent.'' For more information on the Oxygen Therapy (Continuous, Intermittent) data elements, we refer readers to the document titled, *Proposed 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*.

Oxygen therapy provides a patient or resident with extra oxygen when medical conditions such as chronic obstructive pulmonary disease, pneumonia, or severe asthma prevent the patient or resident from getting enough oxygen from breathing. Oxygen administration is a resource-intensive intervention, as it requires specialized equipment such as a source of oxygen, delivery systems (for example, oxygen concentrator, liquid oxygen containers, and high-pressure systems), the patient interface (for example, nasal cannula or mask), and other accessories (for example, regulators, filters, tubing). These data elements capture patient or resident use of two types of oxygen therapy (continuous and intermittent) which are reflective of intensity of care needs, including the level of monitoring and bedside care required. Assessing the receipt of this service is important for care planning and resource use for PAC providers.

The proposed data elements were developed based on similar data elements that assess oxygen therapy, currently in use in the MDS 3.0 (''Oxygen Therapy'') and OASIS–C2 (''Oxygen (intermittent or continuous)''), and a data element tested in the PAC PRD that focused on intensive oxygen therapy (''High O2 Concentration Delivery System with FiO2 > 40%'').

As a result of input from expert advisors, we solicited public comment on the single data element, Oxygen (inclusive of intermittent and continuous oxygen use), from August 12 to September 12, 2016. Several commenters supported the importance of the Oxygen data element, noting feasibility of this item in PAC, and the relevance of it to facilitating care coordination and supporting care transitions, but suggesting that the extent of oxygen use be documented. A full report of the comments 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*.

As a result of public comment and input from expert advisors about the importance and clinical usefulness of documenting the extent of oxygen use, we expanded the single data element to include two sub-elements, intermittent and continuous.

Therefore, we are proposing that the Oxygen Therapy (Continuous, Intermittent) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Oxygen Therapy (Continuous, Intermittent) data elements to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Respiratory Treatment: Suctioning (Scheduled, as Needed)

We are proposing that the Suctioning (Scheduled, As needed) data elements meet the definition of standardized patient assessment data element with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Suctioning data element, and two sub-elements, ''Scheduled'' and ''As needed.'' These sub-elements capture two types of suctioning. ''Scheduled'' indicates suctioning based on a specific frequency, such as every hour; ''As needed'' means suctioning only when indicated. For more information on the Suctioning (Scheduled, As needed) data elements, we refer readers to the document titled, *Proposed 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*.

Suctioning is a process used to clear secretions from the airway when a person cannot clear those secretions on his or her own. It is done by aspirating secretions through a catheter connected to a suction source. Types of suctioning include oropharyngeal and nasopharyngeal suctioning, nasotracheal suctioning, and suctioning through an artificial airway such as a tracheostomy tube. Oropharyngeal and nasopharyngeal suctioning are a key part of many patients' care plans, both to prevent the accumulation of secretions than can lead to aspiration pneumonias (a common condition in patients with inadequate gag reflexes), and to relieve obstructions from mucus plugging during an acute or chronic respiratory infection, which often lead to desaturations and increased respiratory effort. Suctioning can be done on a scheduled basis if the patient is judged to clinically benefit from regular interventions; or can be done as needed, such as when secretions become so prominent that gurgling or choking is noted, or a sudden

desaturation occurs from a mucus plug. As suctioning is generally performed by a care provider rather than independently, this intervention can be quite resource-intensive if it occurs every hour, for example, rather than once a shift. It also signifies an underlying medical condition that prevents the patient from clearing his/her secretions effectively (such as after a stroke, or during an acute respiratory infection). Generally, suctioning is necessary to ensure that the airway is clear of secretions which can inhibit successful oxygenation of the individual. The intent of suctioning is to maintain a patent airway, the loss of which can lead to death, or complications associated with hypoxia.

The proposed data elements are based on an item currently in use in the MDS 3.0 (''Suctioning'' without the two sub-elements), and data elements tested in the PAC PRD that focused on the frequency of suctioning required for patients with tracheostomies (''Trach Tube with Suctioning: Specify most intensive frequency of suctioning during stay [Every__hours]'').

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Suctioning (Scheduled, As needed) data elements are feasible for use in PAC, and that they indicate important treatment that would be clinically useful to capture both within and across PAC providers. We solicited public comment on the suctioning data element currently included in the MDS 3.0 between August 12, to September 12, 2016. Several commenters wrote in support of this data element, noting feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. We also received comments suggesting that we examine the frequency of suctioning in order to better understand the use of staff time, the impact on a patient or resident's capacity to speak and swallow, and intensity of care required. Based on these comments, we decided to add two sub-elements (scheduled and as needed) to the suctioning element. The proposed data elements, Suctioning (Scheduled, As needed) includes both the principal suctioning data element that is included on the MDS 3.0 and two sub-elements, ''scheduled'' and ''as needed.'' A full report of the comments 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*.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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*.

Therefore, we are proposing that the Suctioning (Scheduled, As needed) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Suctioning (scheduled, as needed) data element to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Respiratory Treatment: Tracheostomy Care

We are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Tracheostomy Care data element. For more information on the Tracheostomy Care data element, we refer readers to the document titled, *Proposed 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*.

A tracheostomy provides an air passage to help a patient or resident breathe when the usual route for breathing is obstructed or impaired. Generally, in all of these cases, suctioning is necessary to ensure that the tracheostomy is clear of secretions which can inhibit successful oxygenation of the individual. Often, individuals with tracheostomies are also receiving supplemental oxygenation. The presence of a tracheostomy, albeit permanent or temporary, warrants careful monitoring and immediate intervention if the tracheostomy becomes occluded or in the case of a temporary tracheostomy, the device used becomes dislodged. While in rare cases the presence of a tracheostomy is not associated with increased care demands (and in some of those instances, the care of the ostomy is performed by the patient) in general the presence of such a device is associated with increased patient risk, and clinical care services will necessarily include close monitoring to ensure that no life-threatening events occur as a result of the tracheostomy, often considered part of the patient's life line. In addition, tracheostomy care, which primarily consists of cleansing, dressing changes, and replacement of the tracheostomy cannula (tube), is also a critical part of the care plan. Regular cleansing is important to prevent infection such as pneumonia and to prevent any occlusions with which there are risks for inadequate oxygenation.

The proposed data element is currently in use in the MDS 3.0 (''Tracheostomy care''). Data elements (''Trach Tube with Suctioning'') that were tested in the PAC PRD included an equivalent principal data element on the presence of a tracheostomy. This data element was found feasible for use in each of the four PAC settings as the data collection aligned with usual work flow.

Clinical and subject matter expert advisors working with our data element contractor agreed that the Tracheostomy Care data element is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types.

We solicited public comment on this data element from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of this item in PAC, and the relevance of this data element to facilitating care coordination and supporting care transitions. A full report of the comments 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*.

A TEP convened by the data element contractor provided input on the

proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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*.

Therefore, we are proposing that the Tracheostomy Care data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Tracheostomy Care data element to the LCDS, and that LTCHs would be required to reporting these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Respiratory Treatment: Non-invasive Mechanical Ventilator (BiPAP, CPAP)

We are proposing that the Non-invasive Mechanical Ventilator (Bilevel Positive Airway Pressure [BiPAP], Continuous Positive Airway Pressure [CPAP]) data elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Non-invasive Mechanical Ventilator data element and two sub-elements, BiPAP and CPAP. For more information on the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data element, we refer readers to the document titled, *Proposed 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*.

BiPAP and CPAP are respiratory support devices that prevent the airways from closing by delivering slightly pressurized air via electronic cycling throughout the breathing cycle (Bilevel PAP, referred to as BiPAP) or through a mask continuously (Continuous PAP, referred to as CPAP). Assessment of non-invasive mechanical ventilation is important in care planning, as both CPAP and BiPAP are resource-intensive (although less so than invasive mechanical ventilation) and signify underlying medical conditions about the patient or resident who requires the use of this intervention. Particularly when used in settings of acute illness or progressive respiratory decline, additional staff (for example, respiratory therapists) are required to monitor and adjust the CPAP and BiPAP settings and the patient or resident may require more nursing resources.

Data elements that assess BiPAP and CPAP are currently included on the OASIS–C2 for HHAs (''Continuous/Bi-level positive airway pressure''), LCDS for the LTCH setting (''Non-invasive Ventilator (BIPAP, CPAP)''), and the MDS 3.0 for the SNF setting (''BiPAP/CPAP''). A data element that focused on CPAP was tested across the four PAC providers in the PAC–PRD study and found to be feasible for standardization. All of these data elements assess BiPAP or CPAP with a single check box, not separately.

Clinical and subject matter expert advisors working with our data element contractor agreed that the standardized assessment of Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements would be feasible for use in PAC, and assess an important treatment that would be clinically useful both within and across PAC provider types.

To solicit additional feedback on the form of the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements best suited for standardization, we asked for public comment on a single data element, BiPAP/CPAP, equivalent (but for labeling) to what is currently in use on the MDS, OASIS, and LCDS, from August 12 to September 12, 2016. Several commenters wrote in support of this data element, noting the feasibility of these items in PAC, and the relevance of these data elements for facilitating care coordination and supporting care transitions. In addition, there was support in the public comment responses for separating out BiPAP and CPAP as distinct sub-elements, as they are therapies used for different types of patients and residents. A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore we are proposing that the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to expand the existing ''Non-invasive Ventilator (BiPAP, CPAP)'' data element on the LCDS, by retaining and renaming the main data element to be Non-invasive Mechanical Ventilator and adding two sub-elements for BiPAP and CPAP. For the purposes of reporting for the FY 2020 LTCH QRP, LTCHs would be required to report the Non-invasive Mechanical Ventilator (BiPAP, CPAP) data elements with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Respiratory Treatment: Invasive Mechanical Ventilator

We are proposing that the Invasive Mechanical Ventilator data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of a single Invasive Mechanical Ventilator data element which, for LTCHs, will be collected from the Invasive Mechanical Ventilator (Weaning) and Invasive Mechanical Ventilator (Non-Weaning) data elements that are already included on the LCDS. For more information on the Invasive Mechanical Ventilator data element, we refer readers to the document titled, *Proposed*

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.*

Invasive mechanical ventilation includes ventilators and respirators that ventilate the patient through a tube that extends via the oral airway into the pulmonary region or through a surgical opening directly into the trachea. Thus, assessment of invasive mechanical ventilation is important in care planning and risk mitigation. Ventilation in this manner is a resource-intensive therapy associated with life-threatening conditions without which the patient or resident would not survive. However, ventilator use has inherent risks requiring close monitoring. Failure to adequately care for the patient or resident who is ventilator dependent can lead to iatrogenic events such as death, pneumonia and sepsis. Mechanical ventilation further signifies the complexity of the patient's underlying medical and or surgical condition. Of note, invasive mechanical ventilation is associated with high daily and aggregate costs.[423]

Data elements that capture invasive mechanical ventilation, but vary in their level of specificity, are currently in use in the MDS 3.0 (''Ventilator or respirator'') and LCDS (''Invasive Mechanical Ventilator: weaning'' and ''Invasive Mechanical Ventilator: non-weaning''), and related data elements that assess invasive ventilator use and weaning status were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') and found feasible for use in each of the four PAC settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing Invasive Mechanical Ventilator use is feasible in PAC, and would be clinically useful both within and across PAC providers.

To solicit additional feedback on the form of a data element on this topic that would be appropriate for standardization, data elements that assess invasive ventilator use and weaning status that were tested in the PAC PRD (''Ventilator—Weaning'' and ''Ventilator—Non-Weaning'') were included in a call for public comment that was open from August 12 to September 12, 2016 because it was being considered for standardization. Several commenters wrote in support of this data element, highlighting the importance of this information in supporting care coordination and care transitions. Some commenters expressed concern about the appropriateness for standardization, given the prevalence of ventilator weaning across PAC providers; the timing of administration; how weaning is defined; and how it weaning status in particular relates to quality of care. These comments guided the decision to propose a single data element focused on current use of invasive mechanical ventilation only, and does not attempt to capture weaning status. A full report of the comments 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.*

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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.*

Therefore, we are proposing that the Invasive Mechanical Ventilator data element that assesses the use of an invasive mechanical ventilator, but does not assess weaning status, meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. However, and as noted above, two data elements that capture invasive mechanical ventilator use and weaning status are already included on the LCDS: Invasive Mechanical Ventilator (Weaning) and Invasive Mechanical Ventilator (Non-Weaning) data elements. Because these two existing data elements both indicate the same information, the presence of invasive ventilator use, we propose that these existing data elements will provide the necessary data on invasive mechanical ventilation use required for standardization. The inclusion of weaning status pertains to other purposes in the LCDS, and does not disrupt the intended standardization of the overarching indication of ventilator use. For purposes of reporting for the FY 2020 LTCH QRP, LTCHs will be required to report these data with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

- Other Treatment: Intravenous (IV) Medications (Antibiotics, Anticoagulation, Other)

We are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Medications data element and three sub-elements, Antibiotics, Anticoagulation, and Other. For more information on the IV Medications (Antibiotics, Anticoagulation, Other) data element, we refer readers to the document titled, *Proposed 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.*

IV medications are solutions of a specific medication (for example, antibiotics, anticoagulants) administered directly into the venous circulation via a syringe or intravenous catheter (tube). IV medications are administered via intravenous push (bolus), single, intermittent, or continuous infusion through a tube placed into the vein (for example, commonly referred to as central, midline, or peripheral ports). Further, IV medications are more resource intensive to administer than oral medications, and signify a higher patient complexity (and often higher severity of illness).

The clinical indications for each of the sub-elements of the IV Medication data element (Antibiotics, Anticoagulants, and Other) are very different. IV antibiotics are used for severe infections when: (1) The bioavailability of the oral form of the medication would be inadequate to kill the pathogen; (2) an oral form of the

[423] Wunsch, H., Linde-Zwirble, W. T., Angus, D. C., Hartman, M. E., Milbrandt, E. B., & Kahn, J. M. (2010). ''The epidemiology of mechanical ventilation use in the United States.'' Critical Care Med 38(10): 1947–1953.

medication does not exist; or (3) the patient is unable to take the medication by mouth. IV anticoagulants refer to anti-clotting medications (that is, ''blood thinners''), often used for the prevention and treatment of deep vein thrombosis and other thromboembolic complications. IV anticoagulants are commonly used in patients with limited mobility (either chronically or acutely, in the post-operative setting), who are at risk of deep vein thrombosis, or patients with certain cardiac arrhythmias such as atrial fibrillation. The indications, risks, and benefits of each of these classes of IV medications are distinct, making it important to assess each separately in PAC. Knowing whether or not patients are receiving IV medication and the type of medication provided by each PAC provider will improve quality of care.

The principal IV Medication data element is currently in use on the MDS 3.0 and there is a related data element in OASIS–C2 that collects information on Intravenous and Infusion Therapies. One sub-element of the proposed data elements, IV Anti-coagulants, and two other data elements related to IV therapy (IV Vasoactive Medications and IV Chemotherapy), were tested in the PAC PRD and found feasible for use in that the data collection aligned with usual work flow in each of the four PAC settings, demonstrating the feasibility of collecting IV medication information, including type of IV medication, through similar data elements in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that standardized collection of information on medications, including IV medications, would be feasible in PAC, and assess an important treatment that would be clinically useful both within and across PAC provider types.

We solicited public comment on a related data element, Vasoactive Medications, from August 12 to September 12, 2016. While commenters supported this data element with one noting the importance of this data element in supporting care transitions, others criticized the need for collecting specifically on Vasoactive Medications, giving feedback that the data element was too narrowly focused. In addition, comment received indicated that the clinical significance of vasoactive medications administration alone was not high enough in PAC to merit mandated assessment, noting that related and more useful information could be captured in an item that assessed all IV medication use.

Overall, public comment indicated the importance of including the additional check box data elements to distinguish particular classes of medications. A full report of the comments 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*.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice. A full report of the TEP discussion 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*.

Therefore, we are proposing that the IV Medications (Antibiotics, Anticoagulation, Other) data elements with a principal data element and three sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Medications (Antibiotics, Anticoagulation, Other) data element to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

- Other Treatment: Transfusions

We are proposing that the Transfusions data element meets the definition of standardized patient assessment data element with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Transfusions data element. For more information on the Transfusions data element, we refer readers to the document titled, *Proposed 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*.

Transfusion refers to introducing blood, blood products, or other fluid into the circulatory system of a person. Blood transfusions are based on specific protocols, with multiple safety checks and monitoring required during and after the infusion in case of adverse events. Coordination with the provider's blood bank is necessary, as well as documentation by clinical staff to ensure compliance with regulatory requirements. In addition, the need for transfusions signifies underlying patient complexity that is likely to require care coordination and patient monitoring, and impacts planning for transitions of care, as transfusions are not performed by all PAC providers.

The proposed data element was selected from three existing assessment items on transfusions and related services, currently in use in the MDS 3.0 (''Transfusions'') and OASIS–C2 (''Intravenous or Infusion Therapy''), and a data element tested in the PAC PRD (''Blood Transfusions''), that was found feasible for use in each of the four PAC settings. We chose to propose the MDS version because of its greater level of specificity over the OASIS–C2 data element. This selection was informed by expert advisors and reviewed and supported in the proposed form by the Standardized Patient Assessment Data TEP held by our data element contractor on January 5 and 6, 2017. A full report of the TEP discussion 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*.

Therefore, we are proposing that the Transfusions data element that is currently in use in the MDS meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Transfusions data element to the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Other Treatment: Dialysis (Hemodialysis, Peritoneal Dialysis)

We are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal Dialysis data element and two sub-elements, Hemodialysis and Peritoneal dialysis. For more information on the Dialysis (Hemodialysis, Peritoneal dialysis) data element, we refer readers to the document titled, *Proposed 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*.

Dialysis is a treatment primarily used to provide replacement for lost kidney function. Both forms of dialysis (hemodialysis and peritoneal dialysis) are resource intensive, not only during the actual dialysis process but before, during and following. Patients and residents who need and undergo dialysis procedures are at high risk for physiologic and hemodynamic instability from fluid shifts and electrolyte disturbances as well as infections that can lead to sepsis. Further, patients or residents receiving hemodialysis are often transported to a different facility, or at a minimum, to a different location in the same facility. Close monitoring for fluid shifts, blood pressure abnormalities, and other adverse effects is required prior to, during and following each dialysis session. Nursing staff typically perform peritoneal dialysis at the bedside, and as with hemodialysis, close monitoring is required.

The principal Dialysis data element is currently included on the MDS 3.0 and the LCDS v3.0 and assesses the overall use of dialysis. The sub-elements for Hemodialysis and Peritoneal dialysis were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization. Clinical and subject matter expert advisors working with our data element contractor opined that the standardized assessment of dialysis is feasible in PAC, and that it assesses an important treatment that would be clinically useful both within and across PAC providers. As the results of expert and public feedback, described below, we decided to propose a data element that includes both the principal Dialysis data element and the two sub-elements (hemodialysis and peritoneal dialysis).

The Hemodialysis data element, which was tested in the PAC PRD, was included in a call for public comment that was open from August 12 to September 12, 2016. Commenters supported the assessment of hemodialysis and recommended that the data element be expanded to include peritoneal dialysis. Several commenters supported the Hemodialysis data element, noting the relevance of this information for sharing across the care continuum to facilitate care coordination and care transitions, the potential for this data element to be used to improve quality, and the feasibility for use in PAC. In addition, we received comment that the item would be useful in improving patient and resident transitions of care. Several commenters also stated that peritoneal dialysis should be included in a standardized data element on dialysis and recommended collecting information on peritoneal dialysis in addition to hemodialysis. The rationale for including peritoneal dialysis from commenters included the fact that patients and residents receiving peritoneal dialysis will have different needs at post-acute discharge compared to those receiving hemodialysis or not having any dialysis. Based on these comments, the Hemodialysis data element was expanded to include a principal Dialysis data element and two sub-elements, hemodialysis and peritoneal dialysis; these are the same two data elements that were tested in the PAC PRD. This expanded version, Dialysis (Hemodialysis, Peritoneal dialysis), are the data elements being proposed. A full report of the comments 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 note that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements were also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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*.

Therefore, we are proposing that the Dialysis (Hemodialysis, Peritoneal dialysis) data elements with a principal data element and two sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to expand the Dialysis data element in current use on the LCDS to include sub-elements for Hemodialysis and Peritoneal dialysis. For the purposes of reporting for 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. 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.

We are inviting public comment on these proposals.

• Other Treatment: Intravenous (IV) Access (Peripheral IV, Midline, Central line, Other)

We are proposing that the IV Access (Peripheral IV, Midline, Central line, Other) data elements meet the definition of standardized patient assessment data element with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data elements consist of the principal IV Access data element and four sub-elements, Peripheral IV, Midline, Central line, and Other. For more information on the IV Access data element, we refer readers to the document titled, *Proposed 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*.

Patients or residents with central lines, including those peripherally inserted or who have subcutaneous central line ''port'' access, always require vigilant nursing care to keep patency of the lines and ensure that such invasive lines remain free from any potentially life-threatening events such as infection, air embolism, or bleeding from an open lumen. Clinically complex patients and residents are likely to be receiving medications or nutrition intravenously. The sub-elements included in the IV Access data elements distinguish between peripheral access and different types of central access. The rationale for distinguishing between a peripheral IV and central IV access is

that central lines confer higher risks associated with life-threatening events such as pulmonary embolism, infection, and bleeding.

The proposed IV Access (Peripheral IV, Midline, Central line, Other) data elements are not currently included on any of the mandated PAC assessment instruments. However, related data elements (for example, IV Medication in MDS 3.0 for SNF, Intravenous or infusion therapy in OASIS–C2 for HHAs) currently assess types of IV access. Several related data elements that describe types of IV access (for example, Central Line Management, IV Vasoactive Medications) were tested across the four PAC providers in the PAC PRD study, and found to be feasible for standardization.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing type of IV access would be feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC provider types.

We asked for public comment on one of the PAC PRD data elements, Central Line Management, from August 12 to September 12, 2016. A central line is one type of IV access. Commenters supported the assessment of central line management and recommended that the data element be broadened to also include other types of IV access. Several commenters supported the data element, noting feasibility and importance for facilitating care coordination and care transitions. However, a few commenters recommended that the definition of this data element be broadened to include peripherally inserted central catheters (''PICC lines'') and midline IVs. Based on public comment feedback and in consultation with clinical and subject matters experts, we expanded the Central Line Management data element to include more types of IV access (Peripheral IV, Midline, Central line, Other). This expanded version, IV Access (Peripheral IV, Midline, Central line, Other), are the data elements being proposed. A full report of the comments 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 note that the IV Access (Peripheral IV, Midline, Central line, Other) data elements were supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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*.

Therefore, we are proposing that the IV access (Peripheral IV, Midline, Central line, Other) data elements with a principal data element and four sub-elements meet the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the IV Access (Peripheral IV, Midline, Central line, Other) data elements to the LCDS and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Nutritional Approach: Parenteral/IV Feeding

We are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Parenteral/IV Feeding data element. For more information on the Parenteral/IV Feeding data element, we refer readers to the document titled, *Proposed 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*.

Parenteral/IV Feeding refers to a patient or resident being fed intravenously using an infusion pump, bypassing the usual process of eating and digestion. The need for IV/parenteral feeding indicates a clinical complexity that prevents the patient or resident from meeting his/her nutritional needs enterally, and is more resource intensive than other forms of nutrition, as it often requires monitoring of blood chemistries, and maintenance of a central line. Therefore, assessing a patient or resident's need for parenteral feeding is important for care planning and resource use. In addition to the risks associated with central and peripheral intravenous access, total parenteral nutrition is associated with significant risks such as embolism and sepsis.

The Parenteral/IV Feeding data element is currently in use in the MDS 3.0, and equivalent or related data elements are in use in the LCDS, IRF–PAI, and the OASIS–C2. An equivalent data element was tested in the PAC PRD (''Total Parenteral Nutrition'') and found feasible for use in each of the four PAC settings, demonstrating the feasibility of collecting information about this nutritional service in these settings.

Total Parenteral Nutrition (an item with the same meaning as the proposed data element, but with the label used in the PAC PRD) was included in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported this data element, noting its relevance to facilitating care coordination and supporting care transitions. After the public comment period, the Total Parenteral Nutrition data element was re-named Parenteral/IV Feeding, to be consistent with how this data element is referred to in the MDS. A full report of the comments 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*.

A TEP convened by the data element contractor provided input on the proposed data elements. This TEP, held on January 5 and 6, 2017, opined that these data elements are appropriate for standardization because they would provide useful clinical information to inform care planning and care coordination. The TEP affirmed that assessment of these services and interventions is standard clinical practice.

A full report of the TEP discussion 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*.

Therefore, we are proposing that the Parenteral/IV Feeding data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to retain and rename the existing and equivalent Total Parenteral Nutrition data element to be Parenteral/IV Feeding on the LCDS, and that LTCHs would be required to report these data for the FY 2020 LTCH QRP

with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Nutritional Approach: Feeding Tube

We are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Feeding Tube data element. For more information on the Feeding Tube data element, we refer readers to the document titled, *Proposed 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*.

The majority of patients admitted to acute care hospitals experience deterioration of their nutritional status during their hospital stay, making assessment of nutritional status and method of feeding if unable to eat orally very important in PAC. A feeding tube can be inserted through the nose or the skin on the abdomen to deliver liquid nutrition into the stomach or small intestine. Feeding tubes are resource intensive and are therefore important to assess for care planning and resource use. Patients with severe malnutrition are at higher risk for a variety of complications.[424] In PAC settings, there are a variety of reasons that patients and residents may not be able to eat orally (including clinical or cognitive status).

The Feeding Tube data element is currently included in the MDS 3.0 for SNFs, and in the OASIS–C2 for HHAs, where it is labeled Enteral Nutrition. A related data element, collected in the IRF–PAI for IRFs (Tube/Parenteral Feeding), assesses use of both feeding tubes and parenteral nutrition. The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of feeding tubes and related nutritional services and devices, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor opined that the Feeding Tube data element is feasible for use in PAC, and supported its importance and clinical usefulness for patients in PAC settings, due to the increased level of nursing care and patient monitoring required for patients who received enteral nutrition with this device.

We solicited additional feedback on an Enteral Nutrition data element (an item with the same meaning as the proposed data element, but with the label used in the OASIS) in a call for public comment that was open from August 12 to September 12, 2016. Several commenters supported the data element, noting the importance of assessing enteral nutrition status for facilitating care coordination and care transitions. After the public comment period, the Enteral Nutrition data element used in public comment was re-named Feeding Tube, indicating the presence of an assistive device. A full report of the comments 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 note that the Feeding Tube data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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*.

Therefore, we are proposing that the Feeding Tube data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Feeding Tube data element to the LCDS and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Nutritional Approach: Mechanically Altered Diet

We are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Mechanically Altered Diet data element. For more information on the Mechanically Altered Diet data element, we refer readers to the document titled, *Proposed 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*.

The Mechanically Altered Diet data element refers to food that has been altered to make it easier for the patient or resident to chew and swallow, and this type of diet is used for patients and residents who have difficulty performing these functions. Patients with severe malnutrition are at higher risk for a variety of complications.[425] In PAC settings, there are a variety of reasons that patients and residents may have impairments related to oral feedings, including clinical or cognitive status. The provision of a mechanically altered diet may be resource intensive, and can signal difficulties associated with swallowing/eating safety, including dysphagia. In other cases, it signifies the type of altered food source, such as ground or puree, that will enable the safe and thorough ingestion of nutritional substances and ensure safe and adequate delivery of nourishment to the patient. Often, patients on mechanically altered diets also require additional nursing supports such as individual feeding, or direct observation, to ensure the safe consumption of the food product. Assessing whether a patient or resident requires a mechanically altered diet is therefore important for care planning and resource identification.

The proposed data element for a mechanically altered diet is currently included on the MDS 3.0 for SNFs. A related data element for modified food consistency/supervision is currently included on the IRF–PAI for IRFs. A related data element is included in the OASIS–C2 for HHAs that collects

[424] Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' Am J of Clinical Nutrition 47(2): 352–356.

[425] Dempsey, D. T., Mullen, J. L., & Buzby, G. P. (1988). ''The link between nutritional status and clinical outcome: can nutritional intervention modify it?'' Am J of Clinical Nutrition 47(2): 352–356.

information about independent eating that requires ''a liquid, pureed or ground meat diet.'' The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor agreed that the proposed Mechanically Altered Diet data element is feasible for use in PAC, and it assesses an important treatment that would be clinically useful both within and across PAC settings. Expert input on the Mechanically Altered Diet data element highlighted its importance and clinical usefulness for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets. We note that the Mechanically Altered Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017. A full report of the TEP discussion 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*.

Therefore, we are proposing that the Mechanically Altered Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Mechanically Altered Diet data element to the LCDS and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

• Nutritional Approach: Therapeutic Diet

We are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. The proposed data element consists of the single Therapeutic Diet data element. For more information on the Therapeutic Diet data element, we refer readers to the document titled, *Proposed 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*.

Therapeutic Diet refers to meals planned to increase, decrease, or eliminate specific foods or nutrients in a patient or resident's diet, such as a low-salt diet, for the purpose of treating a medical condition. The use of therapeutic diets among patients in PAC provides insight on the clinical complexity of these patients and their multiple comorbidities. Therapeutic diets are less resource intensive from the bedside nursing perspective, but do signify one or more underlying clinical conditions that preclude the patient from eating a regular diet. The communication among PAC providers about whether a patient is receiving a particular therapeutic diet is critical to ensure safe transitions of care.

The Therapeutic Diet data element is currently in use in the MDS 3.0. The testing of similar nutrition-focused data elements in the PAC PRD, and the current assessment of various nutritional services across the four PAC settings, demonstrates the feasibility of collecting information about this nutritional service in these settings.

Clinical and subject matter expert advisors working with our data element contractor supported the importance and clinical usefulness of the proposed Therapeutic Diet data element for patients in PAC settings, due to the increased monitoring and resource use required for patients on special diets, and agreed that it is feasible for use in PAC and that it assesses an important treatment that would be clinically useful both within and across PAC settings. We note that the Therapeutic Diet data element was also supported by the TEP that discussed candidate data elements for Special Services, Treatments, and Interventions during a meeting on January 5 and 6, 2017.

Therefore, we are proposing that the Therapeutic Diet data element meets the definition of standardized patient assessment data with respect to special services, treatments, and interventions under section 1899B(b)(1)(B)(iii) of the Act. We are proposing to add the Therapeutic Diet data element to the LCDS, and that LTCHs would be required to begin reporting these data for the FY 2020 LTCH QRP with respect to LTCH admissions and discharges 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.

We are inviting public comment on these proposals.

(4) Medical Condition and Comorbidity Data

We are proposing 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 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 proposed 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 proposed rule.

We are inviting public comment on this proposal.

(5) Impairment Data

Hearing and vision impairments are conditions that, if unaddressed, affect activities of daily living, communication, physical functioning, rehabilitation outcomes, and overall quality of life. Sensory limitations can lead to confusion in new settings, increase isolation, contribute to mood disorders, and impede accurate assessment of other medical conditions. Failure to appropriately assess, accommodate, and treat these conditions increases the likelihood that patients will require more intensive and prolonged treatment. Onset of these conditions can be gradual, so individualized assessment with accurate screening tools and follow-up evaluations are essential to determining which patients need hearing- or vision-specific medical attention or assistive devices and accommodations, including auxiliary aids and/or services, and to ensure that person-directed care plans are developed to accommodate a patient's needs. Accurate diagnosis and management of hearing or vision impairment would likely improve rehabilitation outcomes and care transitions, including transition from institutional-based care to the community. Accurate assessment of hearing and vision impairment would be expected to lead to appropriate treatment, accommodations, including the provision of auxiliary aids and services during the stay, and ensure that patients continue to have their vision and hearing needs met when they leave the facility.

Accurate individualized assessment, treatment, and accommodation of hearing and vision impairments of patients and residents in PAC would be expected to have a positive impact on the National Quality Strategy's domains of patient and family engagement, patient safety, care coordination, clinical process/effectiveness, and efficient use of health care resources. For example, standardized assessment of hearing and vision impairments used in PAC will support ensuring patient safety (for example, risk of falls), identifying accommodations needed during the stay, and appropriate support needs at the time of discharge or transfer. Standardized assessment of these data elements will enable or support clinical decision-making and early clinical intervention; person-centered, high quality care (for example, facilitating better care continuity and coordination); better data exchange and interoperability between settings; and longitudinal outcome analysis. Hence, reliable data elements assessing hearing and vision impairments are needed to initiate a management program that can optimize a patient or resident's prognosis and reduce the possibility of adverse events.

- Hearing

We are proposing that the Hearing data element meets the definition of standardized patient assessment data with respect to impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Hearing data element. This data element assesses level of hearing impairment, and consists of one question. For more information on the Hearing data element, we refer readers to the document titled, *Proposed 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*.

Accurate assessment of hearing impairment is important in the PAC setting for care planning and resource use. Hearing impairment has been associated with lower quality of life, including poorer physical, mental, and social functioning, and emotional health.[426] [427] Treatment and accommodation of hearing impairment led to improved health outcomes, including but not limited to quality of life.[428] For example, hearing loss in elderly individuals has been associated with depression and cognitive impairment,[429] [430] [431] higher rates of incident cognitive impairment and cognitive decline,[432] and less time in occupational therapy.[433] Accurate assessment of hearing impairment is important in the PAC setting for care planning and defining resource use.

The proposed data element was selected from two forms of the Hearing data element based on expert and stakeholder feedback. We considered the two forms of the Hearing data element, one of which is currently in use in the MDS 3.0 (Hearing) and another data element with different wording and fewer response option categories that is currently in use in the OASIS–C2 (Ability to Hear). Ability to Hear was also tested in the PAC PRD and found to have substantial agreement for inter-rater reliability across PAC settings (kappa of 0.78).[434]

Several data elements that assess hearing impairment were presented to the Standardized Patient Assessment Data TEP held by our data element contractor. The TEP did not reach consensus on the ideal number of

[426] Dalton DS, Cruickshanks KJ, Klein BE, Klein R, Wiley TL, Nondahl DM. The impact of hearing loss on quality of life in older adults. *Gerontologist.* 2003;43(5):661–668.

[427] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[428] Horn KL, McMahon NB, McMahon DC, Lewis JS, Barker M, Gherini S. Functional use of the Nucleus 22-channel cochlear implant in the elderly. *The Laryngoscope.* 1991;101(3):284–288.

[429] Sprinzl GM, Riechelmann H. Current trends in treating hearing loss in elderly people: a review of the technology and treatment options—a mini-review. *Gerontology.* 2010;56(3):351–358.

[430] Lin FR, Thorpe R, Gordon-Salant S, Ferrucci L. Hearing Loss Prevalence and Risk Factors Among Older Adults in the United States. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences.* 2011;66A(5):582–590.

[431] Hawkins K, Bottone FG, Jr., Ozminkowski RJ, et al. The prevalence of hearing impairment and its burden on the quality of life among adults with Medicare Supplement Insurance. *Qual Life Res.* 2012;21(7):1135–1147.

[432] Lin FR, Metter EJ, O'Brien RJ, Resnick SM, Zonderman AB, Ferrucci L. Hearing Loss and Incident Dementia. *Arch Neurol.* 2011;68(2):214–220.

[433] Cimarolli VR, Jung S. Intensity of Occupational Therapy Utilization in Nursing Home Residents: The Role of Sensory Impairments. *J Am Med Dir Assoc.* 2016;17(10):939–942.

[434] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

response categories or phrasing of response options, which are the primary differences between the current MDS (Hearing) and OASIS (Ability to Hear) items. The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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.*

The PAC PRD form of the data element (Ability to Hear) was included in a call for public comment that was open from August 12 to September 12, 2016. This data element includes three response choices, in contrast to the Hearing data element (in use in the MDS 3.0 and being proposed for standardization), which includes four response choices. Several commenters supported the use of the Ability to Hear data element, although some commenters raised concerns that the three-level response choice was not compatible with the current, four-level response used in the MDS, and favored the use of the MDS version of the Hearing data element. In addition, we received comments stating that standardized assessment related to hearing impairment has the ability to improve quality of care if information on hearing is included in medical records of patients and residents, which would improve care coordination and facilitate the development of patient- and resident-centered treatment plans. Based on comments that the three-level response choice (Ability to Hear) was not congruent with the current, four-level response used in the MDS (Hearing), and support for the use of the MDS version of the Hearing data element received in the public comment, we are proposing the Hearing data element. A full report of the comments 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.*

Therefore, we are proposing the Hearing data element currently in use in the MDS. We are proposing to add the Hearing data element to the LCDS. LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions 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. The Hearing data element would be assessed at admission only due to the relatively stable nature of hearing impairment, making it unlikely that this assessment would change between the start and end of the PAC stay. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe it is unnecessary.

We are inviting public comment on these proposals.

- Vision

We are proposing that the Vision data element meets the definition of standardized patient assessment data element with respect to impairments under section 1899B(b)(1)(B)(v) of the Act. The proposed data element consists of the single Vision (Ability To See in Adequate Light) data element that consists of one question with five response categories. For more information on the Vision data element, we refer readers to the document titled, *Proposed 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.*

Evaluation of an individual's ability to see is important for assessing for risks such as falls and provides opportunities for improvement through treatment and the provision of accommodations, including auxiliary aids and services, which can safeguard patients and improve their overall quality of life. Further, vision impairment is often a treatable risk factor associated with adverse events and poor quality of life. For example, individuals with visual impairment are more likely to experience falls and hip fracture, have less mobility, and report depressive symptoms.[435 436 437 438 439 440 441]

Individualized initial screening can lead to life-improving interventions such as accommodations, including the provision of auxiliary aids and services, during the stay and/or treatments that can improve vision and prevent or slow further vision loss. For patients with some types of visual impairment, use of glasses and contact lenses can be effective in restoring vision.[442] Other conditions, including glaucoma [443] and age-related macular degeneration,[444 445] have responded well to treatment. In addition, vision impairment is often a treatable risk factor associated with adverse events which can be prevented and accommodated during the stay. Accurate assessment of vision impairment is important in the LTCH setting for care planning and defining resource use.

The Vision data element that we are proposing for standardization was tested as part of the development of the MDS 3.0 and is currently in use in that assessment. Similar data elements, but with different wording and fewer response option categories, are in use in the OASIS–C2 and was tested in post-acute providers in the PAC PRD and found to be clinically relevant, meaningful for care planning, reliable (kappa of 0.74),[446] and feasible for use in each of the four PAC settings.

Several data elements that assess vision were presented to the TEP held by our data element contractor. The TEP

[435] Colon-Emeric CS, Biggs DP, Schenck AP, Lyles KW. Risk factors for hip fracture in skilled nursing facilities: who should be evaluated? *Osteoporos Int.* 2003;14(6):484–489.

[436] Freeman EE, Munoz B, Rubin G, West SK. Visual field loss increases the risk of falls in older adults: the Salisbury eye evaluation. *Invest Ophthalmol Vis Sci.* 2007;48(10):4445–4450.

[437] Keepnews D, Capitman JA, Rosati RJ. Measuring patient-level clinical outcomes of home health care. *J Nurs Scholarsh.* 2004;36(1):79–85.

[438] Nguyen HT, Black SA, Ray LA, Espino DV, Markides KS. Predictors of decline in MMSE scores among older Mexican Americans. *J Gerontol A Biol Sci Med Sci.* 2002;57(3):M181–185.

[439] Prager AJ, Liebmann JM, Cioffi GA, Blumberg DM. Self-reported Function, Health Resource Use, and Total Health Care Costs Among Medicare Beneficiaries With Glaucoma. *JAMA ophthalmology.* 2016;134(4):357–365.

[440] Rovner BW, Ganguli M. Depression and disability associated with impaired vision: the MoVies Project. *J Am Geriatr Soc.* 1998;46(5):617–619.

[441] Tinetti ME, Ginter SF. The nursing home life-space diameter. A measure of extent and frequency of mobility among nursing home residents. *J Am Geriatr Soc.* 1990;38(12):1311–1315.

[442] Rein DB, Wittenborn JS, Zhang X, et al. The Cost-effectiveness of Welcome to Medicare Visual Acuity Screening and a Possible Alternative Welcome to Medicare Eye Evaluation Among Persons Without Diagnosed Diabetes Mellitus. *Archives of ophthalmology.* 2012;130(5):607–614.

[443] Leske M, Heijl A, Hussein M, et al. Factors for glaucoma progression and the effect of treatment: The early manifest glaucoma trial. *Archives of Ophthalmology.* 2003;121(1):48–56.

[444] Age-Related Eye Disease Study Research G. A randomized, placebo-controlled, clinical trial of high-dose supplementation with vitamins c and e, beta carotene, and zinc for age-related macular degeneration and vision loss: AREDS report no. 8. *Archives of Ophthalmology.* 2001;119(10):1417–1436.

[445] Takeda AL, Colquitt J, Clegg AJ, Jones J. Pegaptanib and ranibizumab for neovascular age-related macular degeneration: a systematic review. *The British Journal of Ophthalmology.* 2007;91(9):1177–1182.

[446] Gage B., Smith L., Ross J. et al. (2012). The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set (Final Report on Reliability Testing, Volume 2 of 3). Research Triangle Park, NC: RTI International.

did not reach consensus on the ideal number of response categories or phrasing of response options, which are the primary differences between the current MDS and OASIS items; some members preferring more granular response options (for example, mild impairment and moderate impairment) while others were comfortable with collapsed response options (that is, mild/moderate impairment). The Development and Maintenance of Post-Acute Care Cross-Setting Standardized Patient Assessment Data Technical Expert Panel 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*. We solicited public comment from August 12 to September 12, 2016, on the Ability to See in Adequate Light data element (version tested in the PAC PRD with three response categories). The data element in public comment differed from the proposed data element, but the comments supported the assessment of vision in PAC settings and the useful information a vision data element would provide. The commenters stated that the Ability to See item would provide important information that would facilitate care coordination and care planning, and consequently improve the quality of care. Other commenters suggested it would be helpful as an indicator of resource use and noted that the item would provide useful information about the abilities of patients and residents to care for themselves. Additional commenters noted that the item could feasibly be implemented across PAC providers and that its kappa scores from the PAC PRD support its validity. Some commenters noted a preference for MDS version of the Vision data element over the form put forward in public comment, citing the widespread use of this data element. A full report of the comments 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*.

Clinical and subject matter expert advisors working with our data element contractor agreed that assessing vision impairment of patients and residents with a standardized data element is feasible in PAC, that it can reliably and accurately identify adults with objective impaired vision, and that this information about impaired vision would be clinically useful to identify needed accommodations and/or treatment both within and across PAC settings.

Therefore, we are proposing the Vision data element from the MDS. We are proposing to add the Vision data element to the LCDS and that LTCHs would be required to report these data for the FY 2020 LTCH QRP with respect to LTCH admissions 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. The Vision data element would be assessed at admission only due to the relatively stable nature of vision impairment, making it unlikely that this assessment would change between the start and end of the PAC stay. Assessment at discharge would introduce additional burden without improving the quality or usefulness of the data, and we believe that it is unnecessary.

We are inviting public comment on these proposals.

11. Proposals Relating to the Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Proposed 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. We are proposing that new LTCHs will be required to begin reporting standardized patient assessment data on the same schedule.

We are inviting public comment on this proposal.

b. Proposed 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*.

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 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 are inviting public comments on this proposal.

c. Proposed Schedule for Reporting Standardized Patient Assessment Data Beginning With the FY 2019 LTCH QRP

We are proposing that the standardized patient assessment data as discussed in section IX.C.10.a. of the preamble of this proposed rule 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 are also proposing 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 this proposed rule, we proposed 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. 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 this proposed rule, we discussed the additional standardized patient 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 only 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 that allow 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. This is because the newest iteration of the LTCH CARE Data Set would have been scheduled for release on April 1, 2016. We are proposing to apply this policy to the reporting of standardized patient assessment data beginning with the FY 2020 LTCH QRP. The tables below illustrate this policy using the FY 2020 and FY 2021 LTCH QRP as examples.

SUMMARY ILLUSTRATION OF INITIAL REPORTING CYCLE FOR NEWLY ADOPTED MEASURE AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING USING CY QUARTERS 2, 3, AND 4 DATA *

Proposed data collection/submission quarterly reporting period *	Proposed data submission quarterly deadlines beginning with the FY 2020 LTCH QRP * ^
Q2: CY 2018 4/1/2018–6/30/2018	CY 2017 Q2 Deadline: November 15, 2018.
Q3: CY 2018 7/1/2018–9/30/2018	CY 2017 Q3 Deadline: February 15, 2019.
Q4: CY 2018 10/1/2018–12/31/2018	CY 2017 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 MEASURE AND STANDARDIZED PATIENT ASSESSMENT DATA REPORTING *

Proposed data collection/submission quarterly reporting period *	Proposed data submission quarterly deadlines beginning with the FY 2021 LTCH QRP * ^
Q1: CY 2019—1/1/2019–3/31/2019	CY 2018 Q1 Deadline: August 15, 2019.
Q2: CY 2019—4/1/2019–6/30/2019	CY 2018 Q2 Deadline: November 15, 2019.
Q3: CY 2019—7/1/2019–9/30/2019	CY 2018 Q3 Deadline: February 15, 2020.
Q4: CY 2019—10/1/2019–12/31/2019	CY 2018 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 inviting public comment on our proposal for standardized 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.

d. Proposed Schedule for Reporting the Proposed Quality Measures Beginning With the FY 2020 LTCH QRP

As discussed in section IX.C.7. of the preamble of this proposed rule, we are proposing to adopt 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. We are proposing that LTCHs would report data on these measures using the LTCH CARE Data Set that is submitted through the QIES ASAP system. 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 currently 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 are inviting public comment on this proposal.

e. Proposed Removal of Interrupted Stay Items From the LTCH CARE Data Set

We are proposing to remove the program interruption items from the LTCH CARE Data Set. Specifically, we are proposing 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 proposed rule.

We are inviting public comment on this proposal.

12. Proposed Changes to Previously Codified Participation Requirements Under the LTCH QRP

We are proposing 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 are inviting public comments on this proposal.

13. Proposed Changes to Previously Codified Data Submission Requirements Under the LTCH QRP

We are proposing 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 are inviting public comments on this proposal.

14. Proposed Changes to Previously Codified Exception and Extension Requirements Under the LTCH QRP

We are proposing 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.

We are inviting public comments on this proposal.

15. Proposed Changes to Previously Codified Reconsiderations Requirements Under the LTCH QRP

We are proposing 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.

We are inviting public comments on this proposal.

16. Proposal To Apply 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.

We note that in our finalized policy we included that LTCHs must meet or exceed a threshold set at 80 percent for completion of measures data collected using the LTCH CARE Data Set submitted through the QIES ASAP system. However, 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. We are inviting public comment on our proposal to extend our current LTCH QRP data completion requirements to the reporting of standardized patient assessment data.

We are also proposing 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 are proposing 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. An LTCH must meet or exceed both thresholds to avoid receiving a 2 percentage point reduction to their 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 are inviting public comment on our proposal to extend our current LTCH QRP data completion requirements to the reporting of standardized patient assessment data. We are also inviting 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.

17. Proposals and 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).

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) will initially be based on data collected from January 1, 2015 through December 31, 2015 and will be displayed based on 4 rolling quarters. 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 this proposed rule, pending the availability of data, we are proposing 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 are proposing 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 are proposing 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 are proposing 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 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 are proposing to transition from calendar year to fiscal year to make these measure data publicly available by October 2018. Thus, we are proposing 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 are proposing 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 proposed rule for additional information regarding the proposed removal of this measure from quality reporting and public display. We also are proposing 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 proposed 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 are proposing 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 are proposing 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 are proposing 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 are inviting 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.

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*.

We are not proposing 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 [447] 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

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 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.

[447] 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).

(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/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 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

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)[448] 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.[449] 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.[450]

As noted in the FY 2017 IPPS/LTCH PPS final rule, 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 entails temporarily allowing inclusion of social risk factors in the risk-adjustment approach for these measures. At the conclusion of the trial, NQF will issue recommendations on the future inclusion of social risk factors in risk adjustment for these quality measures, and we will closely review their findings.

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, we are seeking 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 are seeking 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 data calculations, among others), so we also welcome 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.

[448] 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*.

[449] 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*.

[450] National Academies of Sciences, Engineering, and Medicine. 2017. Accounting for social risk factors in Medicare payment. Washington, DC: The National Academies Press.

(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, we are proposing 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 FY 46701 through 46709). In this proposed rule, we are proposing factors to consider in removing or retaining measures effective upon finalization of this 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. Proposed 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 this proposed rule, we are proposing: (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 are proposing 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 are also proposing 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 are also proposing 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 are inviting 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. If finalized, these factors and criteria will become effective upon finalization of this proposed 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.

3. Proposed New Quality Measure for the FY 2020 Payment Determination and Subsequent Years—Medication Continuation Following Inpatient Psychiatric Discharge

a. Background

We are proposing one new measure, Medication Continuation following Inpatient Psychiatric Discharge, 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.[451] [452] 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

[451] 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.

[452] 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.

or drugs compared to those who adhere to their medication regimen.[453] Patients with bipolar disorder who do not adhere to their medications have increased suicide risk.[454] 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.[455 456 457 458 459]

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.[460 461 462 463 464 465] Furthermore, patients and caregivers interviewed during the development of this measure indicated the importance of the facility's role in communicating information about medications to the patient, pharmacy, and outpatient providers.[466]

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.[467] 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.[468]

The MAP Hospital Workgroup classified the measure as ''Refine and Resubmit Prior to Rulemaking.'' [469] 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.[470] The MAP also requested additional details on the measure, such as: (1) The definition of medication dispensation; (2) how does the facility 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.[471] 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.[472]

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.[473] 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

[453] 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.

[454] 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.

[455] 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.*

[456] 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.*

[457] 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.*

[458] 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.*

[459] 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.*

[460] Douaihy AB, Kelly TM, Sullivan C. Medications for substance use disorders. Social work in public health. 2013;28(3–4):264–278.

[461] Haddad PM, Brain C, Scott J. Nonadherence with antipsychotic medication in schizophrenia: challenges and management strategies. Patient related outcome measures. 2014;5:43–62.

[462] Hung CI. Factors predicting adherence to antidepressant treatment. Current opinion in psychiatry. 2014;27(5):344–349.

[463] 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.

[464] Mitchell AJ. Understanding Medication Discontinuation in Depression. BMedSci Psychiatric Times. 2007;24(4).

[465] 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.

[466] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016.

[467] MAP Hospital Workgroup, Preliminary Analysis Worksheet. December 2017.

[468] National Quality Forum, Measure Applications Partnership. Meeting Transcript, Day 1 of 2—In-Person Meeting. 2016.

[469] *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=84452.*

[470] National Quality Forum, Measure Application Partnership. MAP 2017 Considerations for Implementing Measures in Federal Programs: Hospitals. 2017.

[471] 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.''

[472] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016.

[473] Adams J. The reliability of provider profiling: a tutorial. Santa Monica, CA: RAND; 2009.

readmitted.[474] [475] [476] 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, the NQF Standing Committee has recommended the measure for endorsement, and we are currently awaiting NQF's final decision. 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, the proposed 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.[477] The measure also supports the CMS Quality Strategy Goal to ''promote effective communication and coordination of care.'' [478] Specifically, the measure addresses three objectives within the goal of ''promoting effective communication and coordination of care'': (1) ''To reduce admissions and readmissions'' [479] as patients with these conditions who do not adhere to their medication regimens are at an increased risk of relapse and readmission; [480] [481] [482] (2) ''to embed best practices to enable successful transitions between all settings of care,'' [483] 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,'' [484] 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 proposed 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.[485] [486] [487] [488] [489] 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

[474] 1 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.

[475] 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.

[476] 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.

[477] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: US Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[478] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: US Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[479] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: US Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[480] 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.

[481] 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.

[482] 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.

[483] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: US Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[484] Centers for Medicare & Medicaid Services. CMS Quality Strategy 2016. Baltimore, MD: US Department of Health and Human Services; 2015. *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[485] 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.*

[486] 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.*

[487] 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.*

[488] 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.*

[489] 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.*

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/HospitalQualityInits/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 50894 through 50896). 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 [490] 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 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 evidence-based medications for the treatment of schizophrenia have an FDA Black Box Warning due to an increased risk of mortality for elderly patients with dementia related psychosis.[491]

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 proposed measure would 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 would 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.[492] If this measure is finalized as proposed, 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.[493] We provided the draft measure information form [494] and draft measure justification form [495] 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 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

[490] 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.''

[491] 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*.

[492] Health Services Advisory Group. Final Methodology Report: Medication Continuation Following Inpatient Discharge. Tampa, FL; 2016.

[493] 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).

[494] *Ibid.*

[495] *Ibid.*

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 the proposed 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 are proposing the Medication Continuation following Inpatient Psychiatric Discharge measure described in this section for the FY 2020 payment determination and subsequent years.

In summary, we are proposing 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	N/A	N/A	Medication Continuation following Inpatient Psychiatric Discharge.

We welcome public comment on our proposal to adopt the Medication Continuation following Inpatient Psychiatric Discharge measure.

4. Summary of Proposed and Previously Finalized Measures for the FY 2020 Payment Determinations and Subsequent Years

If the Medication Continuation following Inpatient Psychiatric Discharge measure is adopted, the number of measures for the FY 2020 payment determination and subsequent years will total 19 as set forth in the table below.

PROPOSED AND 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.
N/A	N/A	Medication Continuation following Inpatient Psychiatric Discharge.**

* Since this measure was finalized in the FY 2017 IPPS/LTCH PPS final rule (57239 through 57246), NQF endorsement has been received.
** New measure proposed for the FY 2020 payment determination and subsequent years.

5. 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'' [496] 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

[496] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Downloads/Measures-under-Consideration-List-for-2016.pdf.*

Inpatient Psychiatric Facilities. We welcome 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 welcome public comments on possible new measures in these or other areas.

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 this proposed rule, we are not proposing 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 this proposed rule, we are proposing 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), 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 proposed 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 this proposed rule, we are proposing 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 are proposing 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, if our proposal in IX.D.7.b. of the preamble of this proposed rule is finalized, 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 would coincide with the deadline to submit an NOP or withdraw from the program.

In addition, we are proposing 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 are inviting 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.

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 this proposed rule, we are proposing 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) 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 53656)). 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, we are proposing to no longer specify the exact dates of the submission period through rulemaking. We are proposing to provide these exact dates through a subregulatory process instead, beginning with the FY 2019 payment determination. We are proposing 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 facilities must submit data ends on March 31, 2018. 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 are also proposing 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 welcome 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.

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. We are not proposing any changes to these policies in this proposed rule.

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 this proposed rule, we are not proposing any changes to the population and sampling methodology or to the minimum case thresholds.

e. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We are not proposing 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. We are not proposing 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 this proposed rule, we are proposing 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 this FY 2018 IPPS/LTCH PPS proposed rule, we are also proposing to update ECE policies in the Hospital Readmissions Reduction Program (in section V.I.12. of the preamble of this proposed rule); the HAC Reduction Program (in section V.K.8. of the preamble of this proposed rule), Hospital IQR Program (in section IX.A.15. of the preamble of this proposed rule), and the PCHQR Program (in section IX.B.10. of the preamble of this proposed rule) in order to align policies. We refer readers to these sections for more details.

b. Proposed 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 we are not making proposals related to these two items. However, to improve cross-program alignment we are proposing 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 are proposing 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 are proposing 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 are proposing 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 has suffered 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 welcome 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 invite public comments on our intent to clarify that we will strive to complete our review of ECE requests within 90 days of receipt.

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) and 1814(l) 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. Proposed 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 EHR 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 EHR 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; and
- Hospitals have had challenges with data mapping and workflow because of the need to collect CY 2017 data while still reporting CY 2016 data.

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 vendors are impacting the capability of hospitals to meet the requirements for CY 2017. As a result, we are proposing modifications to the CY 2017 final policies in this proposed rule, which would reduce CQM reporting requirements in order for hospitals and vendors to address these issues.

In this proposed rule, we are proposing 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 are proposing 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 proposed 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 this proposed rule, we discuss and seek feedback on future potential CQMs for the Hospital IQR Program and the Medicare and Medicaid EHR Incentive Programs for eligible hospitals and CAHs.

b. Proposed Changes to Policies Regarding Electronic Reporting of CQMs for CY 2017

In response to concerns from stakeholders, we are proposing 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 are proposing 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 are not proposing to modify any other aspects of the policies for reporting CQMs electronically for CY 2017, including the submission periods, nor are we proposing 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 proposed rule.

We believe 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. 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 vendors more time to plan for reporting, and account for and schedule hospital-specific scenarios such as EHR upgrades or system transitions. We recognize that eligible hospitals and CAHs are concerned about their capability of meeting the CY 2017 requirements established in the FY 2017 IPPS/LTCH PPS final rule and believe that these modified reporting requirements for CY 2017 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 are inviting public comment on our proposals to modify the CY 2017 CQM reporting requirements for the Medicare and Medicaid EHR Incentive Programs as described above.

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

CQMs for Eligible Hospitals and CAHs Beginning With CY 2017—Continued

Short name	Measure name	NQF #
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.
(+) NQF endorsement has been removed.

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 and the CMS Quality Strategy [497] and incorporate updated standards and terminology in current CQMs, including updating the electronic specifications for these CQMs, and creating de novo CQMs, we plan to expand the set of CQMs available for reporting under the EHR Incentive Programs in 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 as described above, which we believe will likely continue into CY 2018, but to a lesser extent than in CY 2017. With the CY 2017 proposed policies reducing reporting requirements and providing additional time for eligible hospitals, CAHs, and vendors to make EHR upgrades and system transitions in CY 2017, we believe that stakeholders would 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.

For CY 2018, we are proposing 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 this proposed rule, we are proposing 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

We are proposing 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 are proposing 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

[497] Available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.html.*

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 this 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 are proposing changes to this previously adopted policy in the Hospital IQR Program and refer readers to section IX.A.8. of the preamble of this proposed rule for more details. Ultimately, we believe that our proposal balances our goal to shift towards electronic reporting of quality measure data with concerns from stakeholders regarding an increased burden to meet CQM reporting requirements.

In addition, the proposal provides eligible hospitals and CAHs with the opportunity to have several years of experience reporting data electronically for the Hospital IQR and Medicare and Medicaid EHR Incentive Programs. Therefore, we believe 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 are proposing for the CY 2017 reporting period. This proposal is being made in conjunction with our proposals discussed in section IX.A.10.d. of the preamble of this proposed rule to align requirements for the Medicare and Medicaid EHR Incentive Programs and the Hospital IQR Program.

We are inviting 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.

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/ehrincentiveprograms*.

For the CY 2018 reporting period, we are proposing 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 are proposing 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 are proposing 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. As described in the 2015 EHR Incentive Programs Final Rule (80 FR 62767), starting in CY 2018, eligible hospitals and CAHs are required to have EHR technology certified to the 2015 Edition.

Starting in CY 2018, we are proposing to require the use of EHR technology certified to the 2015 Edition for CQM reporting. Furthermore, we are proposing 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 are proposing 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 proposed rule. We are inviting public comment on these proposals.

F. Clinical Quality Measurement for Eligible Professionals (EPs) Participating in the Medicaid EHR Incentive Program in 2017

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. Proposed 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, we are proposing 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 are proposing 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. 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 note 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. 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).

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 one 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 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 are inviting public comment on this proposal, including on whether making the proposed change would create burdens for EPs or States.

2. Proposed Modifications to CQM Reporting Requirements for Medicaid EPs Under the Medicaid EHR Incentive Program

We also are proposing 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). Because MIPS is replacing PQRS, in order to keep CQM specifications current, we are proposing to align the CQMs for Medicaid EPs with those updated annually for MIPS. Specifically, we are proposing 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 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 welcome 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 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 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 are proposing 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 propose 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 note 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 are inviting 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, CMS will consider making these proposed changes to the CQM reporting requirements effective beginning with the reporting period in 2018.

G. Changes to the Medicare and Medicaid EHR Incentive Programs

1. Proposed Revisions to the EHR Reporting Period in 2018

We received additional feedback from EPs, hospitals, hospital associations, and other clinical associations indicating that additional time may be necessary for testing and implementation of the new application programming interface (API) functionality requirement for Stage 3 citing inability to meet the required timeframe for implementation of Stage 3 and complexity of the new functionality and associated requirements for the Patient Electronic Access to Health Information (80 FR 62841 through 62846) and Coordination of Care Through Patient Engagement (80 FR 62846 through 62852) objectives. The API functionality supports health care providers and patient electronic access to health information, which is key to improving the free flow of health information, quality improvement, and patient engagement. Because this functionality is included as part of the 2015 Edition Base EHR definition (and thus must be part of CEHRT) (80 FR 62675 through 62676), APIs may be enabled by a health care provider or organization for their own use of third party applications with their CEHRT, such as for quality improvement. An API could also be enabled by a health care provider to give patients access to their health information through a third-party application with more flexibility than is often found in many current patient portals. From the health care provider perspective, an API could complement a specific provider branded patient portal or could also potentially make one unnecessary if patients are able to use software applications designed to interact with an API that could support their ability to view, download, and transmit their health information to a third party (80 FR 62842). We want to ensure that health

care providers have the opportunity to thoroughly test their systems and make adjustments in order to successfully attest for the EHR reporting period in CY 2018. In addition, we believe that health care providers may need extra time to fully implement and test workflows with the 2015 Edition of CEHRT, which is required beginning in CY 2018 (80 FR 62874 through 62875).

The Office of the National Coordinator for Health Information Technology (ONC) monitors technical development and progress toward certification to evaluate readiness among the health IT industry for implementation of technology certified to 2015 Edition certification criteria. One part of this evaluation involves monitoring products in the certification process, which is supplemented by discussions with health IT developers, ONC-Authorized Testing Laboratory (ONC–ATLs), and ONC-Authorized Certification Body (ONC–ACBs). Health IT developers have conveyed to the ONC that some of the 2015 Edition certification criteria required additional effort, including implementation of new functionalities (including APIs) and facilitation of greater interoperability in comparison to previous Editions. 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. For example, new transitions of care certification criterion rigorously assesses a product's ability to create and receive an interoperable Consolidated-Clinical Document Architecture (C–CDA). The 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). It also indicated that it did not anticipate any significant delays toward the delivery and roll out of products to customers because of this additional effort. This timing was expressed as a goal of developers to enable health care providers to engage in upgrades, training, and other improvements that would be needed to begin using the 2015 Edition CEHRT in 2018.

In addition, the ONC also compares data such as program tracking and projections related to the release of the previous Editions of CEHRT to help inform its evaluation of progress during this current transition period for the 2015 Edition. In particular, ONC has reviewed historical data for actual participation and implementation of technologies certified to the 2014 Edition during the transition year in CY 2014, when users were transitioning from technology certified to the 2011 Edition to technology certified to the 2014 Edition. In 2014, projections indicated expectations of market readiness of greater than 90 percent by the end of the CY 2014. However, subsequent analysis found that the actual market coverage for hospitals was approximately 98 percent at the end of CY 2014, meaning that 98 percent of hospitals had implemented the 2014 Edition by the end of CY 2014. However, attestations for the EHR Incentive Program for CY 2014 indicated a potential lag in implementation and variability in the amount of time required by hospitals to complete implementation of the technology and the subsequent training, technical processes, and operational and clinical workflows required for successful use. Attestation data show that 9 percent of eligible hospitals and CAHs used EHR technology certified to the 2011 Edition for part or all of their EHR reporting period.

In addition, 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. 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 supports an analysis that supports an estimate of greater than 85 percent of hospitals will be ready by the end of CY 2017. However, a more conservative approach—based on the identified variance in implementation timelines for hospitals may be necessary to support the hospitals that may require additional time to successfully implement technology certified to the 2015 Edition.

In addition, the historical data indicates EPs are more likely to use a wider range of products, including products which individually make up a smaller segment of the overall market. Therefore, when market factors are taken into account, there exists a larger proportion of readiness that is unknown due to the wider range of products used by EPs. Therefore, a more conservative approach is necessary and supports an estimate of greater than 74 percent readiness by the end of CY 2017 for EPs.

Thus, while we expect a majority of EPs, eligible hospitals and CAHs participating in the EHR Incentive Programs to be ready to begin using 2015 Edition CEHRT in CY 2018, it is reasonable to assume there will still be some who will not be ready and will require a longer timeframe for successful implementation. In addition, it is likely that there will be a proportion of them that have the technology implemented in time for the beginning of CY 2018 who would similarly benefit from additional time to implement new processes and workflows supporting their use of certified EHR technology in the EHR Incentive Program. This is especially important given requirements in the ONC Health IT Certification program which leverage new functionalities such as APIs which also require adherence to existing security and privacy standards. We stated in the 2015 EHR Incentive Programs Final Rule (80 FR 62842 through 62843) that the requirement to conduct and review a security risk analysis in compliance with HIPAA Security Rule would include the certified API enabled as a part of the health care provider's CEHRT.

For the reasons discussed above, we are proposing to modify the EHR reporting periods 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. This would mean that 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 would attest to meaningful use of CEHRT 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 are proposing corresponding changes to the definition of ''EHR reporting period'' and ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4.

We are inviting public comment on our proposal.

2. Exception for Decertified EHR Technology for EPs, Eligible Hospitals, and CAHs Seeking To Avoid the Medicare Payment Adjustment

The 21st Century Cures Act (Pub. L. 114–255) was enacted on December 13, 2016. 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 professional has been decertified under ONC's Health IT Certification Program. Similarly, section 4002(b)(2) of the 21st Century Cures Act 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. We include proposals below to implement these amendments with respect to EPs, eligible hospitals, and CAHs. We note 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.

The ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule (''EOA final rule'') (81 FR 72404), effective December 19, 2016, created a regulatory framework for the ONC's direct review of health information technology (health IT) certified under the ONC Health IT Certification Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Program and terminating certifications issued to certified health IT. Prior to the EOA final rule, ONC-Authorized Certification Bodies (ONC–ACBs) had the only authority to terminate or revoke certification of health IT under the program, which they used on previous occasions. On September 23, 2015, we posted an FAQ discussing the requirements for using a decertified CEHRT.[498]

Once all administrative processes, if any, are complete, then notice of a ''termination of certification'' is listed on the Certified Health IT Product List (CPHL) Web page.[499] As appropriate, ONC will also publicize the termination of certification of health IT through other communication channels (for example, ONC list serve(s)). Further, when ONC terminates the certification of a health IT product, the health IT developer is required to notify all potentially affected customers in a timely manner.

We further note that in comparison to termination actions taken by ONC and ONC–ACBs, a health IT developer may voluntarily withdraw a certification that is in good standing under the ONC Health IT Certification Program. A voluntary withdrawal may be the result of the health IT developer going out of business, the developer no longer supporting the product, or for other reasons that are not in response to ONC–ACB surveillance, ONC direct review, or a finding of non-conformity by ONC or an ONC–ACB.[500] In such instances, ONC will list these products on the ''Inactive Certificates'' [501] Web page of the CHPL.

We are proposing to revise § 495.102(d) to add a new exception for EPs 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 by the EP has been decertified under ONC's Health IT Certification Program. We are proposing 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. We considered but are not proposing this exception also for the CY 2017 payment adjustment year because it would require us to reprocess claims for potentially the entire CY 2017, which would be costly and administratively burdensome. ONC provides that there is a 6-step process that usually occurs when implementing a certified EHR technology system.[502] We believe that if an EP has to procure new certified EHR technology they will likely have to go through some phases of this cycle again and understand that it would be time consuming and may take up to a year to implement.

We are proposing an EP may qualify for this exception if their certified EHR technology was decertified either before 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. If the 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, the EP may qualify for this exception. For example, if an EP intended to attest to meaningful use for a 90-day EHR reporting period beginning on April 1, 2016, the EP could apply for this exception if their certified EHR technology was decertified at any time during the 12-month period beginning on April 1, 2015 and ending on March 31, 2016, or if their certified EHR technology was decertified at any time during their 90-day EHR reporting period beginning on April 1, 2016. We believe a 12-month period is reasonable because we understand the burden placed on EPs related to time and funds needed to purchase and deploy new certified EHR technology including the process that goes along with implementing new certified EHR technology.

In addition, we are proposing that the EP must demonstrate in its application and through supporting documentation if available that the EP 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 are proposing 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 are proposing to revise § 412.64(d)(4) to add a new category of exception for eligible hospitals that 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 by the eligible hospital has been decertified under ONC's Health IT Certification Program. We are proposing this exception would be available beginning with the FY 2019 payment adjustment year. We considered but are not proposing to make this exception available beginning with the FY 2018 payment adjustment year because making this exception available beginning with the FY 2018

[498] *https://questions.cms.gov/faq.php?isDept=0&search=decertify&searchType=keyword&submitSearch=1&id=5005.*

[499] The ''list can be found at: *https://chpl.healthit.gov/#/decertifications/products.*

[500] For further descriptions of certification statuses, we refer readers to the CHPL Public User Guide.

[501] The ''Inactive Certificates'' Web page can be found at: *https://chpl.healthit.gov/#/decertifications/inactive.*

[502] *https://www.healthit.gov/providers-professionals/ehr-implementation-steps.*

payment adjustment would be administratively burdensome, since previous guidance at FAQ 12657 indicated that providers could apply for a hardship if their product was decertified prior to the end of the EHR reporting period.[503] Therefore, we believe that an eligible hospital would have already received a hardship exception under this circumstance. We also note that to date no certifications have been terminated under ONC's direct review authority. We are proposing an eligible hospital may qualify for this exception if their certified EHR technology was decertified either before or during the applicable EHR reporting period for the payment adjustment year. We refer readers to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 for the applicable EHR reporting periods for payment adjustment years for eligible hospitals. For example, under § 495.4, for the FY 2019 payment adjustment year, the EHR reporting period is any continuous 90-day period in CY 2017. If the 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, the eligible hospital may qualify for this exception. For example, if an eligible hospital intended to attest to meaningful use for a 90-day EHR reporting period beginning on April 1, 2017, the eligible hospital could apply for this exception if their certified EHR technology was decertified at any time during the 12-month period beginning on April 1, 2016 and ending on March 31, 2017, or if their certified EHR technology was decertified at any time during their 90-day EHR reporting period beginning on April 1, 2017.

We believe a 12-month period is reasonable for the same reasons stated above for EPs. In addition, we are proposing that the eligible hospital must demonstrate in its application and through supporting documentation if available that the eligible hospital 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 are proposing 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 are proposing to revise § 413.70(a)(6) to add a new category of exception for CAHs that 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 by the CAH has been decertified under ONC's Health IT Certification Program. We are proposing this exception would be available beginning with the FY 2018 payment adjustment year. We are proposing a CAH may qualify for this exception if their certified EHR technology was decertified either before or during the applicable EHR reporting period for the payment adjustment year. We refer readers to the definition of ''EHR reporting period for a payment adjustment year'' under § 495.4 for the applicable EHR reporting periods for payment adjustment years for CAHs. For example, under § 495.4, for the FY 2018 payment adjustment year, the EHR reporting period is either CY 2018 or a continuous 90-day period in CY 2018, depending on whether the CAH has successfully demonstrated meaningful use in a prior year. If the 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, the CAH may qualify for this exception. For example, if a CAH intended to attest to meaningful use for a 90-day EHR reporting period beginning on April 1, 2018, the CAH could apply for this exception if their certified EHR technology was decertified at any time during the 12-month period beginning on April 1, 2017 and ending on March 31, 2018, or if their certified EHR technology was decertified at any time during their 90-day EHR reporting period beginning on April 1, 2018. We believe a 12-month period is reasonable for the same reasons stated above for EPs. In addition, we are proposing that the CAH must demonstrate in its application and through supporting documentation if available that the CAH 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 are proposing 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 are inviting public comment on these proposals. We considered alternative timeframes for decertification to the proposed 12-month period preceding the applicable EHR reporting period. We are requesting public comments on whether this 12-month timeframe is reasonable or whether another period should be considered.

3. Ambulatory Surgical Center (ASC)-Based Eligible Professionals (EPs)

Section 16003 of the 21st Century Cures Act 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.

The statute refers to an EP who furnishes ''substantially all'' of his or her covered professional services in an ASC. Therefore, we must identify the minimum percentage of an EP's covered professional services that must be furnished in an ASC setting in order for the EP to be considered as furnishing ''substantially all'' of his or her covered professional services in an ASC. To this end, we are proposing two alternative definitions of an ASC-based EP and requesting public comment to determine the final definition.

We are proposing to define an ASC-based EP under § 495.4 as 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 two years before the payment

[503] *https://questions.cms.gov/faq.php?isDept=0&search=decertified&searchType=keyword&submitSearch=1&id=5005.*

adjustment year. The percentage of covered professional services in this proposed definition is the same as our definition of a hospital-based MIPS eligible clinician under the Quality Payment Program (§ 414.1305 and 81 FR 77238 through 77240). In the alternative, we are proposing to define an ASC-based EP as an EP who furnishes 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 percentage of covered professional services in this alternative proposal is the same as our definition of a hospital-based EP for the EHR Incentive Programs (§ 495.4 and 75 FR 44439 through 44442). Under these proposals, we would use claims for services furnished in CY 2015 to determine whether an EP is ASC-based for the CY 2017 payment adjustment year, and we would use claims for services furnished in CY 2016 to determine whether an EP is ASC-based for the CY 2018 payment adjustment year. We are also proposing to use Place of Service (POS) code 24 to identify services furnished in an ASC and are requesting 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 analyzed claims data from CYs 2015 and 2016 to estimate how many EPs would be considered ASC-based under our proposal and alternative proposal. Under our proposed definition of ''substantially all,'' for CY 2015, we found that 380 EPs billed at least 75 percent of their covered professional services in POS 24, out of 523,000 Medicare EPs, which equals approximately .07 percent of Medicare EPs. For CY 2016, we found that 404 EPs billed at least 75 percent of their covered professional services in POS 24, out of 508,575 Medicare EPs, which equals approximately .08 percent of Medicare EPs.

Under our alternative proposed definition of ''substantially all,'' for CY 2015, we found that 176 EPs billed at least 90 percent of their covered professional services in POS 24, out of 523,000 Medicare EPs, which equals approximately .03 percent of Medicare EPs. For CY 2016, we found that 197 EPs billed at least 90 percent of their covered professional services in POS 24, out of 508,575 Medicare EPs, which equals approximately .04 percent of Medicare EPs.

We are inviting public comment on these proposals.

4. 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. At a minimum, EPs, eligible hospitals, and CAHs would be required to use EHR technology certified to the 2014 Edition certification criteria for their respective EHR reporting periods in 2015 through 2017. They may also upgrade to the 2015 Edition to meet the required certified EHR technology definition for the EHR reporting periods in 2015, 2016, or 2017, or they may use a combination of 2014 and 2015 Editions if they have modules from both editions that meet the requirements for the meaningful use objectives and measures or if they fully upgrade during an EHR reporting period. 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 comments on the Stage 3 proposed rule requesting that we allow health care providers to use the 2014 and 2015 Editions of CEHRT in 2018 (80 FR 62874 through 62875). We also received feedback from EPs, eligible hospitals and hospital associations after the 2015 EHR Incentive Program final rule was published. The feedback expressed concerns regarding the burden that will likely occur as a result of the new functionalities required in the implementation of the Stage 3 requirements including an increase in the cost of care without better patient outcomes.

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. Furthermore, we believe that there are many benefits for switching to EHR technology certified to the 2015 Edition. At this time, our analysis shows that progress toward certification and upgrade of systems should enable 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 to upgrade systems to the 2015 Edition and successfully attest for an EHR reporting period in 2018.

We will work with ONC to monitor the deployment and implementation status of EHR technology certified to the 2015 Edition. If we identify a change in the current trends and significant issues with the certification and deployment of the 2015 Edition, we will 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.

One possibility is the flexibility to use technology certified to the 2014 Edition or the 2015 Edition for an EHR reporting period in 2018. Another option is allowing a combination of EHR technologies certified to the 2014 Edition and 2015 Edition to be used for an EHR reporting period in 2018, for those EPs, eligible hospitals, and CAHs that are not able to fully implement EHR technology certified to the 2015 Edition.

We are inviting public comment on these options for offering flexibility in CY 2018 with regard to EHR certification requirements.

X. Proposed 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. Proposed Changes Relating to Electronic Signature on the Certification and Settlement Summary Page of the Medicare Cost Report

In this proposed rule, 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 are proposing to revise § 413.24(f)(4)(iv) to allow providers to use an electronic signature. For Medicare cost reporting purposes, we are proposing 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 believe that 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 are proposing 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. 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 are proposing 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.

Only when the checkbox is checked would the signature line be accepted with an electronic signature. 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 are proposing 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 are inviting public comments on our proposals.

3. Proposed 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 this proposed rule, we are proposing 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 are further proposing 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 this 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 the Certification and Settlement

Summary page. However, if the provider chooses to do so, this page would have to be mailed to its contractor. 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. 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 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 are inviting public comments on this proposal.

4. Clarifications Relating to the Items Required To Be Submitted by Providers With the Medicare Cost Report

a. Settlement Summary and Certification Statement

In this proposed rule, we are clarifying 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. Section 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. 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. We are clarifying that ''a statement of certain worksheet totals found within the electronic file'' is not a separate item but rather 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 this proposed rule, we are proposing to revise § 413.24(f)(4)(iv) to clarify this, as further discussed in section X.A.5. of the preamble of this proposed 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 this proposed rule, we are proposing to remove the language in § 413.24(f)(4)(iv) which sets forth this expired transition period. Specifically, we are proposing 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. 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.

5. Proposed Revisions to 42 CFR 413.24(f)(4)(iv)

In this proposed rule, to reflect our proposals discussed earlier, we are proposing 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. 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 are further proposing 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. 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. 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 are proposing 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 are proposing 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.

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 are proposing to remove the transition period language in § 413.24(f)(4)(iv).

Finally, we are proposing 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.'' This language has appeared on the Certification and Settlement Summary page for many years. 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 are inviting public comments on these proposals.

B. Clarification of Limitations on the Valuation of Depreciable Assets Disposed of On or After December 1, 1997

In this section of this proposed rule, we are proposing 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 this proposed rule, 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'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 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 Balanced Budget Act 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 Balanced Budget Act of 1997 (Pub. L. 105–33) 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 Public Law 105–33, 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 was concerned with 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 Public Law 105–33. In that rule, we stated that, under the provisions of section 4404 of Public Law 105–33, ''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, we are proposing 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.

XI. Proposed Changes Relating to Survey and Certification Requirements

A. Proposed Revisions to the Application and Re-Application Procedures for National Accrediting Organizations (AOs), Provider and Supplier Conditions, and Posting of Survey Reports and Acceptable Plans of Corrections (PoCs)

1. Background

Health care facilities must demonstrate compliance with the Medicare conditions of participation (CoPs), conditions for coverage (CfCs), or conditions for certification (depending on the type of facility) to be eligible to receive Medicare payments. Section 1865 of the Act allows health care facilities that are ''provider entities'' to demonstrate this compliance through accreditation by an accreditation program of a private, national accrediting organization (AO) that is approved by the Secretary. An AO must demonstrate the ability to effectively evaluate a facility's compliance using accreditation standards that meet or exceed the applicable Medicare conditions, as well as survey processes that are comparable to those survey methods, procedures, and forms required by CMS for conducting Federal surveys for the same health care facility type, which are generally outlined in regulations and specified in the State Operations Manual (SOM).

Section 1865(a)(2) of the Act requires that the Secretary base its decision to approve or deny the Medicare accreditation program application of an accrediting organization after considering at least the following factors: (a) Program requirements for the accreditation program to meet or exceed Medicare requirements; (b) survey procedures that are comparable to those of Medicare; (c) the ability to provide adequate resources for conducting surveys; (d) the capacity to furnish information for use by CMS in enforcement activities; (e) monitoring procedures for providers or suppliers identified as being out of compliance with conditions or requirements; and (f) the ability to provide the necessary data for validation surveys to the Secretary. In addition, section 1865(a)(2) of the Act specifies that the Secretary shall consider other factors with respect to determining the AOs ability to meet or exceed applicable conditions, therefore meaning that CMS has the ability to determine ''other factors'' when considering an AO for deemed status.

CMS has responsibility for oversight and approval of AO accreditation programs used for Medicare certification purposes, and for ensuring that providers and suppliers that are accredited under an approved AO accreditation program meet the quality and patient safety standards required by the Medicare conditions and requirements. The Medicare regulations at 42 CFR 488.5 set forth the detailed requirements that a national AO must satisfy in order to receive approval, and maintain recognition, of a Medicare accreditation program. Section 488.5 also details the procedures that CMS follows in reviewing applications from AOs.

The results of surveys conducted by State Survey Agencies of a facility's compliance with Medicare conditions and requirements of CMS-certified facilities are reported using the CMS Form 2567, ''Statement of Deficiencies and Plan of Correction'' (OMB No. 0938–0391). These reports describe any findings of noncompliance with Federal requirements (also referred to as ''deficiencies'') that the surveyors may have found. If there are cited deficiencies, a facility must submit an acceptable plan of correction (PoC) for achieving compliance to CMS describing how and when, within a reasonable timeframe, it will correct them. Failure to correct deficiencies will lead to the facility's termination from Medicare participation.

CMS makes survey reports and acceptable PoCs publicly available through a variety of settings as part of the Department's commitment to transparency, and to providing all health care consumers and the general public with access to quality and safety information. CMS began posting redacted CMS Form 2567 survey data for skilled nursing facilities and nursing facilities on its *Nursing Home Compare* Web site in July 2012. In March 2013, CMS began posting on its Web site the CMS Form-2567 surveys reports based on complaint investigations for short-term acute care hospitals and critical access hospitals (CAHs).[504] In addition, two Web sites owned by private entities also publish the public CMS survey data of nursing homes, short-term acute care hospitals, and CAHs, based on the CMS survey information. The *ProPublica* Web site [505] and the Association for Health Care Journalist (AHCJ) Web sites, respectively, provide search engines that refer back to the CMS Form 2567 data that CMS has made available. These Web sites enable all health care consumers and the general public across the country to learn about the performance of these providers in order to make more informed decisions about where to get health care. We also believe that release of this information encourages these health care providers to improve the quality of care and services they provide. Such information can also be obtained by the public directly from State Survey Agencies.

AOs perform their own accreditation surveys and issue their own survey reports which provide information on accredited facilities' compliance with Federal standards. These facilities include: Hospitals, psychiatric hospitals, CAHs, home health agencies (HHAs), hospices, ambulatory surgery

[504] Survey & Certification Policy Memorandum (SC–13–21–ALL). Available at: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-21.pdf.*

[505] ProPublica (2016) Web site: *http://projects.propublica.org/nursing-homes/.*

centers (ASCs), outpatient physical therapy and speech-language pathology services (OPTs), and rural health clinics (RHCs).[506] These facilities participate in Medicare based on their accreditation from a CMS-approved AO and are not subject to routine surveys from State survey agencies.

By contrast, AOs currently do not make their survey reports and accompanying PoCs publicly available. We believe it is important to continue to lead the effort to make information regarding a health care facility's compliance with health and safety requirements found in survey reports publicly available through our various provider and supplier *Compare* sites, including hospital and home health *Compare* sites to increase transparency. CMS recognizes, based on the above references to CMS *Compare* sites and other resources which make survey reports publically available, that these survey reports vary in the type of information accessible to the public (complaint) based on the provider or supplier type. For example, the current CMS Survey and Certification site for hospital 2567 downloads (*https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandCompliance/Hospitals.html*) only contains complaint surveys; no recertification survey reports are posted. In addition, there has been an increasing concern in terms of AO disparity rates based on the AO deficiency findings compared to serious, condition-level deficiencies found by the State Survey Agencies. For example, in FY 2015, the disparity rates increased by 1 percent to 39 percent for hospitals and decreased by 6 percent to 69 percent for psychiatric hospitals, from FY 2014. This continued trend of high disparity rates from FY 2012 to FY 2015 raises serious concerns regarding the AOs' ability to appropriately identify and cite health and safety deficiencies during the survey process. Therefore, we believe that posting AO survey reports and acceptable PoCs would address some of the concerns of reporting hospital information from both CMS and AOs, as well as the disparity between serious deficiency findings, and provide a more comprehensive picture to health care consumers and the public in general.

As the number of health care facilities participating in Medicare by virtue of their accreditation and deemed status increases, the number of survey reports and acceptable PoC available to health care consumers decreases. The table below illustrates that 40 percent of Medicare-participating providers or suppliers with an accreditation option participate in Medicare via accreditation and deemed status. In addition, 89 percent of hospitals and psychiatric hospitals across the country participate in Medicare via accreditation and deemed status. This represents a significant number of hospital and other health care facility survey reports and acceptable PoCs that are currently not available to health care consumers. This information is not available to assist health care consumers in their decision making when selecting a health care facility in which to receive care for themselves or a loved one. Therefore, we believe that it is critical that accrediting organizations with CMS-approved accreditation programs make available publicly all survey reports and acceptable plans of correction on their Web sites.

TOTAL MEDICARE PARTICIPATING FACILITIES—FY 2015 DEEMED VERSUS NON-DEEMED

Program type	Deemed * (percentage)	Non-deemed ** (percentage)	Total
Hospital	3,500 (89)	432 (11)	3,932
Psychiatric Hospital	424 (89)	53 (11)	477
CAH	420 (32)	887 (68)	1,307
HHA	4,450 (47)	5,008 (53)	9,458
Hospice	1,694 (40)	2,573 (60)	4,267
ASC	1,499 (27)	3,973 (73)	5,472
OPT	175 (8)	1,957 (92)	2,132
RHC	253 (6)	3,862 (94)	4,115
Total	12,415 (40)	18,745 (60)	31,160

* As reported by accrediting organizations.
** Surveyed by a State survey agency for compliance with Medicare conditions.

2. Proposed Regulation Changes

In an effort to increase transparency, in this proposed rule, we are proposing to require AOs with CMS-approved accreditation programs to post final accreditation survey reports and acceptable 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. Therefore, we are proposing to require AOs to have their final accreditation survey reports and acceptable PoCs available on their Web sites.

Establishing the standard for posting both accredited and nonaccredited provider and supplier survey reports, which would include initial and recertification surveys, and acceptable 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 acceptable PoCs would allow for a more comprehensive way to show a provider's or supplier's compliance with all health and safety requirements.

Therefore, we are proposing to revise § 488.5 of the regulations to incorporate this proposed requirement. We are proposing 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 agrees to make all Medicare provider or supplier final accreditation survey reports (including statements of deficiency findings) as well as acceptable PoCs publicly available on

[506] Note that other types of facilities may also participate in Medicare via an approved accreditation program, but to date, no AO has sought and received approval for any of these additional facility types.

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 are performed onsite or offsite.

In addition, pursuant to section 1834(e) of the Act, State Survey Agencies do not evaluate suppliers of the technical component of advanced diagnostic imaging services. CMS-approved advanced diagnostic imaging AOs are the only source of compliance data for suppliers of the technical component of advanced diagnostic imaging services. Therefore, we believe it is critical that these AOs also be required to post survey reports and acceptable PoCs on their Web sites. Otherwise, it will not be possible to provide health care consumers with compliance information about Medicare-participating suppliers of advanced diagnostic imaging services. We are proposing to amend our regulations at 42 CFR 414.68 governing imaging accreditation under Medicare by redesignating paragraphs (c)(7) through (c)(14) as paragraphs (c)(8) through (c)(15), respectively, and adding a new paragraph (c)(7) to require that each national advanced diagnostic imaging AO that applies or reapplies for CMS approval of its Medicare advanced diagnostic imaging accreditation program must provide a statement acknowledging that it agrees to make all Medicare advanced diagnostic imaging final accreditation survey reports as well as acceptable PoCs publicly available on its Web site within 90 days after such information is made available to the supplier of advanced diagnostic imaging services for the most recent 3 years. This provision would apply to all full, follow-up, focused, and complaint surveys, regardless of whether they are performed onsite or offsite.

We are inviting public comments on these proposals.

B. Proposed 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 Proposed 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.[507] 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, we are proposing 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. Proposed Changes to Regulations

In this proposed rule, we are proposing 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 are proposing 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 notice is required but the method for these providers or suppliers

[507] 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/.*

for providing public notice is not specified, to allow for flexibility.

In addition, we are proposing 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 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 are proposing 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 this 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 are inviting public comments on our proposals. In addition, we are seeking 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.

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 proposed policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2018 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's Web site at: *http://www.medpac.gov*.

XIII. Other Required Information

A. Publicly Available Data

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*. Following is a listing of the IPPS-related files that are available.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, Parts II and III from FY 2014 Medicare cost reports used to create the proposed FY 2018 IPPS wage index. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.M. of the preamble of this proposed rule.

Processing year	Wage data year	PPS fiscal year
2017	2014	2018
2016	2013	2017
2015	2012	2016
2014	2011	2015
2013	2010	2014
2012	2009	2013
2011	2008	2012
2010	2007	2011
2009	2006	2010
2008	2005	2009
2007	2004	2008

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Periods Available: FY 2007 through FY 2018 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2013 occupational mix survey data to be used to compute the occupational mix adjustment wage indexes. Multiple versions of this file are created each year. For a complete schedule on the release of different versions of this file, we refer readers to the wage index schedule in section III.M. of the preamble of this proposed rule.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2018 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-AService-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2018 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Periods Available: FY 2005 through FY 2018 IPPS Update.

5. FY 2018 IPPS SSA/FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Social Security Administration (SSA) and the Federal Information Processing Standards (FIPS), county name, and a list of Core-Based Statistical Areas (CBSAs).

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2018 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: Internet at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year.html*.

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited Web site.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text.html.*

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number as published in each year's update of the Medicare hospital inpatient prospective payment system. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: FY 1985 through FY 2018.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: FY 2005 through FY 2018 IPPS Update

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY–1994-through-Present.html.*

Periods Available: FY 1994 through FY 2018 IPPS Update.

11. AOR/BOR Tables

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR tables are ''Before Outliers Removed'' and the AOR is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.)

Two versions of this file are created each year to support the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: FY 2005 through FY 2018 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2018 IPPS Update.

13. Hospital Readmissions Reduction Program Supplemental File

This file contains information on the calculation of the Hospital Readmissions Reduction Program (HRRP) payment adjustment. Variables include the proxy excess readmission ratios for acute myocardial infarction (AMI), pneumonia (PN) and heart failure (HF), coronary obstruction pulmonary disease (COPD), total hip arthroplasty (THA)/total knee arthroplasty (TKA), and coronary artery bypass grafting (CABG) and the proxy readmissions payment adjustment for each provider included in the program. In addition, the file contains information on the number of cases for each of the applicable conditions excluded in the calculation of the readmission payment adjustment factors. It also contains MS–DRG relative weight information to estimate the payment adjustment factors. The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2018 IPPS Update.

14. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for FY 2018. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments and estimated per claim uncompensated care payment amounts. The file supports the rulemaking.

Media: Internet at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Period Available: FY 2018 IPPS Update.

B. Collection of Information Requirements

1. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the

affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

2. ICRs for Add-On Payments for New Services and Technologies

Section II.H.1. of the preamble of this proposed rule discusses add-on payments for new services and technologies. Specifically, this section states that applicants for add-on payments for new medical services or technologies for FY 2019 must submit a formal request. A formal request includes a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement. In addition, the request must contain a significant sample of the data to demonstrate that the medical service or technology meets the high-cost threshold.

We believe the burden associated with this requirement is exempt from the PRA under 5 CFR 1320.3(c), which defines the agency collection of information subject to the requirements of the PRA as information collection imposed on 10 or more persons within any 12-month period. This information collection does not impact 10 or more entities in a 12-month period. For FYs 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, and 2018, we received 1, 4, 5, 3, 3, 5, 5, 7, 9, 9, and 9 applications, respectively. We note that 3 of the 9 applications for FY 2018 were withdrawn prior to the publication of the proposed rule as indicated in section II.H.6. of the preamble of this proposed rule.

3. ICRs for the Occupational Mix Adjustment to the Proposed FY 2018 Wage Index (Hospital Wage Index Occupational Mix Survey)

Section III.E. of the preamble of this proposed rule discusses the occupational mix adjustment to the proposed FY 2018 wage index. While the preamble does not contain any new ICRs, we note that there is an OMB approved information collection request associated with the hospital wage index.

Section 304(c) of Public Law 106–554 amended section 1886(d)(3)(E) of the Act to require us to collect data at least once every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. We collect the data via the occupational mix survey.

The burden associated with this information collection requirement is the time and effort required to collect and submit the data in the Hospital Wage Index Occupational Mix Survey to CMS. The aforementioned burden is subject to the PRA; it is currently approved under OMB control number 0938–0907.

4. Hospital Applications for Geographic Reclassifications by the MGCRB

Section III.I.2. of the preamble of this proposed rule discusses proposed changes to the wage index based on hospital reclassifications. As stated in that section, under section 1886(d)(10) of the Act, the MGCRB has the authority to accept short-term IPPS hospital applications requesting geographic reclassification for wage index and to issue decisions on these requests by hospitals for geographic reclassification for purposes of payment under the IPPS.

The burden associated with this application process is the time and effort necessary for an IPPS hospital to complete and submit an application for reclassification to the MGCRB. The burden associated with this requirement is subject to the PRA. The current information collection requirement for this application process is approved under OMB Control Number 0938–0573 in 2014 but expired on February 28, 2017. A request for an extension of this currently approved collection requirement under OMB control number 0938–0573 is currently awaiting OMB approval and can be accessed at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201612-0938-023*.

5. 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 this proposed 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 the PRA. However, our estimate of the burden associated with this data submission is discussed in section I.J. of Appendix A of this proposed rule.

6. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

The Hospital IQR Program (formerly referred to as the Reporting Hospital Quality Data for Annual Payment (RHQDAPU) Program) was originally established to implement section 501(b) of the MMA, Public Law 108–173. This program expanded our voluntary Hospital Quality Initiative. The Hospital IQR Program originally consisted of a ''starter set'' of 10 quality measures. The collection of information associated with the original starter set of quality measures was previously approved under OMB control number 0938–0918. All of the information collection requirements previously approved under OMB control number 0938–0918 have been combined with the information collection request currently approved under OMB control number 0938–1022. We no longer use OMB control number 0938–0918. 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. Below, we describe the burden changes for IPPS hospitals due to the proposals in this proposed rule.

In section IX.A. of the preamble of this proposed rule, we are making the following proposals that we expect to

affect our burden estimates: (1) Updates to the electronic clinical quality measure (eCQM) reporting requirements with regard to the number of eCQMs and quarters of data for the FY 2019 and FY 2020 payment determinations; (2) updates to our previously finalized eCQM validation procedures for the FY 2020 payment determination and subsequent years; and; (3) begin voluntary reporting on the new Hybrid Hospital-Wide 30-Day Readmission measure for the CY 2018 reporting period. Details on these proposals, as well as the expected burden changes, are discussed below.

This proposed rule also includes proposals to: (1) Update the eCQM certification requirements for the FY 2019 and FY 2020 payment determinations; (2) 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; (3) refine the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (NQF #0166 and 0228) to replace the questions on pain management for the FY 2020 payment determination and subsequent years; (4) refine the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Measure to include the National Institutes of Health (NIH) Stroke Scale data for the FY 2023 payment determination and subsequent years; (5) provide confidential reports of measure data stratified by dual eligible status for the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization and Hospital 30-day, All-Cause, Risk Standardized Mortality Rate (RSRR) for Pneumonia measures; and (6) align the naming of the Extraordinary Circumstances Exceptions (ECE) Policy for the FY 2020 payment determination and subsequent years. As discussed further below, we do not expect these proposals to affect our burden estimates.

In prior rules (81 FR 57260), we have estimated that reporting eCQMs for the Hospital IQR Program measures could be accomplished by staff with a mean hourly wage of $16.42 per hour,[508] and we are retaining that wage rate, and applying it broadly for all of our calculations in this proposed rule, as we have done previously (81 FR 57260). We note that more recent wage data has become available, and we intend to update the wage rate used in these calculations in the FY 2018 IPPS/LTCH PPS final rule. We have chosen to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, as has been done in 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 ($16.42 × 2 = $32.84) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate cost burden to hospitals using a wage plus benefits estimate of $32.84 throughout the discussion below for the Hospital IQR Program.

b. Burden Estimates for the Proposed Updates to the eCQM Reporting Requirements

In the FY 2017 IPPS/LTCH PPS final rule, we finalized policies to require hospitals to submit a full year (four quarters) (81 FR 57159) of data for at least eight eCQMs of the available eCQMs (81 FR 57157) for both the FY 2019 and FY 2020 payment determinations. In section IX.A.8. of the preamble of this proposed rule, we are proposing the following changes to these finalized policies: (1) Revise the CY 2017 reporting period/FY 2019 payment determination eCQM reporting requirements, such that hospitals are required to report six eCQMs and to submit two, self-selected, calendar quarters of data; and (2) revise the CY 2018 reporting period/FY 2020 payment determination eCQM reporting requirements such that hospitals are required to report six eCQMs for the first three quarters of CY 2018.

(1) Calculations for the CY 2017 Reporting Period/FY 2019 Payment Determination

As in previous years, we believe the total burden associated with the eCQM reporting policy 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 proposal to require: (1) Reporting on at least six of the available eCQMs; and (2) submission of two self-selected quarters of eCQM data, would result in a burden reduction of 3 hours and 20 minutes (200 minutes) per hospital for the FY 2019 payment determination. This estimate was calculated by considering the burden difference between the updated eCQM reporting requirements proposed for the FY 2019 payment determination (10 minutes per record × 6 eCQMs × 2 quarters = 120 minutes for 2 quarters of reporting) and the eCQM reporting requirements previously finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57157 through 57159) (10 minutes per record × 8 eCQMs × 4 quarters = 320 minutes for 4 quarters of reporting). Through these calculations (120 minutes–320 minutes), we arrived at a reduction of 200 minutes per hospital per year, or 3 hours and 20 minutes per hospital per year, for the FY 2019 payment determination.

In total, for the FY 2019 payment determination, we expect our proposal to require hospitals to report data on six eCQMs for two quarters (as compared to our previously finalized requirements to report data on eight eCQMs for four quarters) to represent an annual burden reduction of 11,000 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program (−200 minutes per hospital/60 minutes per hour × 3,300 hospitals = −11,000 hours). Using the wage estimate described above, we expect this to represent a cost reduction of $361,240 ($32.84 hourly wage × 11,000 annual hours reduction) across all 3,300 IPPS hospitals participating in the Hospital IQR Program.

(2) Calculations for the CY 2018 Reporting Period/FY 2020 Payment Determination

Using the same estimate as described above of 10 minutes per record per quarter, if our proposed updates to the CY 2018 reporting period/FY 2020 payment determination are finalized, we anticipate our proposal to require: (1) Reporting on at least 6 of the available eCQMs; and (2) submission of the first three quarters of CY 2018 eCQM data, would result in a burden reduction of 2 hours and 20 minutes (140 minutes) per hospital for the FY 2020 payment determination as compared to the previously finalized requirements to report eight eCQMs for four quarters for the FY 2020 payment determination (81 FR 57157 through 57159). This estimate was calculated by considering the burden difference between the updated eCQM reporting requirements proposed for the FY 2020 payment determination (10 minutes per record × 6 eCQMs × 3 quarters = 180 minutes for 3 quarters of reporting) and the eCQM reporting

[508] Occupational Outlook Handbook. Available at: *http://www.bls.gov/oes/2012/may/oes292071.htm.*

requirements previously finalized for the FY 2020 payment determination (10 minutes per record × 8 eCQMs × 4 quarters = 320 minutes for 4 quarters of reporting). Through these calculations (180 minutes–320 minutes), we arrived at a reduction of 140 minutes per hospital per year, or 2 hours and 20 minutes per hospital per year, for the FY 2020 payment determination as compared to the previously finalized requirements for the FY 2020 payment determination. In total, this would represent an annual burden reduction of 7,700 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program (−140 minutes per hospital/60 minutes per hour × 3,300 hospitals) and a cost reduction of $252,868 ($32.84 hourly wage × 7,700 annual hours reduction) across all 3,300 IPPS hospitals.

c. Burden Estimate for the Proposed Modifications to eCQM Certification Requirements for the FY 2019 and FY 2020 Payment Determinations and Subsequent Years

In section IX.10.d of the preamble of this proposed rule, we discuss our proposed changes to the Hospital IQR Program eCQM submission requirements to align them with the Medicare EHR Incentive Program for eligible hospitals and CAHs. Specifically, for the CY 2017 reporting period/FY 2019 payment determination, we are proposing that: (1) A hospital using EHR technology certified to the 2014 or 2015 Edition, but 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 it is updated to a more recent version of the eCQM specifications. For the CY 2018 reporting period/FY 2020 payment determination, we are proposing that: (1) A hospital using EHR technology certified to the 2015 Edition, but 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) an EHR certified for all available eCQMs under the 2015 Edition of CEHRT would not need to be recertified each time it is updated to a more recent version of the eCQM specifications. Further, we are proposing that: (1) For the CY 2017 reporting period, hospitals would be required to use the most recent version of the CQM electronic specifications; 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; Spring 2017 version of the eCQM specifications and any applicable addenda. For eCQM specifications, we refer readers to the eCQI Resource Center Web site at: *https://ecqi.healthit.gov/*. Because the use of certified EHR technology is already required for the Medicare EHR Incentive Program, we believe that these proposals will have no effect on burden for hospitals under the Hospital IQR Program.

d. Burden Estimates for the Proposed Modifications to the Existing Validation Processes

(1) Calculations for Proposed Modifications to the Validation of eCQM Data for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.11. of the preamble of this proposed rule, we discuss our proposal to adopt a modification to the existing eCQM data validation process for the Hospital IQR Program data beginning with validation for the FY 2020 payment determination. First, we are proposing to require eight cases to be submitted per quarter for eCQM validation for the FY 2020 payment determination and subsequent years. We are making this proposal in conjunction with our proposal to require two quarters of data for the CY 2017 eCQM reporting period and our proposal to require three quarters of data for the CY 2018 eCQM reporting period. Accordingly, if those eCQM reporting proposals are finalized, we are proposing that the number of required case files for validation would be 16 records (eight cases per quarter over two quarters) for the FY 2020 payment determination and 24 records (eight cases per quarter over three quarters) for the FY 2021 payment determination. We note that, as discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57176), CY 2017 eCQM data will be validated beginning in CY 2018 for the FY 2020 payment determination and subsequent years. Therefore, CY 2018 data will be validated beginning in CY 2019 for the FY 2021 payment determination. Second, we are proposing to add additional exclusion criteria to our hospital and case selection process for eCQM validation for the CY 2018 reporting period/FY 2020 payment determination and subsequent years. Third, we are proposing to continue our previously finalized medical record submission requirements for the FY 2021 payment determination and subsequent years as well as to provide clarification to our finalized policy. We believe the updates to the exclusions and maintaining previously finalized medical record submission requirements will have no effect on burden for hospitals. We discuss the burden associated with the proposed eCQM 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 16 records we are proposing that hospitals submit for validation for the FY 2020 payment determination, we estimate a total burden of approximately 21 hours (80 minutes × 16 records/60 minutes per hour) for each hospital selected for participation in eCQM validation for the FY 2020 payment determination. We estimate that the total burden would be approximately 4,200 hours across the 200 hospitals selected for eCQM validation (21 hours per hospital × 200 hospitals = 4,200 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 4,333 hours across up to 200 hospitals selected for eCQM validation (4,200 hours estimated in this proposed rule −8,533 hours estimated in the FY 2017 IPPS/LTCH PPS final rule = −4,333 hours). Using the estimated hourly labor cost of $32.84, we estimate an annual cost reduction of $142,296 (4,333 hours × $32.84 per hour) across the 200 hospitals selected for eCQM validation due to our proposal to decrease the number of records collected for validation from 32 records to 16 records for the FY 2020 payment determination.

(2) Calculations for Proposed Modifications to the Validation of eCQM Data for the FY 2021 Payment Determination and Subsequent Years

Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) per record for the 24 records we are proposing that hospitals submit for eCQM validation for the FY 2021 payment determination, we estimate a total burden of approximately 32 hours (80 minutes × 24 records/60 minutes per hour) for each hospital selected for participation in eCQM validation. We estimate that the total burden would be approximately 6,400 hours across the 200 hospitals selected

for eCQM validation (32 hours per hospital × 200 hospitals = 6,400 hours). We note that compared to our total burden estimate of 8,533 hours previously estimated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57261) for the FY 2020 payment determination and subsequent years, this would represent a burden reduction of approximately 2,133 hours across up to 200 hospitals selected for eCQM validation for the FY 2021 payment determination (6,400 hours estimated for the FY 2021 payment determination in this proposed rule—8,533 hours estimated in the FY 2017 IPPS/LTCH PPS final rule = −2,133 hours). Using the estimated hourly labor cost of $32.84, we estimate an annual cost reduction of $70,048 (2,133 hours × $32.84 per hour) across the 200 hospitals selected for eCQM validation due to our proposal to reduce the number of records collected from 32 records as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178) to 24 records for the FY 2021 payment determination.

(3) Calculations for Proposed Modifications to the eCQM Validation Exclusions for the FY2020 Payment Determination and Subsequent Years

In section IX.A.11.b. of the preamble of this proposed rule, we are proposing a new eCQM validation exclusion criterion. Specifically, hospitals that do not have at least five discharges for at least one reported eCQM (among the six required eCQMs proposed for the CY 2017 and CY 2018 eCQM reporting periods) included in their QRDA I file submissions would be excluded from the random sample of up to 200 hospitals selected for eCQM validation for the FY 2020 payment determination and subsequent years. In summary, for the FY 2020 payment determination and subsequent years, we would exclude hospitals meeting the newly proposed exclusion criterion discussed above and/or either of the two exclusion criteria finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178). Lastly, we are proposing that the three exclusions would be applied before the random selection of 200 hospitals for eCQM validation, such that hospitals meeting any of these exclusions would not be eligible for selection.

In section IX.A.11.b. of the preamble of this proposed rule, we are proposing to exclude the following cases from validation for those hospitals selected to participate in eCQM 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 proposals will impact the burden experienced by hospitals because, while they influence which hospitals and cases would be selected, they would not change the number of hospitals that must participate in eCQM validation, the number of records that would be collected for validation, or the validation reporting requirements for the hospitals selected.

(4) Calculations for the Proposed Modifications to the Medical Record Submission Requirements for the FY 2021 Payment Determination and Subsequent Years

In section IX.A.11.b. of the preamble of this proposed rule, we are proposing for the FY 2021 payment determination and subsequent years, to apply the medical record submission requirements that were finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179) only for the FY 2020 payment determination. Specifically, we are proposing that for hospitals participating in eCQM validation we: (1) Would require submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner; and (2) would maintain the previously finalized policy that the accuracy of eCQM data submitted for validation would not affect a hospital's validation score (81 FR 57180). We do not expect these proposals to influence our burden estimates, as we are proposing to continue existing policies.

(5) Calculations for the Proposed Educational Review Process for Chart-Abstracted Measures for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.11.c. of the preamble of this proposed rule, we are proposing to formalize the process of allowing hospitals to use an educational review process to correct incorrect validation results for the first three quarters of validation for chart-abstracted measures. Secondly, we are proposing 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. Under this proposal, the educational review request process, as well as CMS' procedures for responding to requests, remain the same for the FY 2020 payment determination and subsequent years, except that revised scores identified through an educational review would be used to correct a hospital's validation score. As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49762), we estimate a burden of 15 minutes per hospital to report structural measure data and to complete all forms, including the reconsideration request form and the educational review form. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for more detailed information on the burden associated with the chart-abstracted validation requirements (81 FR 57260). Although this proposal may allow hospitals to avoid the formal reconsideration process, we do not expect this proposal to influence our burden estimates for the chart-abstracted measures validation process as it would not change the requirements for selecting hospitals for validation of chart-abstracted measures nor change the chart-abstracted validation reporting requirements for the selected hospitals.

e. Burden Estimate for the Proposed Voluntary Reporting on the Hybrid Hospital-Wide 30-Day Readmission Measure for the CY 2018 Reporting Period

In section IX.A.7.a. of the preamble of this proposed rule, we are proposing voluntary reporting on the Hybrid Hospital-Wide 30-Day Readmission 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). 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 proposed rule, we are proposing that hospitals 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 voluntarily reporting this measure to be similar to our estimates for eCQM reporting (that is 10 minutes per measure, per quarter). We anticipate that approximately 100 hospitals would voluntarily report the Hybrid Hospital-Wide 30-Day Readmission measure. Therefore, using the estimate of 10 minutes per measure per quarter, we estimate that our proposal would result in a burden increase of 0.67 hours (40 minutes) per participating hospital for

the one year (4 quarters) during which this pilot would 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 Hospital-Wide 30-Day Readmission 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 wage estimate described above, we estimate this to represent a cost increase of $2,200 ($32.84 hourly wage × 67 annual hours) across up to 100 hospitals voluntarily participating in the pilot. We note that the claims-based version of the Hospital-Wide All-Cause Unplanned Readmission (HWR) 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 Proposed 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 proposed rule, we are proposing to update the HCAHPS Survey measure by replacing the current 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. In addition, consistent with previous years (81 FR 57261), the burden estimate for the Hospital IQR Program excludes the burden associated with the HCAHPS survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981.

g. Burden Estimate for the Proposed 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 proposed rule, we are proposing to update 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 proposed update would 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 Confidential and Potential Future Public Reporting of Readmission Measure Data Stratified by Social Risk Factors

In section IX.A.13 of the preamble of this proposed rule we discuss our intent to provide confidential reports to hospitals that include measure data stratified by dual eligible status for the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization and Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSRR) for Pneumonia measures. In addition to confidential reporting, we are seeking comment on options for public display of measure data stratified by social risk factor indicators on the *Hospital Compare* Web site. Because this proposal is related to the way we display data, and not the methods of data collection implemented by the hospitals, we believe no additional burden on hospitals would result from confidential reporting of stratified measure data using social risk factor indicators. We note that all measures for which we might consider confidential reporting or public display of stratified measure data would already be included in the Hospital IQR Program, and as claims-based measures, we do not expect any additional burden because these data are already reported to the Medicare program for payment purposes.

i. Burden Estimate for the Proposed Changes to the Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy for the FY2020 Payment Determination and Subsequent Years

In section IX.A.15.b. of the preamble of this proposed rule we discuss our intent to align the naming of this exception policy and update 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 proposals, we believe the updates will have no effect on burden for hospitals.

j. Summary of Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022, we estimate: (1) A total burden reduction of 11,000 hours (−11,000 hours due to the proposed updates to the CY 2017 eCQM reporting requirements) and a total cost reduction of $361,240 (−11,000 hours × $32.84 per hour) for the FY 2019 payment determination; (2) a total burden reduction of 11,966 hours (−7,700 hours due to the proposed updates to the CY 2018 eCQM reporting requirements—4,333 hours due to the proposed updates to the eCQM validation procedures for the FY 2020 payment determination + 67 hours for the proposed Hybrid Hospital-Wide 30-Day Readmission measure pilot) and a total cost reduction of $392,963 (−11,866 hours × $32.84 per hour) for the FY 2020 payment determination; and (3) a total burden reduction of 2,133 hours (−2,133 hours due to the proposed updates to eCQM validation procedures for the FY 2021 payment determination) and a total cost reduction of $70,048 (−2,133 hours × $32.84 per hour) for the FY 2021 payment determination. These are the burden estimate totals for which we are requesting OMB approval under OMB number 0938–1022.

HOSPITAL IQR PROGRAM FY 2019 PAYMENT DETERMINATION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for FY 2019 payment determination							
	Estimated time per record (minutes) FY 2019	Number reporting quarters per year FY 2019	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly proposed annual burden (hours) across IPPS hospitals for FY 2019 payment determination	Previously finalized annual burden (hours) across IPPS hospitals for FY 2019 payment determination per the FY 2017 IPPS/LTCH PPS final rule	Net difference in annual burden hours
Reporting on 6 eCQMs for 2 Quarters.	60 (10 minutes × 6 measures).	2	3,300	1	2	6,600	17,600	−11,000
	Total Change in Burden Hours: −11,000							
	Total Cost Estimate: Hourly Wage ($32.84) × Change in Burden Hours (−11,000) = −$361,240							

HOSPITAL IQR PROGRAM FY 2020 PAYMENT DETERMINATION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for FY 2020 payment determination							
	Estimated time per record (minutes) FY 2020	Number reporting quarters per year FY 2020	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly proposed annual burden (hours) across IPPS hospitals for FY 2020 payment determination	Previously finalized annual burden (hours) across IPPS hospitals per the FY 2017 IPPS/LTCH PPS final rule	Net difference in annual burden hours
Reporting on 6 eCQMs for 3 Quarters.	60 (10 minutes × 6 measures).	3	3,300	1	3	9,900	17,600	−7,700
FY 2020 eCQM Validation	80	2	200	8	21	4,200	8,533	−4,333
Hybrid Hospital-Wide 30-Day Readmission Measure Voluntary Pilot.	10	4	100	1	0.67	67	0	67
	Total Change in Burden Hours: −11,966							
	Total Cost Estimate: Hourly Wage ($32.84) × Change in Burden Hours (−11,966) = −$392,963							

HOSPITAL IQR PROGRAM FY 2021 PAYMENT DETERMINATION BURDEN ESTIMATES

Activity	Annual recordkeeping and reporting requirements under OMB control number 0938–1022 for FY 2021 payment determination							
	Estimated time per record (minutes) FY 2021	Number reporting quarters per year FY 2021	Number of IPPS hospitals reporting	Average number records per hospital per quarter	Annual burden (hours) per hospital	Newly proposed annual burden (hours) across IPPS hospitals for FY 2021 payment determination	Previously finalized annual burden (hours) across IPPS hospitals per the FY 2017 IPPS/LTCH PPS final rule	Net difference in annual burden hours
FY 2021 eCQM Validation	80	3	200	8	32	6,400	8,533	−2,133
	Total Change in Burden Hours: −2,133							
	Total Cost Estimate: Hourly Wage ($32.84) × Change in Burden Hours (−2,133) = −$70,048							

7. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

As discussed in sections IX.B. of the preamble of this proposed rule, section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. 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 for the program requirements that we have previously adopted. Below we discuss only changes in burden that would result from the proposals in this proposed 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 performing chart abstraction indicates that this work is performed by a different labor category than we previously thought. In addition, our previous labor cost is 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 proposing to revise our hourly labor cost estimate to $32.84.[509]

This labor cost is based on the 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.'' [510] 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 would 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 is $16.42 per hour, before inclusion of overhead and fringe benefits.

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 proposing to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, as is currently done in other CMS quality reporting programs.[511] 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 ($16.42 × 2 = $32.84) to estimate total cost is a reasonably accurate estimation method. Accordingly, we are proposing to use an hourly labor cost estimate of $32.84 ($16.42 base salary + $16.42 fringe and overhead) for calculation of burden forthwith. We note that more recent wage data has become available, and we intend to update the wage rate used in these calculations in the FY 2018 IPPS/LTCH PPS final rule.

We are inviting public comment on this proposal.

b. Estimated Burden of PCHQR Program Proposals for the FY 2020 Program Year

In section IX.B.4. of the preamble of this proposed rule, we are proposing 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 proposal in section IX.B.3. of the preamble of this proposed rule, we are proposing to 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)). If all of these proposals are finalized, the PCHQR Program measure set would consist of 18 measures for the FY 2020 program.

Our proposal to remove the three chart-abstracted measures would reduce the burden associated with quality data reporting on PCHs. Based on the FY 2013 IPPS/LTCH 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 proposed 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 41,536 hours per year across the 11 PCHs.[512]

We do not anticipate any increase in burden on the PCHs corresponding to our proposal 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 proposals, we estimate a reduction of 40,910 hours of burden per year associated with the proposals above for all 11 PCHs beginning with the FY 2020 program. Coupled with our revised estimated salary costs, we estimate that these proposed changes would result in a reduction in annual labor costs of $1,364,078 (41,537.1 hours × $32.84 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 0938–1175. The information collection will be revised and submitted to OMB.

8. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.J. of the preamble of this proposed rule, we discuss proposed requirements for the Hospital VBP Program. Specifically, in this proposed rule, with respect to quality measures, we are proposing to: (1) Remove the current 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

[509] *https://www.bls.gov/oes/2012/may/oes292071.htm.*

[510] *http://www.bls.gov/bls/infohome.htm.*

[511] See, *e.g.,* FY2016 IPPS/LTCH Final Rule at 80 FR 49764 FN 153.

[512] 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).

(Composite) (NQF #0531) (Modified PSI 90) beginning with the PY 2023 program year.

As required under section 1886(o)(2)(A) of the Act, Hospital VBP Program measures, including the proposed 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.

9. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As discussed in section IX.C.7. of the preamble of this proposed rule, we are proposing to replace the current pressure ulcer measure beginning with the FY 2020 LTCH QRP and adopt two new measures (one process and one outcome) related to ventilator weaning also beginning with the FY 2020 LTCH QRP.

LTCH QRP Quality Measures Proposed in This FY 2018 IPPS/LTCH PPS Proposed 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 proposed rule, we are proposing 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).

In this proposed rule, we are proposing 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. The data for these measures will be collected using the LTCH CARE Data Set Version 4.00.

The LTCH CARE Data Set Version 4.00, effective April 1, 2018, will also 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 proposing to adopt in this proposed rule.

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), would 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 proposed measure would be reduced from the burden and cost to report the current measure. Specifically, we believe that there would 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 would 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 proposed Compliance with SBT by Day 2 of the LTCH Stay quality measure would 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 proposing 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 would 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 proposed Ventilator Liberation Rate quality measure would 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 proposing will be completed by registered nurses and respiratory therapists. Individual providers 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 would 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 proposing to remove the program interruption items from the LTCH CARE Data Set. Specifically, we are proposing 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 would be reduced. Specifically, we believe that there would 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 would 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.b. of the preamble of this proposed rule, we are proposing requirements related to the reporting of standardized patient assessment data beginning with the FY 2019 LTCH QRP. Some of the proposed data elements are already included on the LTCH CARE Data Set, and our proposal to characterize those data elements as standardized patient assessment data will not result in an additional reporting burden for LTCHs. However, we are proposing 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. We estimate that it will take an LTCH's clinical staff 7.5 minutes to report the data elements required with respect to admissions and 5.1 minutes to report the data elements required with respect to discharges, for a total of additional 12.6 minutes. This equates to an increase of 30,784 hours in burden for all LTCHs (0.21 hours × 146,592 discharges). We believe that the additional LTCH CARE Data Set data elements we are proposing will be completed by registered nurses (approximately 45 percent of the time), licensed vocational nurses (approximately 45 percent of the time) and respiratory therapists (approximately 10 percent of the time). We estimate 146,592 discharges from 426 LTCHs annually.

We obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2016 National Occupational Employment and Wage Estimates (*https://www.bls.gov/oes/current/oes_nat.htm*). The mean hourly wage for a RN (BLS occupation code: 29–1141) is $34.70, for a respiratory therapist (BLS occupation code: 29–1126) is $29.15, and for a licensed vocational nurse (BLS occupation code: 29–2061) is $21.56. Individual providers determine the staffing resources necessary. However, to account for overhead and fringe benefits, we have doubled the mean hourly wage, making it $69.40 for an RN, $58.30 for a respiratory therapist, and $43.12 for a licensed vocational nurse. Given the clinician times and wages above completing an average of 344 sets of LTCH CARE Data Set assessments per provider per year, the total cost related to the additional standardized patient assessment data elements is estimated at $4,080.30 per LTCH annually, or $1,738,206 for all LTCHs annually.

In summary, the 4.5-minute increase in burden for the two proposed ventilator weaning quality measures is offset with the 3 minute reduction in burden for the proposed 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. In addition, we are proposing that data for the new standardized data elements will be collected by LTCHs and reported to CMS using the LTCH CARE Data Set (LTCH CARE Data Set Version 4.00, effective April 1, 2018) for the purpose of fulfilling the requirements of the IMPACT Act. This results in an additional 12.6 minutes of burden for the proposed standardized data elements, with a net burden of 10.5 minutes. Overall, the cost associated with the proposed changes to the LTCH QRP is estimated at an additional $3,187.15 per LTCH annually, or $1,357,726 for all LTCHs annually.

The proposed 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-Quality-Reporting-Measures-Information.html*.

For a discussion of burden related to LTCH CARE Data Set Version 4.00, we refer readers to section I.M. of Appendix A of the preamble of this proposed rule.

10. 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 (81 FR 57265 through 57266) final rule 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 materials associated with OMB 0938–1171, the OMB Paperwork Reduction Act materials for this Program. We are proposing provisions that affect the FY 2019 payment determination (through procedural requirements that occur in FY 2018) and the FY 2020 payment determination and subsequent years. ICRs associated with proposals for each period are discussed in more detail below.

a. Burden Associated With Procedural Proposals for the FY 2019 Payment Determination and Subsequent Years

For FY 2018 and subsequent years we are proposing: (1) Updates to the Extraordinary Circumstances Exception (ECE) process (affecting submission of ECE requests in FY 2018, which would impact payment determination year FY 2019 and subsequent years); (2) to adopt measure removal factors, including criteria for determining when a measure is ''topped-out,'' and measure retention factors (which could affect measures for the FY 2020 payment determination and subsequent years); and (3) changes associated with procedural deadlines (which affects FY 2019 payment determination and subsequent years).

For the ECE proposals, we are specifically proposing to: (1) Specify that ECE forms can 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) we will strive to complete our review of ECE requests within 90 days of receipt. These changes to the ECE process would 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 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 proposing 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 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 proposing 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.

b. Burden Associated With Proposal for the FY 2020 Payment Determination and Subsequent Years

For FY 2020 and subsequent years, we are proposing one measure, Medication Continuation following Inpatient Psychiatric Discharge. This measure is claims based and therefore does not require facilities to report any additional data. Because this measure does not require facilities to submit any additional data, we do not believe that there is any associated burden associated with this proposal.

11. ICRs for the Electronic Health Record (EHR) Incentive Programs and Meaningful Use

In section IX.E. of the preamble of this proposed rule, we discuss proposed policies for eligible hospitals and CAHs reporting CQMs electronically under the Medicare and Medicaid EHR Incentive Programs. As outlined in this proposed rule, we are proposing 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 2 self-selected quarters of data; and (2) revise the number of CQMs eligible hospitals and CAHs are required to report electronically for CY 2017 to 6 (self-selected) available CQMs. In addition, we are proposing the following CQM reporting requirements for CY 2018: (1) 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 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 would be required to report at least 6 (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, would 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 would have a submission period that would be the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019.

Because the proposed reporting requirements for data collection regarding the reporting of CQMs electronically under the Medicare and Medicaid EHR Incentive Programs would 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 are not proposing modifications for the CQMs reporting requirements by attestation. Therefore, there would be no change in burden associated with attestation of CQMs.

In section IX.F. of the preamble of this proposed rule, we discuss proposed 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 proposed policies. State attestation systems would 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 Advanced 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 proposals, 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 proposed CQM 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.

In section IX.G.1. of the preamble of this proposed rule, we discuss our proposals to change the EHR reporting period in 2018 from the full CY 2018 to any continuous 90-day period within CY 2018 for all returning EPs, eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs. We do not believe that modifying the EHR reporting period would cause an increase in burden as the reporting requirements for a 90 day reporting period are virtually the same for a full calendar year reporting period and the same objectives and measures will be used for reporting for a full calendar year reporting or a 90 day reporting period.

In section IX.G.2. of the preamble of this proposed rule, as required by the 21st Century Cures Act (Pub. L. 114–255), we are proposing 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 this proposed rule, as required by the 21st Century Cures Act, we are proposing 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 would cause an increase in burden as CMS would identify the EPs who might meet this requirement.

For the expected effects relating to the above proposals, we refer readers to section I.O. of Appendix A of this proposed rule.

We are requesting public comments on these information collection and recordkeeping requirements.

12. ICRs Relating to Proposed Electronic Signature and Electronic Submission of the Certification and Settlement Summary Page of Medicare Cost Reports

In section X.A. of the preamble of this proposed rule, we discuss 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 proposing 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 would be no new data collection from providers resulting from our proposal. The proposal to allow 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.

13. ICRs Relating to Survey and Certification Requirements

a. Proposed Transparency in Survey Reports and Plans of Correction

In section XI.A. of the preamble of this proposed rule, we are proposing to require accrediting organizations (AO) to post survey results and findings (that is, statements of deficiency findings) as well as any associated acceptable plans of correction (PoCs), and make this information publicly available on its Web site within 90 days after such information is made available to those facilities, for the most recent 3 years.

According to data and information available to us, as of September 30, 2016, there are approximately 12,434 deemed facilities (providers and suppliers) across all CMS-approved programs that have surveys (either initial and renewal, including complaints) for which an AO would be required to make survey reports and associated PoCs publicly available under our proposal.[513] [514] [515] The CY 2016 Advanced Diagnostic Imaging (ADI) AO annual data submission lists approximately 16,873 ADI suppliers and locations that have surveys (initial, renewal, complaint, and mid-cycle) (approximately 2,128) for which AOs of ADI suppliers would be required to make survey reports and PoCs publicly available on their Web site under our proposal. Unlike Medicare- and Medicaid-certified providers and suppliers, there are no prescriptive statutory, regulatory, or policy requirements regarding the frequency of ADI AOs surveys.

We do not have sufficient data to determine the burden associated with the information collection requirements under our proposal. Therefore, we are requesting public comments on the potential costs and burden associated with our proposal on AOs regarding modifying their existing public Web sites and uploading of survey reports and PoCs.

b. Proposed Changes in Public Notices of Terminations

In section XI.B. of the preamble of this proposed rule, we are proposing 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 would be permitted to use other methods of notification in light of the expanded use of information technology. We also are proposing 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 proposed 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.P. of Appendix A of this proposed rule for additional information.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS–1677–P

Fax: (202) 395–6974; or

Email: OIRA_submission@omb.eop.gov.models.

C. Request for Information on CMS Flexibilities and Efficiencies

CMS is committed to transforming the health care delivery system—and the Medicare program—by putting an additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes. We seek to reduce burdens for hospitals, physicians, and patients, improve the quality of care, decrease costs, and ensure that patients and their providers and physicians are making the best health care choices possible. These are the reasons we are including this Request for Information in this proposed rule.

As we work to maintain flexibility and efficiency throughout the Medicare program, we would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families. We aim to increase quality of care, lower costs improve program integrity, and make the health care system more effective, simple and accessible.

We would like to take this opportunity to invite the public to submit their ideas for regulatory, subregulatory, policy, practice, and procedural changes to better accomplish these goals. Ideas could include payment system redesign, elimination or streamlining of reporting, monitoring and documentation requirements, aligning Medicare requirements and processes with those from Medicaid and other payers, operational flexibility, feedback mechanisms and data sharing that would enhance patient care, support of the physician-patient relationship in care delivery, and facilitation of individual preferences. Responses to this Request for Information could also include recommendations regarding when and how CMS issues regulations and policies and how CMS can simplify rules and policies for beneficiaries, clinicians, physicians, providers, and suppliers. Where practicable, data and specific examples would be helpful. If the proposals involve novel legal questions, analysis regarding CMS' authority is welcome for CMS' consideration. We are particularly interested in ideas for incentivizing organizations and the full range of relevant professionals and paraprofessionals to provide screening, assessment and evidence-based treatment for individuals with opioid use disorder and other substance use disorders, including reimbursement methodologies, care coordination, systems and services integration, use of paraprofessionals including community paramedics and other strategies. We are requesting commenters to provide clear and concise proposals that include data and specific examples that could be implemented within the law.

We note that this is a Request for Information only. Respondents are encouraged to provide complete but concise responses. This Request for Information is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This Request for Information does not commit the U.S. Government to contract for any supplies or services or make a grant award.

[513] FY 2016 Report to Congress (RTC): Review of Medicare's Program Oversight of Accrediting Organizations (AOs) and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Validation Program—Section 2, Table 5.

[514] CMS Survey and Certification Web site for hospital Form CMS–2567 (Statement of Deficiencies and Plan or Correction) downloads: *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/Hospitals.html.*

[515] ProPublica (2016) Web site: *http://projects.propublica.org/nursing-homes/.*

Further, CMS is not seeking proposals through this Request for Information and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Request for Information; all costs associated with responding to this Request for Information will be solely at the interested party's expense. We note that not responding to this Request for Information does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this Request for Information announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this Request for Information. CMS will not respond to comment submissions in response to this Request for Information in the FY 2018 IPPS/LTCH PPS final rule. Rather, CMS will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. CMS may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this Request for Information. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Request for Information may be used by the Government for program planning on a nonattribution basis. Respondents should not include any information that might be considered proprietary or confidential. This Request for Information should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the public comments received, or a summary of those public comments.

D. Response to Public Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all public comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the public comments in the preamble of that document.

List of Subjects

42 CFR Part 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 414

Administrative practice and procedures, Biologics, Drugs, Health facilities, Health professions, Kidney diseases, Medicare, 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 proposed rule, the Centers for Medicare and Medicaid Services is proposing to amend 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 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:

* * * * *

■ 6. Section 412.23 is amended by revising paragraphs (e)(2)(ii), (e)(3)(vi), and (e)(7)(iii) and adding paragraph (j) 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.

* * * * *

(j) *Long-term care neoplastic disease hospitals*—(1) *General.* For cost reporting periods beginning on or after January 1, 2015, a long-term care neoplastic disease hospital must be 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.* Payment for inpatient operating costs for hospitals classified under paragraph (j)(1) of this section is made as set forth in § 412.526(c)(3). Payment for capital costs for hospitals classified under paragraph (j)(1) of this section is made as set forth in § 412.526(c)(4).

■ 7. Section 412.64 is amended by—

■ a. Revising paragraph (d)(1)(vii);

■ b. Adding paragraph (d)(4)(iii); 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 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.

* * * * *

(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 Medicare inpatient operating costs to its total Medicare 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 (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 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 412.140 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.

* * * * *

■ 14. 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.

* * * * *

■ 15. 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, the hospital must submit documentation of the approval of sole community hospital or rural referral center status to the MGCRB no later than the first business day after January 1.

(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.* For the exceptions in this paragraph to apply, the hospital must submit documentation of the approval of rural referral center status to the MGCRB no later than the first business day after January 1.

(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.

* * * * *

■ 16. 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 classification, 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 of public display at the Office of the Federal Register 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.

(2) A request for termination must be received by the MGCRB within 45 days of the date of public display at the Office of the Federal Register 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 termination is to apply.

* * * * *

■ 17. 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.

* * * * *

■ 18. 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.

* * * * *

■ 19. 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)(5).

* * * * *

■ 20. 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.

* * * * *

■ 21. 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:

* * * * *

■ 22. 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.

* * * * *

■ 23. Section 412.560 is amended by revising the section heading, paragraphs (a), (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; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 24. The authority citation 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.

■ 25. 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 _____ and ending _____ 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 beginning on or after October 1, 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.

* * * * *

■ 26. 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:

* * * * *

■ 27. 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 revision 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.

* * * * *

■ 28. 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 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 29. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

■ 30. Section 414.68 is amended by redesignating paragraphs (c)(7) through (14) as paragraphs (c)(8) through (15), respectively, and adding new paragraph (c)(7) to read as follows:

§ 414.68 Imaging accreditation.

* * * * *

(c) * * *

(7) A statement acknowledging that the organization agrees to make all Medicare final accreditation survey reports (including statements of deficiencies) and acceptable plans of correction publicly available on the organization's Web site within 90 days after such information is made available to those facilities for the most recent 3 years, on an ongoing basis. This acknowledgement includes all full, follow-up, focused, and complaint surveys, regardless of whether they are performed onsite or offsite.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 31. 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).

■ 32. 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

■ 33. 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).

■ 34. 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

■ 35. 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).

■ 36. 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 final accreditation survey reports (including statements of deficiencies) and acceptable plans of correction publicly available on the organization's Web site within 90 days after such information is made available to those facilities for the most recent 3 years, on an ongoing basis. This acknowledgement includes all triennial, full, follow-up, focused, and complaint surveys, regardless of whether they are performed onsite or offsite.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 37. 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)).

■ 38. 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

■ 39. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 40. Section 495.4 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.

■ 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:

* * * * *

■ 41. 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: April 10, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 11, 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—Proposed 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 proposed 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 proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would 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 proposed standard Federal payment rate that would 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 proposed rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge. 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 proposed 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 proposing to make 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 proposed 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 proposed 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 proposed rule are listed in section VI. of this Addendum and are available via the Internet on the CMS Web site.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 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 are proposing to use for determining the proposed prospective payment rates for FY 2018.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the Internet 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 proposed rule for a complete discussion on the proposed 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
Proposed Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.725	−0.725
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.175	0.0	−2.175
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.75	−0.425	1.025	−1.15

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 proposed 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 proposed 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 proposing to apply 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 proposing to apply 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 proposed rule, the imputed floor is set to expire effective October 1, 2017, and we are not proposing to extend the imputed floor policy.

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 (FYs 2011 through 2016), 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 proposed 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. Thus, 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 proposed rule, we are proposing that if the selection of additional hospitals pursuant to section 410A(g)(6) of Public Law 108–173 (as added by section 15003 of Public Law 114–255) is 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). 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. We refer the reader to section V.L.3. of the preamble to this proposed rule for complete details on the rural community hospital demonstration program and our proposed methodology for calculating budget neutrality for this demonstration.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. 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 proposing to rebase and revise the national labor-related and nonlabor-related shares (based on the proposed 2014-based hospital market basket discussed in section IV. of the preamble of this proposed 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 proposed rule, we are proposing to 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 are proposing to 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.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the Internet on the CMS Web site.

2. Computing the National Average Standardized Amount

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 are proposing to calculate 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 proposed rule, we are proposing to use the revised and rebased 2014-based IPPS operating and capital market baskets for FY 2018. As discussed in section V.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2018 applicable percentage increase (which is based on IHS Global Insight, Inc.'s (IGI's) fourth quarter 2016 forecast of the proposed 2014-based IPPS market basket) by the MFP adjustment (the 10-year moving average of MFP for the period ending FY 2018) of 0.4 percentage point, which is calculated based on IGI's fourth quarter 2016 forecast.

In addition, in accordance with section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are proposing to further update the standardized amount for FY 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 2016 fourth quarter forecast of the hospital market basket increase (as discussed in Appendix B of this proposed rule), the forecast of the hospital market basket increase for FY 2018 for this proposed rule is 2.9 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 could be applied to the standardized amount. We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion on the proposed 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 would be applied to update the national standardized amount. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the Internet on the CMS Web site reflect these differential amounts.

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 proposed recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in Appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed 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 proposed 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 are proposing to adjust 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 apply budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed 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, we are proposing to continue to include all applicable data from subsection (d) hospitals participating in BPCI Models 1, 2, and 4 in our IPPS payment modeling and ratesetting calculations.

• 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 proposing to continue 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 are proposing to apply the proposed readmissions payment adjustment factor and the proposed hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

For the purpose of calculating the proposed FY 2018 readmissions payment adjustment factors, we are proposing to use excess readmission ratios and aggregate payments for excess readmissions based on admissions from the prior fiscal year's applicable period because hospitals have had the opportunity to review and correct these data before the data were made public under the policy we adopted regarding the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act. For FY 2018, in this proposed rule, we are proposing to calculate the readmissions payment adjustment factors using excess readmission ratios and aggregate payments for excess readmissions based on admissions from the finalized applicable period for FY 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 proposed policy regarding the reporting of hospital-specific readmission rates for FY 2018 in section V.I.3.f. of the preamble of this proposed rule. (For additional information on our general policy for the reporting of hospital-specific readmission rates, consistent with section 1886(q)(6) of the Act, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53399 through 53400).)

In addition, for FY 2018, in this proposed rule, for the purpose of modeling aggregate payments when determining all budget neutrality factors, we are proposing to use proxy hospital VBP payment adjustment factors for FY 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 will receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under age 65 who are uninsured and an additional statutory adjustment, will be available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2018 (as we did for the last 4 fiscal years), we are proposing to include estimated empirically justified Medicare DSH payments that will be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• 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 proposed rule and below, we are proposing to continue the FY 2014 finalized methodology under which we would take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

• We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2018. Similar to FY 2017, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2018.

a. Proposed 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 proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

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 proposed 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 proposed FY 2018 relative weights, and the FY 2017 pre-reclassified wage data, and applied the same proposed FY 2018 hospital readmissions payment adjustments and estimated FY 2018 hospital VBP payment adjustments applied above.

Based on this comparison, we computed a proposed budget neutrality adjustment factor equal to 0.997573 and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we also are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor of 0.997555 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 are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this proposed rule.

To compute a proposed 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 proposed 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 proposed FY 2018 hospital readmissions payment adjustment and the estimated FY 2018 hospital VBP payment adjustment; and
- Aggregate payments using the proposed FY 2018 relative weights and the proposed FY 2018 pre-reclassified wage indexes, applied the proposed 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 proposed FY 2018 hospital readmissions payment adjustments and estimated FY 2018 hospital VBP payment adjustments applied above.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2017 to FY 2018. By applying this methodology, we determined a proposed budget neutrality adjustment factor of 1.000465 for proposed changes to the wage index.

c. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2018, we used FY 2016 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2018 labor-related share percentages, proposed FY 2018 relative weights and proposed 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 proposed FY 2018 hospital readmissions payment adjustments and the estimated FY 2018 hospital VBP payment adjustments; and
- Aggregate payments using the proposed FY 2018 labor-related share percentages, proposed FY 2018 relative weights, and proposed FY 2018 wage data after such reclassifications, and applied the same proposed 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 proposed rule, which is available via the Internet on the CMS Web site. This table reflects reclassification crosswalks proposed for FY 2018, and apply the proposed policies explained in section III. of the preamble to this proposed rule. Based on these simulations, we calculated a proposed budget neutrality adjustment factor of 0.988522 to ensure that the effects of these provisions are budget neutral, consistent with the statute.

The proposed 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 proposed FY 2018 budget neutrality adjustment reflects FY 2018 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of the proposed rule.

d. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) is equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.H. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

As noted above and as discussed in section III.H.2. of the preamble of this proposed rule, the imputed floor is set to expire effective October 1, 2017, and we are not proposing to extend the imputed floor policy.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2018, we are proposing to calculate a national rural Puerto

Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the proposed 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 will use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous (share a border with) to the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2018 rural Puerto Rico wage index is calculated based on the average of the proposed 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 budget neutrality adjustment factor, we are proposing to use FY 2016 discharge data to simulate payments and the proposed post-reclassified national wage indexes and compared the following:

- National simulated payments without the proposed national rural floor; and
- National simulated payments with the proposed national rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor of 0.993672. The national adjustment was applied to the national wage indexes to produce a proposed national rural floor budget neutral wage index.

e. Proposed 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 proposing to implement the required +0.4588 percent adjustment to the standardized amount. This is a permanent adjustment to payment rates. 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. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, 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) Proposed 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 proposed FY 2018 outlier threshold, we simulated payments by applying proposed FY 2018 payment rates and policies using cases from the FY 2016 MedPAR file. Therefore, in order to determine the proposed 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 final rule (81 FR 57282), we are using 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 final rule (80 FR 49779–49780), 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 2018 Proposed Rule Data Files''') a more detailed summary table by provider with the monthly charges that were used to compute the charge inflation factor. We 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	517,993,138,897	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 is 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.

As we have done in the past, in this proposed rule, we are proposing to establish the proposed 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 this proposed rule. We are proposing 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 also are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained below). We are proposing that, if more recent data become 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 did for the last 4 fiscal years, we are proposing 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 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, we calculated a proposed December 2015 operating national average case-weighted CCR of 0.274139 and a proposed 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, 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 this proposed rule, in accordance with section 10324(a) of the Affordable Care Act, we created a wage index floor of 1.0000 for all hospitals located in States determined to be frontier States. We note that the frontier State floor adjustments would be calculated and applied after rural floor budget neutrality adjustments are calculated for all labor market areas, in order to ensure that no hospital in a frontier State would receive a wage index less than 1.0000 due to the proposed rural floor adjustment. In accordance with section 10324(a) of the Affordable Care Act, the frontier State adjustment will not be subject to budget neutrality, and will only be extended to hospitals geographically located within a frontier State. However, for purposes of estimating the proposed outlier threshold for FY 2018, it was necessary to adjust the proposed wage index of those eligible hospitals in a frontier State when calculating the proposed outlier threshold that results in outlier payments being 5.1 percent of total payments for FY 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 proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments.

As we did in establishing the FY 2009 outlier threshold (73 FR 57891), in our projection of FY 2018 outlier payments, we are proposing not to make any adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled upon cost report settlement. We continue to believe that, due to the policy implemented in the June 9, 2003 Outlier Final Rule (68 FR 34494), CCRs will no longer fluctuate significantly and, therefore, few hospitals

will actually have these ratios reconciled upon cost report settlement. In addition, it is difficult to predict the specific hospitals that will have CCRs and outlier payments reconciled in any given year. We note that we have instructed MACs to identify for CMS any instances where (1) a hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that period. Our simulations assume that CCRs accurately measure hospital costs based on information available to us at the time we set the outlier threshold. For these reasons, we are proposing not to make any assumptions regarding the effects of reconciliation on the outlier threshold calculation.

As described in sections V.I. and V.J. respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) 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, we also are proposing for FY 2018 to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2018, we are proposing to include estimated FY 2018 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we 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 used 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 are proposing 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.

(2) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a lower percentage of outlier payments for capital-related costs than for operating costs. We project that the thresholds for FY 2018 will result in outlier payments that will equal 5.1 percent of operating DRG payments and 5.66 percent of capital payments based on the Federal rate.

In accordance with section 1886(d)(3)(B) of the Act, we are proposing to reduce the FY 2018 standardized amount by the same percentage to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the standardized amount based on the proposed FY 2018 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate
National	0.948999	0.943414

We are proposing to apply the outlier adjustment factors to the proposed 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 1.17 or capital CCRs greater than 0.161, 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 proposed 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 would be effective for discharges occurring on or after October 1, 2017 and would 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 proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would 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 proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that we published a manual update (Change Request 3966) to our outlier policy on October 12, 2005, which updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update covered an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their 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 ratio at any time as long as the guidelines of Change Request

3966 are followed. In addition, as mentioned above, we published an additional manual update (Change Request 7192) to our outlier policy on December 3, 2010, which also updated Chapter 3, Section 20.1.2 of the Medicare Claims Processing Manual. The manual update outlines the outlier reconciliation process for hospitals and Medicare contractors. To download and view the manual instructions on outlier reconciliation, we refer readers to the CMS Web site: *http://www.cms.hhs.gov/manuals/downloads/clm104c03.pdf.*

(3) FY 2016 Outlier Payments

Our current estimate, using available FY 2016 claims data, is that actual outlier payments for FY 2016 were approximately 5.37 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 proposed rule. We will provide an estimate of actual FY 2017 outlier payments in the FY 2019 IPPS/LTCH PPS proposed rule.

5. Proposed 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 proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2018. The proposed 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 proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 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 proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we will apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2018.

The proposed 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 proposed FY 2018 national standardized amount. The second through fifth columns display the proposed 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 PROPOSED 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.	Labor (62%): $3,625.34.	Labor (62%): $3,625.34.	Labor (62%): $3,625.34.
	Nonlabor (38%): $2,221.98.	Nonlabor (38%): $2,221.98.	Nonlabor (38%): $2,221.98.	Nonlabor (38%): $1,853.60.
Proposed FY 2018 Update Factor.	1.0175	0.99575	1.01025	0.9885.

CHANGES FROM FY 2017 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2018 STANDARDIZED AMOUNTS—Continued

	Hospital submitted quality data and is a meaningful EHR user	Hospital submitted quality data and is NOT a meaningful EHR user	Hospital did NOT submit quality data and is a meaningful EHR user	Hospital did NOT submit quality data and is NOT a meaningful EHR user
Proposed FY 2018 MS-DRG Recalibration Budget Neutrality Factor.	0.997573	0.997573	0.997573	0.997573.
Proposed FY 2018 Wage Index Budget Neutrality Factor.	1.000465	1.000465	1.000465	1.000465.
Proposed FY 2018 Reclassification Budget Neutrality Factor.	0.988522	0.988522	0.988522	0.988522.
Proposed FY 2018 Operating Outlier Factor.	0.948999	0.948999	0.948999	0.98999.
Proposed 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.
Proposed National Standardized Amount for FY 2018 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (68.3/31.7).	Labor: $3,822.07 Nonlabor: $1,773.93	Labor: $3,740.37 Nonlabor: $1,736.01	Labor: $3,794.84 Nonlabor: $1,761.29	Labor: $3,713.14. Nonlabor: $1,723.37.
Proposed 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: $3,469.52 Nonlabor: $2,126.48	Labor: $3,395.36 Nonlabor: $2,081.02	Labor: $3,444.80 Nonlabor: $2,111.33	Labor: $3,370.64. Nonlabor: $2,065.87.

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. While we are not proposing any changes at this time, we are 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.

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the Internet on the CMS Web site), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2018. This section addresses two types of adjustments to the standardized amounts that are made in determining the proposed prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national 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 proposed rule, we are proposing to 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 are proposing to 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 proposed rule, we discuss the data and methodology for the proposed FY 2018 wage index.

2. Proposed 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 are proposing 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 are proposing 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 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 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 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 and 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 proposed 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, we are proposing for FY 2018 to continue to use such a cap, as our proposal is based on OPM's COLA factors (updated by the methodology described above).

Applying this methodology, the COLA factors that we are proposing 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 used to determine the proposed 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). 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.

C. Calculation of the Proposed 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 proposed rule, includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 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 proposed 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
Proposed Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.725	−0.725
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.175	0.0	−2.175
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Hospital-Specific Rate	1.75	−0.425	1.025	−1.15

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 proposed rule.

In addition, because SCHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital-specific rate for an SCH is adjusted by the proposed MS–DRG reclassification and recalibration

budget neutrality factor of 0.997573, 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 proposed rule, for FY 2018, we are not proposing to make a documentation and coding adjustment to the hospital-specific rate. We refer readers to section II.D. of the preamble of this proposed rule for a complete discussion regarding our proposed policies and previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case-mix.

Also, as discussed in section V.M. of the preamble of this proposed 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 proposed 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. Proposed 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 are proposing to use to determine the capital Federal rate for FY 2018, which would 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 Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2018

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2018. In particular, we explain why the proposed FY 2018 capital Federal rate would increase approximately 1.03 percent, compared to the FY 2017 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 2.4 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Proposed 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 proposed update factor for FY 2018 under that framework is 1.2 percent based on a projected 1.2 percent increase in the proposed 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 proposed FY 2018 CIPI projection in that same section of this Addendum. Below we describe the policy adjustments that we are proposing to apply in the update framework for FY 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 proposed 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 proposed update for FY 2018. We estimate that 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 proposing to make 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 proposing not to make 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 proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 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 proposing to use an intensity measure that is based on an average of cost per discharge data from the 5-year period beginning with FY 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 proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2018.

Above, we described the basis of the components we are proposing to use to develop the proposed 1.2 percent capital update factor under the capital update framework for FY 2018 as shown in the following table.

CMS PROPOSED FY 2018 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	1.2
Intensity:	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Subtotal	1.2
Effect of FY 2016 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Proposed Update	1.2

*The capital input price index represents the proposed 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. Proposed Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A single set of thresholds is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier thresholds are set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments.

For FY 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 would equal 5.66 percent for inpatient capital-related payments based on the capital Federal rate in FY 2018. Therefore, we are proposing to apply an outlier adjustment factor of 0.9434 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 proposed FY 2018 outlier adjustment of 0.9434 is a 0.51 percent change from the FY 2017 outlier adjustment of 0.9386. Therefore, the net change in the proposed outlier adjustment to the capital Federal rate for FY 2018 is 1.0051(0.9434/0.9386). Thus, the proposed outlier adjustment would increase the FY 2018 capital Federal rate by 0.51 percent compared to the FY 2017 outlier adjustment.

3. Proposed Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes. 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 proposed 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 proposed FY 2018 GAFs. To achieve budget neutrality for the changes in the national GAFs, based on calculations using updated data, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9997 for FY 2018 to the previous cumulative FY 2017 adjustment factor of 0.9850, yielding an adjustment factor of 0.9847 through FY 2018.

We then compared estimated aggregate capital Federal rate payments based on the FY 2017 MS–DRG relative weights and the

proposed FY 2018 GAFs to estimated aggregate capital Federal rate payments based on the cumulative effects of the proposed FY 2018 MS–DRG classifications and relative weights and the proposed FY 2018 GAFs. The proposed incremental adjustment factor for DRG classifications and changes in relative weights is 0.9994. The proposed cumulative adjustment factor for MS–DRG classifications and changes in relative weights and for changes in the GAFs through FY 2018 is 0.9842. (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 proposed cumulative adjustment factor of 0.9992 (the product of the proposed incremental national GAF budget neutrality adjustment factor of 0.9997 and the proposed incremental DRG budget neutrality adjustment factor of 0.9994) 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 proposed rule). We refer readers to sections V.M. and VI.C. of the preamble of this proposed rule for a complete discussion of these issues.

4. Proposed 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 proposing to establish an update of 1.2 percent in determining the FY 2018 capital Federal rate for all hospitals. As a result of this proposed update, the proposed 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 final rule (81 FR 57294), we are proposing to establish a national capital Federal rate of $451.37 for FY 2018. The proposed national capital Federal rate for FY 2018 was calculated as follows:

- The proposed FY 2018 update factor is 1.0120; that is, the proposed update is 1.2° percent.
- The proposed 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 0.9992.
- The proposed FY 2018 outlier adjustment factor is 0.9434.
- 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 proposed 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 proposing to make additional adjustments in the capital Federal rate for these factors, other than the proposed 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 proposed factors and adjustments for FY 2018 affects the computation of the proposed FY 2018 national capital Federal rate in comparison to the FY 2017 national capital Federal rate. The proposed FY 2018 update factor has the effect of increasing the capital Federal rate by 1.02° percent compared to the FY 2017 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.08° percent. The proposed FY 2018 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.51 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 proposed changes would increase the proposed national capital Federal rate by approximately 1.03° percent compared to the FY 2017 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2017 CAPITAL FEDERAL RATE AND FY 2018 PROPOSED CAPITAL FEDERAL RATE

	FY 2017	Proposed FY 2018	Proposed change	Proposed percent change
Update Factor [1]	1.0090	1.0120	1.0120	1.20
GAF/DRG Adjustment Factor [1]	0.9990	0.9992	0.9992	−0.08
Outlier Adjustment Factor [2]	0.9386	0.9434	1.0051	0.51
Removal of One-Time 2-Midnight Policy Adjustment Factor	1.0060	1/1.006	0.9940	−0.6
Capital Federal Rate	$446.79	$451.37	1.0103	[3] 1.03

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the proposed incremental change from FY 2017 to FY 2018 resulting from the application of the proposed 0.9992 GAF/DRG budget neutrality adjustment factor for FY 2018 is a proposed net change of 0.9992 (or −0.08 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 proposed net change resulting from the application of the proposed FY 2018 outlier adjustment factor is 0.9434/0.9386 or 1.0051 (or 0.51 percent).

[3] Proposed percent change may not sum due to rounding.

In this proposed rule, we also are providing the following chart that shows how the proposed FY 2018 capital Federal rate differs from the final FY 2017 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).

COMPARISON OF FACTORS AND ADJUSTMENTS: PROPOSED FY 2018 CAPITAL FEDERAL RATE AND FINAL FY 2017 CAPITAL FEDERAL RATE

	Final FY 2017	Proposed FY 2018	Change	Percent change
Update Factor [1]	1.0090	1.0120	1.0120	1.20
GAF/DRG Adjustment Factor [1]	0.9990	0.9992	0.9992	−0.08
Outlier Adjustment Factor [2]	0.9386	0.9434	1.0051	0.51
Permanent 2-midnight Policy Adjustment Factor	1.002	N/A	1.000	0.00
One-Time 2-midnight Policy Adjustment Factor	1.006	1/1.006	0.9940	−0.60
Capital Federal Rate	$446.79	$451.37	1.0103	1.03

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 proposed 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 $26,713.

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 proposed rule, we are proposing to rebase and revise the IPPS operating and capital market baskets to reflect a 2014 base year. For a complete discussion of this proposed rebasing, we refer readers to section IV. of the preamble of this proposed rule.

2. Forecast of the CIPI for FY 2018

Based on IHS Global Insight, Inc.'s fourth quarter 2016 forecast, for this proposed rule, we are forecasting the proposed 2014-based CIPI to increase 1.2 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 3.2 percent increase in other capital expense prices in FY 2018, partially offset by a projected 1.6 percent decline in vintage-weighted interest expense prices in FY 2018. The weighted average of these three factors produces the forecasted 1.2 percent increase for the proposed 2014-based CIPI in FY 2018.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Proposed 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. (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.)

In this FY 2018 IPPS/LTCH PPS proposed rule, 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 IHS Global Insight, Inc.'s 2016 fourth quarter forecast, we estimate that the proposed 2014-based IPPS operating market basket update for FY 2018 is 2.9 percent (that is, the estimate of the market basket rate-of-increase). However, we are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2018. 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), and RNHCIs, the proposed FY 2018 rate-of-increase percentage that would be applied to the FY 2017 target amounts in order to determine the FY 2018 target amounts is 2.9 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 proposed rule and section V. of the Addendum to this proposed rule for the proposed update changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2018. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2018

A. Proposed LTCH PPS Standard Federal Payment Rate for 2018

1. Overview

In section VIII. of the preamble of this proposed rule, we discuss our proposed 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 proposed rule.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2.b. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

Notwithstanding those provisions, however, section 411(e) of Public Law 114–10 (the MACRA) requires a 1.0 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 proposed rule.) Accordingly, in this proposed rule, we are proposing an annual update to the LTCH PPS standard Federal payment rate of 1.0 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 proposing 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 proposed full update of 1.0 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 Proposed FY 2018 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice, for FY 2018, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2018, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2018 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the proposed changes related to the area wage adjustment (that is, proposed changes to the wage data and proposed labor-related share) in accordance with § 412.523(d)(4) and a proposed budget neutrality adjustment factor for the proposed change to the SSO payment methodology (discussed in VIII.D. of the preamble of this proposed 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 proposed rule, as required by statute, we are proposing an annual update to the LTCH PPS standard Federal payment rate of 1.0 percent for FY 2018 (as described above). Accordingly, under § 412.523(c)(3)(xiii), we are proposing to apply a factor of 1.01 to the FY 2017 LTCH PPS standard Federal payment rate of $42,476.41 to determine the proposed FY 2018 LTCH PPS standard Federal payment rate. Also, under proposed § 412.523(c)(3)(iv), in conjunction with the provisions of § 412.523(c)(4), we are proposing to apply an annual update to the LTCH PPS standard Federal payment rate of −1.0 percent (that is, a proposed 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 proposing to apply an area wage level budget neutrality factor to the proposed FY 2018 LTCH PPS standard Federal payment rate of 1.000077, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed 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 proposing a budget neutrality adjustment of 0.9672 for our proposed changes to the SSO payment methodology (discussed in VIII.D. of the preamble of this proposed rule). Accordingly, we are proposing an LTCH PPS standard Federal payment rate of $41,497.20 (calculated as $42,476.41 × 1.01 × 1.000077

× 0.9672) 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 proposing an LTCH PPS standard Federal payment rate of $40,675.49 (calculated as $42,476.41 × 0.99 × 1.000077 × 0.9672) for FY 2018.

B. Proposed 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. Proposed Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (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://www.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 proposing to continue 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 proposed FY 2018 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum of this proposed 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 proposed rule, the revisions to the CBSA-based delineations also were adopted under the IPPS, effective beginning October 1, 2016.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's 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 (Wages and Salaries; Employee Benefits; Professional Fees Labor-Related; Administrative and Business Support Services; and All-Other: Labor-Related Services) and a labor-related portion of capital costs using the applicable LTCH PPS market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we revised and rebased the market basket used under the LTCH PPS by adopting the newly created FY 2009-based LTCH-specific market basket. In addition, 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 proposed rule, we are proposing to establish 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 proposing to establish that the labor-related share for FY 2018 would include 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 fourth quarter 2016 forecast of the 2013-based LTCH market basket, we are proposing to establish a labor-related share under the LTCH PPS for FY 2018 of 66.3 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, we also are proposing that if more recent data become available, we would use that data, if appropriate, to determine the final FY 2018 labor-related share in the final rule.

The proposed labor-related share for FY 2018 is the sum of the FY 2018 relative importance of each labor-related cost category, and would reflect 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 62.1 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 proposing to take 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 62.1 percent for the operating cost amount to determine the total proposed labor-related share for FY 2018. Therefore, we are proposing that the labor-related share under the LTCH PPS for FY 2018 is 66.3 percent.

4. Proposed 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 this 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, we are proposing to use 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 proposed rule. We are proposing to compute the proposed 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 proposed 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. We also are proposing to continue to apportion wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2018, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data would be determined by using an average of all of the urban areas within the State and the LTCH PPS wage index value for rural areas with no IPPS wage data would be determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2014 IPPS wage data that we are proposing to use to determine the proposed FY 2018 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with the methodology discussed above, we calculated the proposed FY 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 proposed rule and available via the Internet on the CMS Web site). We note that, as IPPS wage data are dynamic, it is possible that urban areas without IPPS wage data will vary in the future.

Based on the FY 2014 IPPS wage data that we are proposing to use to determine the proposed FY 2018 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed LTCH PPS standard Federal payment rate wage index value for proposed rural areas with no IPPS wage data for FY 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 proposed FY 2018 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 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 proposed rule and available via the Internet on the CMS Web site.

5. Proposed Budget Neutrality Adjustment for Proposed Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage-level adjustment budget neutrality factor that will be applied to the standard Federal 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 proposed rule, for FY 2018 LTCH PPS standard Federal payment rate cases, in accordance with § 412.523(d)(4), we are proposing to apply an area wage level adjustment budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the proposed adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments using a methodology that is consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). Specifically, we are proposing to determine an area wage level adjustment

budget neutrality factor that would be applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 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 proposed FY 2018 wage index values (as shown in Tables 12A and 12B listed in the Addendum to this proposed rule and available via the Internet on the CMS Web site) and the proposed FY 2018 labor-related share of 66.3 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 proposed FY 2018 area wage level adjustments (calculated in Step 2) to determine the proposed area wage level adjustment budget neutrality factor for FY 2018 LTCH PPS standard Federal payment rate payments.

Step 4—We then applied the proposed FY 2018 area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2018 LTCH PPS standard Federal payment rate after the application of the proposed 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 proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2018 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.000077. Accordingly, in section V.A. of the Addendum to this proposed rule, to determine the proposed FY 2018 LTCH PPS standard Federal payment rate, we are proposing to apply an area wage level adjustment budget neutrality factor of 1.000077, in accordance with § 412.523(d)(4). The proposed FY 2018 LTCH PPS standard Federal payment rate shown in Table 1E of the Addendum to this proposed rule reflects this adjustment factor.

C. Proposed 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 this proposed 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 proposing 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 are proposing to update 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 proposed 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 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 proposal for FY 2018 continues to use a 25-percent cap, as our proposal is based on OPM's COLA factors (updated by the methodology described earlier).

Applying this methodology, the COLA factors that we are proposing to establish 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.

PROPOSED COST-OF-LIVING ADJUSTMENT FACTORS FOR ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2018

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 COLA factors for the City and County of Honolulu, County of Kauai, and County of Maui and County of Kalawao to be 1.29 compared to the FY 2013 COLA factor of 1.25 (which were 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 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 used to determine the proposed 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). 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.

D. Proposed 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, if our proposed SSO payment method is finalized, CCRs would no longer be used to determine the payment adjustment for SSO cases. Therefore, if our proposed SSO policies are finalized, this discussion would no longer be relevant to all HCO and site neutral payment rate calculations.

As noted earlier, currently in determining HCO, SSO, 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 are proposing to use the most recent data to determine the LTCH total CCR ceiling for FY 2018 in this proposed rule. Specifically, in this proposed rule, using our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2016 update of the Provider Specific File (PSF), which is the most recent data available, we are proposing to establish an LTCH total CCR ceiling of 1.276 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. Also, consistent with our historical practice, we are proposing that if more recent data become available, we would use it to establish the LTCH total CCR ceiling for FY 2018 in the final rule. (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 proposed rule, using our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2016 update of the PSF, we are proposing to establish LTCH PPS statewide average total CCRs for urban and rural hospitals that would 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 proposed rule (and available via the Internet on the CMS Web site). Consistent with our historical practice, we also are proposing that if more recent data become available, we would use that data to determine the LTCH PPS statewide average total CCRs for FY 2018 in the 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 December 2016. Therefore, consistent with our existing methodology, we are proposing to use 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 of 0.466 and furthermore implies costs exceeded charges, as with Connecticut, we are proposing to use 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 are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

d. Reconciliation of HCO and SSO Payments

Under the HCO policy for cases paid under either payment rate at § 412.525(a)(4)(iv)(D) and the current SSO policy 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 proposed changes to the SSO payment methodology discussed in section VIII.D. of the preamble of this proposed rule, we are proposing to remove estimated cost as a consideration for payment to SSO cases. As such, consistent with our proposed changes to the SSO payment methodology, we are proposing that SSO payments would no longer be subject to reconciliation. Specifically, we are proposing to revise paragraph (f) of § 412.529 to specify that SSO payments would be reconciled only for discharges occurring before October 1, 2017. We note that this proposal is dependent upon adoption of our proposed SSO payment methodology, and if those changes are not finalized, we would not finalize this proposal either.

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. Proposed 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), we are proposing to revise § 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 proposing to make conforming changes to § 412.523(d)(1) to specify that the provisions under proposed § 412.525(a)(2)(ii) would 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 Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2018

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, we are proposing to continue to use the same general approach as in previous years, but the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases would 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 this proposed rule, we are proposing 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 proposed payment rates and policies for these cases presented in this proposed rule). Specifically, based on the most recent complete LTCH data available (that is, LTCH claims data from the December 2016 update of the FY 2016 MedPAR file and CCRs from the December 2016 update of the PSF), we are proposing to determine a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 of $30,081 that 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 proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,081).

We note 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 $22,728. However, based on the most recent available data at the time of this 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 2017, which exceeds the 8 percent target by 0.6 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 particular, 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 proposed HCO threshold would be $29,934, and thus represents a 36-percent increase from the final FY 2017 HCO threshold of $21,943. However, this increase is in line with previous proposed increases of the HCO threshold, such as the 38-percent increase from FY 2016 ($16,432) to our proposed FY 2017 HCO threshold ($22,728). We further note that the proposed FY 2017 HCO threshold was established based on the most recent data available at that time (specifically, the December 2015 update of the FY 2015 MedPAR file and the December 2015 update of the PSF), and in the FY 2017 final rule, based on the March 2016 update of the FY 2015 MedPAR file and the March 2016 update to the PSF, we finalized a somewhat lower HCO threshold of $21,943. Consistent with our historical practice of using the best data available, we are proposing that, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 in the final rule, we would use the most recent available LTCH claims data and CCR data at that time.

We also note 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 gain 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 are not proposing 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 continue to believe 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. As we explained in the FY 2017 proposed and final rules, 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 are inviting 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. Maintaining the fixed-loss amount at the current level would result in HCO payments that are substantially more than the current statutorily required 7.975 HCO percent target for LTCH PPS standard Federal payment rate cases because a lower fixed-loss amount results in more cases qualifying as outlier cases, as well as higher HCO payments for qualifying cases because the maximum loss that an LTCH must incur before receiving an HCO payment (that is, the fixed-loss amount) would be smaller. For these reasons, we continue to believe it is necessary and appropriate to propose an increase to 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 proposed § 412.525(a)(2)(ii).

In summary, for this proposed rule, for FY 2018, we are proposing to determine 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 proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined so that estimated HCO payments would be projected to equal 7.975 percent of estimated total LTCH PPS standard Federal payment rate cases, consistent with section 1886(m)(7)(B) of the Act as discussed above. Furthermore, in accordance with § 412.523(d)(1) and consistent with section 1886(m)(7)(A) of the Act as discussed above, we are proposing to continue to apply a budget neutrality factor to LTCH PPS standard Federal payment rate cases to offset our historic 8 percent HCO target for LTCH PPS standard Federal payment rate cases that would be necessary to achieve budget neutrality if the estimated aggregate HCO payments were set to be equal to 8 percent. As described in detail above, our calculation of the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2018 of $30,081 is generally consistent with the methodology used to establish the FY 2017 LTCH PPS fixed-loss amount (absent the modification from an HCO target of 8 percent to the now statutorily required 7.975 percent HCO target).

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, we are proposing that LTCH PPS standard Federal payment rate cases (that is, LTCH discharges that meet the criteria for exclusion from the site neutral payment rate) would continue to be paid based on the LTCH PPS standard Federal payment rate, and would include all of the existing payment adjustments under § 412.525(d), such as the adjustments for SSO cases under § 412.529. 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 note that, under our proposed change to the SSO policy discussed in section VIII.D. of the preamble of this proposed rule, SSO cases would still be eligible to qualify for an HCO payment.) Therefore, for an SSO case in FY 2018, we are proposing to establish that the HCO payment would be 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed fixed-loss amount of $30,081 and the amount paid under the proposed SSO policy as specified in § 412.529).

4. Proposed 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.) 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 proposed 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, for FY 2018, we are proposing 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 proposing a fixed-loss amount for site neutral payment rate cases of $26,713, which is the same proposed FY 2018 IPPS fixed-loss amount discussed in section II.A.4.g.(1) of the Addendum to this 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 are proposing 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).

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 we are proposing to continue to use the policy adopted for FY 2017.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate our proposed fixed-loss threshold of $26,713 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 proposed revised § 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 are proposing to apply a proposed 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 note that, consistent with the policy adopted for FY 2017, under this proposal the proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (80 FR 57309).

Under the approach for applying the budget neutrality adjustment to the site neutral payment rate portion of the transitional blended payment rate in FY 2016 and FY 2017, there is no need to perform any calculation of the site neutral payment rate case HCO payment budget neutrality adjustment under our finalized policy. Because of our actuarial assumptions discussed earlier, we project that our proposal to use the IPPS fixed-loss threshold for the site neutral payment rate cases would result in HCO payments for those cases that are similar in proportion as is seen in IPPS cases assigned to the same MS–DRG; that is, 5.1 percent. In other words, we estimated that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments (80 FR 49805 and 81 FR 57307).

E. Proposed Update to the IPPS Comparable/Equivalent Amounts To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (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 proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) 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 would 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, would result in overall Medicare DSH payments of 66.52 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 this proposed rule, for FY 2018, we are proposing 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 are proposing that if more recent data become available, if appropriate, we would use that data to determine this factor in the final rule.

F. Computing the Proposed 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 for a case by the applicable LTCH PPS wage index (the proposed FY 2018 values are shown in Tables 12A through 12B listed in section VI. of the Addendum of this proposed rule and are available via the Internet on the CMS Web site). The proposed 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 proposed FY 2018 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2018 of $41,497.20, as discussed in section V.A. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed 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 proposed FY 2018 LTCH PPS wage index value for CBSA 16974 is 1.0563 (obtained from Table 12A listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2018 of 0.9158 (obtained from Table 11 listed in section VI. of the Addendum of this proposed rule and available via the Internet on the CMS Web site). The LTCH submitted quality reporting data for FY 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 proposed FY 2018 LTCH PPS standard Federal payment rate ($41,497.20) by the proposed labor-related share (66.3 percent) and the proposed wage index value (1.0563). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (33.7 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9158) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2018 ($39,421.67). The table below illustrates the components of the calculations in this example.

Proposed LTCH PPS Standard Federal Prospective Payment Rate	$41,497.20
Proposed Labor-Related Share	× 0.663
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $27,512.64
Proposed Wage Index (CBSA 16974)	× 1.0563
Proposed Wage-Adjusted Labor Share of LTCH PPS Standard Federal Payment Rate	= $29,061.60
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($41,497.20 × 0.337)	+ $13,984.56
Proposed Adjusted LTCH PPS Standard Federal Payment Amount	= $43,046.16
Proposed MS–LTC–DRG 189 Relative Weight	× 0.9158
Proposed Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $39,421.67

VI. Tables Referenced in This Proposed Rule and Available Only Through the Internet on the CMS Web Site

This section lists the tables referred to throughout the preamble of this proposed rule and in this Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 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 proposed 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—Proposed Secondary Diagnosis Order Additions to the CC Exclusion List; Table 6G.2—Proposed Principal Diagnosis Order Additions to the CC Exclusion List; Table 6H.1—Proposed Secondary Diagnosis Order Deletions to the CC Exclusion List; Table 6H.2—Proposed Principal Diagnosis Order Deletions to the CC Exclusion List; Table 6I.1—Proposed Additions to the MCC List; Table 6I.2—Proposed Deletions to the MCC List; Table 6J.1—Proposed Additions to the CC List; Table 6J.2—Proposed Deletions to the CC List; and Table 6P—Proposed 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 proposed 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 proposed rule, we are not providing the hospital-level data as a table associated with this proposed rule. The hospital-level data for the FY 2018 HAC Reduction Program will be made publicly available once it has undergone the review and corrections process.

Finally, Table 18 associated with this proposed rule contains the proposed 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 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled, ''FY 2018 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download.''

Table 2—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2018
Table 3—Proposed Wage Index Table by CBSA—FY 2018
Table 5—List of Proposed 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—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
Table 6H.2—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2018
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
Table 6J.2—Proposed Deletions to the CC List—FY 2018
Table 6P—Proposed 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—December 2016 GROUPER V34.0 MS–DRGs
Table 7B—Medicare Prospective Payment System Selected Percentile Lengths of Stay: FY 2016 MedPAR Update—December 2016 GROUPER V35.0 MS–DRGs
Table 8A—Proposed FY 2018 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B—Proposed FY 2018 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 10—Proposed New Technology Add-On Payment Thresholds for Applications for FY 2019
Table 15—Proposed Proxy FY 2018 Readmissions Adjustment Factors
Table 16—Proposed Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2018
Table 18—Proposed FY 2018 Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2018 proposed rule are available only through the Internet on the CMS Web site at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1677–P:

Table 8C—Proposed FY 2018 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2017 through September 30, 2018
Table 12A—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2017 through September 30, 2018
Table 12B—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2017 through September 30, 2018
Table 13A—Proposed Composition of Low Volume Quintiles for MS–LTC–DRGs—FY 2018
Table 13B—Proposed No Volume MS LTC–DRG Crosswalk for FY 2018

TABLE 1A—PROPOSED 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 = 1.75 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.425 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.025 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.15 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,822.07	$1,773.93	$3,740.37	$1,736.01	$3,794.84	$1,761.29	$3,713.14	$1,723.37

TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR

[(62 percent labor share/38 percent nonlabor share if wage index is less than or equal to 1)—FY 2018]

Hospital submitted quality data and is a meaningful EHR user (update = 1.75 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = −0.425 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.025 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −1.15 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$3,469.52	$2,126.48	$3,395.36	$2,081.02	$3,444.80	$2,111.33	$3,370.64	$2,065.87

TABLE 1C—PROPOSED 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	$3,469.52	$2,126.48

[1] For FY 2018, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE

[FY 2018]

	Rate
National	$451.37

TABLE 1E—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE

[FY 2018]

	Full update (1 percent)	Reduced update * (−1.0 percent)
Standard Federal Rate	$41,497.20	$40,675.49

* 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 proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (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 proposed rule is a major rule as defined in 5 U.S.C. 804(2). We estimate that the proposed changes for FY 2018 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $3.1 billion increase in FY 2018 proposed payments, including a $3.8 billion increase in FY 2018 proposed operating payments (or 1.7 percent change), an estimated $212 million increase in FY 2018 proposed capital payments (or 2.4 percent change), and an estimated $1.0 billion increase in proposed uncompensated care payments (or a 1.2 percent change). As noted in section II.A. of this Appendix, all expenditures are classified as transfers to Medicare providers. These proposed changes are relative to payments made in FY 2017. The impact analysis of the proposed capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience a decrease in payments by $173 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 proposed rule. In addition, our operating payment impact estimate includes the proposed 1.75 percent hospital update to the standardized amount (which includes the estimated 2.9 percent market basket update less 0.4 percentage point for the proposed 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 proposed 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 proposed payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget has reviewed this proposed rule.

B. Statement of Need

This proposed rule is necessary in order to make payment and policy changes under the Medicare IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS.

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 proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of proposed policies, we refer readers to the section of the proposed rule where each proposal is discussed. These sections include the rational for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2018, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case while holding all other payment policies constant. We use the best data available, but, generally, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, or case-mix. In addition, we discuss limitations of our analysis for specific proposals in the discussion of those proposals 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 March 2017, there were 3,292 IPPS acute care hospitals included in our analysis. This represents approximately 54 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,385 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, 11 cancer hospitals, and 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. With the exception of the IPFQR provisions presented in section IX.D. of the preamble of this proposed 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 proposed rule. The impact of the proposed update and proposed 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 March 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, 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, 263 rehabilitation hospitals and 870 rehabilitation units, and approximately 415 LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and 513 psychiatric hospitals and 1,113 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 proposed 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, and RNHCIs, we are proposing that the update of the rate-of-increase limit (or target amount) would be the estimated FY 2018 percentage increase in the proposed 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 proposed rule, we are proposing to revise and rebase the IPPS operating market basket to a 2014 base year. Therefore, we are proposing to use 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, and RNHCs that are paid based on reasonable costs subjects to the rate-of-increase limits. Consistent with current law, based on IHS Global Insight, Inc.'s 2016 fourth quarter forecast of the proposed 2014-based IPPS market basket increase, we are estimating the FY 2018 update to be 2.9 percent (that is, the estimate of the market basket rate-of-increase). We are proposing that if more recent data become available for the final rule, we would use them to calculate the IPPS operating market basket update for FY 2018. However, the Affordable Care Act requires an adjustment for multifactor productivity (currently estimated to be 0.4 percentage point for FY 2018) and a 0.75 percentage point reduction to the market basket update, resulting in a 1.75 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section IV.B. of the preamble of this proposed rule. Children's hospitals, the 11 cancer hospitals, the 5 short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and 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 would be the percentage increase in the proposed 2014-based IPPS operating market basket for FY 2018, estimated at 2.9 percent, without the reductions described previously under the Affordable Care Act.

The impact of the proposed 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 Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and proposed payment rate updates for the IPPS for FY 2018 for operating costs of acute care hospitals. The proposed 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 would increase by 1.7 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 proposed 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 proposed rule. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall proposed payment changes.

We have prepared separate impact analyses of the proposed changes to each system. This section deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the most recent available data to enable us to estimate the impacts on payments per case of certain changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in payments per case presented 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 proposed changes to the operating PPS do not incorporate cost data, data from the most recently available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not make adjustments for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each proposed change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 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 proposed impact of payments under the capital IPPS, or 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 proposed changes:

- The effects of the proposed application of the adjustment required under section 15005 of the 21st Century Cures Act and the applicable percentage increase (including the proposed market basket update, the proposed multifactor productivity adjustment, and the applicable percentage reduction in accordance with the Affordable Care Act) to the standardized amount and hospital-specific rates.
- The effects of the 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 proposed rule.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 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 proposed rule) that would be effective for FY 2018.
- The effects of the proposed rural floor with the application of the proposed national budget neutrality factor to the wage index.
- The effects of the proposed frontier State wage index adjustment under the statutory provision that requires that hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. This provision is not budget neutral.
- The 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 proposed FY 2018 policies relative to payments based on FY 2017 policies that include the applicable percentage increase of 1.75 percent (or 2.9 percent market basket update with a proposed reduction of 0.4 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 proposed 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, we are proposing that hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 1.025 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 proposed 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 would 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, we are proposing that hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable

percentage increase of −0.425 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 proposed 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 would receive an applicable percentage increase of −1.15 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 proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2018 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each proposed change.

Our final comparison illustrates the percent change in payments per case from FY 2017 to FY 2018. Two factors not discussed separately have significant impacts here. The first factor is the proposed update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are proposing to update the standardized amounts for FY 2018 using a proposed applicable percentage increase of 1.75 percent. This includes our forecasted IPPS operating hospital market basket increase of 2.9 percent with a 0.4 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 would receive a proposed update of 1.025 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 would receive an update of −0.425 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 would receive an update of −1.15 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 1.75 percent if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed 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 proposed 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 2,491 hospitals located in urban areas included in our analysis. Among these, there are 1,349 hospitals located in large urban areas (populations over 1 million), and 1,142 hospitals in other urban areas (populations of 1 million or fewer). In addition, there are 801 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 proposed 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 2,391, 1,363, 1,028, and 901, respectively.

The next three groupings examine the impacts of the proposed changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 2,211 nonteaching hospitals in our analysis, 835 teaching hospitals with fewer than 100 residents, and 246 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next three rows examine the impacts of the proposed changes on rural hospitals by special payment groups (SCHs, and RRCs). There were 243 RRCs, 317 SCHs, and 129 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 2014 or FY 2013 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.

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2018

	Number of hospitals [1]	Proposed hospital rate update and adjustments (1) [2]	Proposed FY 2018 weights and DRG changes with application of recalibration budget neutrality (2) [3]	Proposed FY 2018 wage data with application of wage budget neutrality (3) [4]	FY 2018 MGCRB reclassifications (4) [5]	Proposed rural floor with application of national rural floor budget neutrality (5) [6]	Proposed application of the frontier wage index and out-migration adjustment (6) [7]	Expiration of MDH status (7) [8]	All proposed FY 2018 changes (8) [9]
All Hospitals	3,292	1.5	0	0	0	0	0.1	−0.1	1.7
By Geographic Location:									
Urban hospitals	2,491	1.6	0	0	−0.1	0	0.1	0	1.8
Large urban areas	1,349	1.6	−0.1	0	−0.4	−0.1	0	0	1.7
Other urban areas	1,142	1.6	0	0	0.3	0.2	0.2	−0.1	1.8
Rural hospitals	801	1.3	0.3	0.1	1.4	−0.2	0.2	−0.9	0.8
Bed Size (Urban):									
0–99 beds	638	1.5	0.4	0.1	−0.6	0.1	0.2	−0.7	1.2
100–199 beds	765	1.6	0.2	0.1	−0.1	0.2	0.2	−0.1	1.9
200–299 beds	445	1.6	0.1	0	0.1	0	0.1	0	1.7

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2018—Continued

	Number of hospitals [1]	Proposed hospital rate update and adjustments (1) [2]	Proposed FY 2018 weights and DRG changes with application of recalibration budget neutrality (2) [3]	Proposed FY 2018 wage data with application of wage budget neutrality (3) [4]	FY 2018 MGCRB reclassifications (4) [5]	Proposed rural floor with application of national rural floor budget neutrality (5) [6]	Proposed application of the frontier wage index and out-migration adjustment (6) [7]	Expiration of MDH status (7) [8]	All proposed FY 2018 changes (8) [9]
300–499 beds	431	1.6	0	0	−0.1	0	0.1	0	1.8
500 or more beds	212	1.5	−0.3	0	−0.2	−0.1	0.1	0	1.7
Bed Size (Rural):									
0–49 beds	313	1.2	0.5	0	0.4	−0.1	0.3	−1.6	0.1
50–99 beds	285	1.3	0.3	0	0.6	−0.2	0.2	−2.2	−0.8
100–149 beds	117	1.3	0.3	0	1.3	0	0.2	−0.1	1.4
150–199 beds	46	1	0.2	0.1	1.8	−0.2	0.1	0	1.7
200 or more beds	40	1.4	0.1	0.2	2.9	−0.2	0	0	2
Urban by Region:									
New England	114	1.6	0.1	−0.4	1.3	1	0	−0.2	1.6
Middle Atlantic	315	1.6	0	−0.1	0.4	−0.3	0.1	0	1.2
South Atlantic	404	1.6	0	0.1	−0.4	−0.3	0	−0.1	1.9
East North Central	385	1.6	0.1	0	−0.2	−0.3	0	0	2
East South Central	147	1.6	0	−0.1	−0.3	−0.2	0	0	1.7
West North Central	160	1.5	−0.1	0.4	−0.8	−0.3	0.7	−0.1	2
West South Central	378	1.6	0	0.5	−0.5	−0.3	0	−0.1	2.1
Mountain	162	1.5	0	−0.2	0	0.3	0.3	0	1
Pacific	375	1.5	−0.1	−0.3	−0.2	0.9	0.1	0	2
Puerto Rico	51	1.6	−0.4	1.4	−1	0.2	0.1	0	1.3
Rural by Region:									
New England	20	1.3	0.2	1.1	2.2	−0.3	0.2	−2.1	1.2
Middle Atlantic	53	1.2	0.4	0	1.1	−0.2	0.2	−1.7	−0.1
South Atlantic	125	1.2	0.3	−0.1	1.8	−0.2	0.2	−0.8	0.4
East North Central	115	1.3	0.2	−0.3	1.2	−0.2	0.1	−1.7	−0.4
East South Central	154	1.5	0.4	0.1	2.4	−0.3	0.1	−0.3	1.6
West North Central	97	1.2	0.1	0	0.1	0.2	0.3	−0.3	1.2
West South Central	154	1.3	0.4	0.3	1.7	−0.3	0.2	−0.7	1.3
Mountain	59	1	0.3	−0.1	0.2	−0.1	0.3	0	1.4
Pacific	24	1.1	0.2	0	1	0.1	0	0	1.2
By Payment Classification:									
Urban hospitals	2,391	1.6	0	0	−0.2	0	0.1	0	1.8
Large urban areas	1,363	1.6	−0.1	0	−0.4	−0.1	0	0	1.7
Other urban areas	1,028	1.6	0	0	0.1	0.2	0.2	0	1.8
Rural areas	901	1.4	0.1	0.1	1.4	0	0.2	−0.7	1.2
Teaching Status:									
Nonteaching	2,211	1.5	0.2	0	0.2	0.1	0.1	−0.3	1.6
Fewer than 100 residents	835	1.6	0.1	0	−0.1	0	0.2	0	1.8
100 or more residents	246	1.5	−0.3	−0.1	−0.1	−0.1	0	0	1.6
Urban DSH:									
Non-DSH	561	1.6	0	0	−0.2	−0.1	0.2	−0.4	1.3
100 or more beds	1,563	1.6	0	0	−0.2	0	0.1	0	1.8
Less than 100 beds	357	1.5	0.4	0.1	−0.1	0.1	0.1	−0.1	2.1
Rural DSH:									
SCH	259	1.1	0.2	0	0	0	0	0	1.2
RRC	271	1.4	0.1	0.2	1.7	0	0.3	−0.3	1.9
100 or more beds	41	1.6	0.2	0.3	1.6	−0.1	0.1	0	1.7
Less than 100 beds	240	1.5	0.7	0	0.6	−0.3	0.7	−4.7	−3.2
Urban teaching and DSH:									
Both teaching and DSH	870	1.6	−0.1	−0.1	−0.3	−0.1	0.1	0	1.7
Teaching and no DSH	94	1.6	−0.1	0	−0.4	−0.2	0.1	0	1.2
No teaching and DSH	1,050	1.6	0.2	0	0	0.3	0.1	0	2
No teaching and no DSH	377	1.6	0	0.1	−0.4	−0.1	0.2	0	1.9
Special Hospital Types:									
RRC	243	1.6	0.1	0.2	2.1	−0.1	0.4	−0.4	1.9
SCH	317	1.1	−0.1	0	−0.1	0.2	0	0	1
SCH and RRC	129	1.1	0	0.1	0.3	0	0	0	1.3
Type of Ownership:									
Voluntary	1,914	1.5	0	0	0	0	0.1	−0.1	1.6
Proprietary	862	1.6	0.2	0.1	0.1	0	0.1	−0.1	1.9
Government	514	1.5	0	0	−0.2	0.2	0.1	−0.1	1.6
Medicare Utilization as a Percent of Inpatient Days:									
0–25	509	1.5	0	0	−0.4	0.2	0	0	1.6
25–50	2,113	1.6	0	0	0	0	0.1	−0.1	1.8
50–65	535	1.5	0.1	0.1	0.6	0	0.1	−0.5	1.2
Over 65	135	1.5	0.6	0.1	−0.5	0.4	0.3	−3.7	−1.5
FY 2018 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	900	1.5	0.1	0.1	1.9	−0.1	0	−0.1	1.7
Non-Reclassified Hospitals	2,392	1.6	0	0	−0.9	0	0.2	−0.1	1.7

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2018—Continued

	Number of hospitals [1]	Proposed hospital rate update and adjustments (1) [2]	Proposed FY 2018 weights and DRG changes with application of recalibration budget neutrality (2) [3]	Proposed FY 2018 wage data with application of wage budget neutrality (3) [4]	FY 2018 MGCRB reclassifications (4) [5]	Proposed rural floor with application of national rural floor budget neutrality (5) [6]	Proposed application of the frontier wage index and out-migration adjustment (6) [7]	Expiration of MDH status (7) [8]	All proposed FY 2018 changes (8) [9]
Urban Hospitals Reclassified	629	1.6	0.1	0.1	1.9	0	0	−0.1	1.7
Urban Nonreclassified Hospitals	1,814	1.6	−0.1	−0.1	−0.9	0	0.1	0	1.8
Rural Hospitals Reclassified Full Year	271	1.3	0.2	0	2.3	−0.1	0	−0.5	1.2
Rural Nonreclassified Hospitals Full Year	482	1.3	0.4	0.1	−0.2	−0.2	0.4	−1.5	0.1
All Section 401 Reclassified Hospitals:	148	1.5	0	0.3	1.4	0.1	0.3	−0.6	1.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	48	1.5	0.6	0.3	3.3	−0.3	0	−1.1	1.1

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2016, and hospital cost report data are from reporting periods beginning in FY 2013 and FY 2014.

[2] This column displays the payment impact of the proposed hospital rate update and other proposed adjustments, including the proposed 1.75 percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 2.9 percent market basket update reduced by 0.4 percentage point for the proposed 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 proposed changes to the Version 35 GROUPER, the proposed 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 proposed recalibration budget neutrality factor of 0.997573 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 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 proposed wage budget neutrality factor, which is calculated separately from the proposed recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 1.000465.

[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 proposed geographic budget neutrality factor of 0.988522.

[6] This column displays the effects of the proposed rural floor based on the continued implementation of the OMB labor market area delineations. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.993672.

[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 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. 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.

a. Effects of the Proposed 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 proposed rule, this column includes the proposed hospital update, including the proposed 2.9 percent market basket update, the proposed reduction of 0.4 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 proposed 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 proposed 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 proposing to make a 1.6 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 2.9 percent market basket update, the proposed reduction of 0.4 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 proposed 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 proposing to make a 1.15 percent update to the hospital-specific rates.

Overall, hospitals would experience a 1.5 percent increase in payments primarily due to the combined effects of the proposed hospital update and the proposed 0.4588 percent adjustment on the national standardized amount and the proposed 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 would experience a 1.15 percent increase in payments; therefore, hospital categories containing hospitals paid under the hospital-specific rate would experience a lower than average increases in payments.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we are calculating a recalibration budget neutrality factor to account for the changes in MS–

DRGs and relative weights to ensure that the overall payment impact is budget neutral.

As discussed in section II.E. of the preamble of this proposed rule, the FY 2018 MS–DRG relative weights would 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 proposed rule.

The ''All Hospitals'' line in Column 2 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 0.997573 to the standardized amount. Hospital categories that generally treat more surgical cases than medical cases would experience a decrease in their payments under the proposed relative weights for reasons that include the proposals regarding operating room procedures described in section II.G. of the preamble of this proposed rule. Rural hospitals would experience a 0.3 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 would experience a decrease in payments by 0.3 percent in part because those hospitals treat more surgical cases than medical cases.

c. Effects of the Proposed 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 proposed 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 proposed payment parameters such as use of the Version 35 MS–DRG GROUPER constant. The proposed FY 2018 occupational mix adjustment is based on the CY 2013 occupational mix survey.

In addition, the column shows the impact of the proposed 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 are proposing to calculate 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 proposed FY 2018 wage budget neutrality factor is 1.000465, and the overall proposed 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 proposed wage budget neutrality adjustment, would lead to no change for all hospitals as shown in Column 3.

In looking at the wage data itself, the proposed national average hourly wage would 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 3,287 hospitals with wage data for both FYs 2017 and 2018, 1,698 or 51.7 percent would experience an average hourly wage increase of 1.02 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed changes in the average hourly wage data for FY 2018 relative to FY 2017. Among urban hospitals, 10 would experience a decrease of 10 percent or more, and 2 urban hospitals would experience an increase of 10 percent or more. One hundred and one urban hospitals would experience an increase or decrease of at least 5 percent or more but less than 10 percent. Among rural hospitals, none would experience an increase of at least 5 percent or more, but 12 rural hospitals would experience a decrease of greater than or equal to 5 percent but less than 10 percent. Three rural hospitals would experience decreases of 10 percent or more. However, 775 rural hospitals would experience increases or decreases of less than 5 percent, while 2,384 urban hospitals would experience increases or decreases of less than 5 percent. No urban hospitals and no rural hospitals experience no change to their wage index. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the proposed wage index before the application of proposed geographic reclassification, the proposed rural floor, the proposed out-migration adjustment, and other proposed wage index exceptions and adjustments. (We refer readers to sections III.G. through III.L. of the preamble of this proposed rule for a complete discussion of the exceptions and adjustments to the wage index.) We note that the proposed ''post-reclassified wage index'' or proposed ''payment wage index,'' which is the proposed wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this proposed rule, which are available via the Internet on the CMS Web site) is used to adjust the labor-related share of a hospital's standardized amount, either 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 proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than would occur in a hospital's proposed payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

Proposed FY 2018 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Increase 10 percent or more	2	0
Increase greater than or equal to 5 percent and less than 10 percent	54	0
Increase or decrease less than 5 percent	2,384	775
Decrease greater than or equal to 5 percent and less than 10 percent	47	12

Proposed FY 2018 percentage change in area wage index values	Number of hospitals	
	Urban	Rural
Decrease 10 percent or more	10	3
Unchanged	0	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 proposed 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 would be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials of MGCRB decisions to the CMS Administrator. Further, hospitals have 45 days from publication of the IPPS proposed rule in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year (we refer readers to the discussion of our proposed revisions to this policy in section III.I.2. of the preamble to this proposed 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 proposing to apply an adjustment of 0.988522 to ensure that the effects of the reclassifications under section 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this proposed rule). Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.4 percent. By region, all the rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this proposed rule and available via the Internet on the CMS Web site reflects the proposed reclassifications for FY 2018.

e. Effects of the Proposed Rural 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 proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index received by rural hospitals in the same State. We would apply a uniform budget neutrality adjustment to the wage index. As discussed in section III.H. of the preamble of this proposed rule, we are not proposing to extend the imputed floor policy. Therefore, column 6 shows the effects of the proposed rural floor only.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a proposed FY 2018 rural floor budget neutrality factor to be applied to the wage index of 0.993672, which would reduce wage indexes by 0.63 percent.

Column 5 shows the projected impact of the proposed rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations. The column compares the proposed post-reclassification FY 2018 wage index of providers before the proposed rural floor adjustment and the proposed post-reclassification FY 2018 wage index of providers with the proposed rural floor adjustment based on the OMB labor market area delineations. Only urban hospitals can benefit from the rural floor. Because the provision is budget neutral, all other hospitals (that is, all rural hospitals and those urban hospitals to which the adjustment is not made) would experience a decrease in payments due to the budget neutrality adjustment that is applied nationally to their wage index.

We estimate that 392 hospitals would receive the proposed rural floor in FY 2018. All IPPS hospitals in our model would have their wage index reduced by the rural floor budget neutrality adjustment of 0.993672. We project that, in aggregate, rural hospitals would experience a 0.63 percent decrease in payments as a result of the application of the proposed rural floor budget neutrality because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project hospitals located in urban areas would experience no change in payments because increases in payments by hospitals benefitting from the rural floor offset decreases in payments by nonrural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the New England region would experience a 1.0 percent increase in payments primarily due to the application of the proposed rural floor in Massachusetts. Thirty-six urban providers in Massachusetts are expected to receive the proposed 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 would receive approximately a 1.3 percent increase in IPPS payments due to the application of the proposed 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 proposed rural floor.

In response to a public comment addressed in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51593), we are providing the payment impact of the proposed rural floor 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 would receive the proposed rural floor wage index for FY 2018. Column 3 displays the percentage of total payments each State would receive or contribute to fund the rural floor with national budget neutrality. The column compares the proposed post-reclassification FY 2018 wage index of providers before the proposed rural floor adjustment and the proposed post-reclassification FY 2018 wage index of providers with the proposed rural floor adjustment. Column 4 displays the estimated payment amount that each State would gain or lose due to the application of the proposed rural floor with national budget neutrality.

PROPOSED FY 2018 IPPS ESTIMATED PAYMENTS DUE TO RURAL FLOOR WITH NATIONAL BUDGET NEUTRALITY

State	Number of hospitals (1)	Proposed number of hospitals that would receive the rural floor (2)	Proposed percent change in payments due to application of rural floor with budget neutrality (3)	Proposed difference (in $ millions) (4)
Alabama	84	3	0.2	3.05
Alaska	6	4	1.4	2.62
Arizona	57	44	0.9	17.47
Arkansas	44	1	−0.3	−3.39
California	299	177	1.3	136.28
Colorado	47	4	0.4	4.97
Connecticut	30	10	0.4	6.31
Delaware	6	0	−0.3	−1.61
Washington, D.C.	7	0	−0.3	−1.67
Florida	171	17	−0.2	−14.93
Georgia	103	0	−0.3	−8.07
Hawaii	12	0	−0.3	−0.83
Idaho	14	0	−0.2	−0.77
Illinois	127	3	−0.3	−15.87
Indiana	85	7	−0.2	−5.92
Iowa	34	0	−0.3	−2.94
Kansas	53	0	−0.3	−2.62
Kentucky	66	0	−0.3	−4.87
Louisiana	94	3	−0.3	−4.21
Maine	17	0	−0.3	−1.59
Massachusetts	57	36	1.3	43.82
Michigan	94	0	−0.3	−13.74
Minnesota	49	0	−0.3	−5.66
Mississippi	60	0	−0.3	−3.4
Missouri	74	0	−0.2	−3.89
Montana	12	4	0	0.08
Nebraska	24	0	−0.3	−1.88
Nevada	23	0	−0.4	−3.04
New Hampshire	13	9	2.5	14.09
New Jersey	64	0	−0.4	−16.05
New Mexico	25	0	−0.2	−1.01
New York	154	21	−0.1	−11.13
North Carolina	84	0	−0.3	−9.6
North Dakota	6	0	−0.2	−0.62
Ohio	128	6	−0.3	−11.62
Oklahoma	84	4	−0.2	−2.81
Oregon	34	5	−0.3	−2.64
Pennsylvania	150	3	−0.3	−16.09
Puerto Rico	51	10	0.2	0.38
Rhode Island	11	0	−0.4	−1.56
South Carolina	56	0	−0.3	−4.66
South Dakota	17	0	−0.2	−0.72
Tennessee	91	6	−0.3	−7.25
Texas	310	0	−0.3	−21.42
Utah	33	1	−0.3	−1.49
Vermont	6	0	−0.2	−0.44
Virginia	73	1	−0.2	−6.7
Washington	48	3	−0.2	−4.36
West Virginia	29	3	−0.1	−0.46
Wisconsin	66	7	−0.2	−3.57
Wyoming	10	0	−0.1	−0.18

f. Effects of the Application of the Proposed 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 48 hospitals located in those States would 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 would 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 248 providers that would 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 would experience a 0.3 percent and 0.4 percent increase in payments, respectively. This out-migration wage adjustment also is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $39 million.

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 158 MDHs, of which we estimate 96 would have been paid under the blended payment of 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 would 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 2.1 percent because 6 out of the 20 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 can expect a decrease in payments of 12 percent.

h. Effects of All FY 2018 Proposed Changes (Column 8)

Column 8 shows our estimate of the proposed changes in payments per discharge from FY 2017 and FY 2018, resulting from all proposed changes reflected in this proposed rule for FY 2018. It includes combined effects of the year to year change of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 1.7 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 proposed annual hospital update of 1.6 percent to the national standardized amount. This proposed annual hospital update includes the 2.9 percent market basket update, the proposed reduction of 0.4 percentage point 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 proposed rule, this column also includes the proposed 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 proposed rule. Hospitals paid under the hospital-specific rate would receive a 1.15 percent proposed hospital update. As described in Column 1, the proposed annual hospital update with the proposed 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 proposed rule, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates would result in a 1.7 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 proposed 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 proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 1.7 percent for FY 2018. Hospitals in urban areas would experience a 1.8 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 0.8 percent in FY 2018.

3. Impact Analysis of Table II

Table II presents the projected impact of the proposed 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 proposed 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 proposed changes presented in Table I. The proposed 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 PROPOSED 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	Proposed FY 2018 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,292	11,842	12,041	1.7
By Geographic Location:				
Urban hospitals	2,491	12,179	12,393	1.8

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2018 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2017 payment per discharge (2)	Estimated average FY 2018 payment per discharge (3)	Proposed FY 2018 changes (4)
Large urban areas	1,349	12,953	13,174	1.7
Other urban areas	1,142	11,311	11,516	1.8
Rural hospitals	801	8,907	8,975	0.8
Bed Size (Urban):				
0–99 beds	638	9,688	9,806	1.2
100–199 beds	765	10,232	10,423	1.9
200–299 beds	445	11,051	11,244	1.7
300–499 beds	431	12,395	12,620	1.8
500 or more beds	212	14,917	15,173	1.7
Bed Size (Rural):				
0–49 beds	313	7,531	7,535	0.1
50–99 beds	285	8,501	8,431	−0.8
100–149 beds	117	8,736	8,861	1.4
150–199 beds	46	9,453	9,617	1.7
200 or more beds	40	10,433	10,643	2
Urban by Region:				
New England	114	13,107	13,311	1.6
Middle Atlantic	315	13,750	13,910	1.2
South Atlantic	404	10,775	10,980	1.9
East North Central	385	11,495	11,726	2
East South Central	147	10,247	10,419	1.7
West North Central	160	11,887	12,127	2
West South Central	378	10,936	11,163	2.1
Mountain	162	12,796	12,928	1
Pacific	375	15,612	15,922	2
Puerto Rico	51	8,770	8,886	1.3
Rural by Region:				
New England	20	12,124	12,264	1.2
Middle Atlantic	53	8,878	8,873	−0.1
South Atlantic	125	8,271	8,302	0.4
East North Central	115	9,221	9,183	−0.4
East South Central	154	7,887	8,012	1.6
West North Central	97	9,742	9,856	1.2
West South Central	154	7,535	7,631	1.3
Mountain	59	10,601	10,754	1.4
Pacific	24	12,463	12,614	1.2
By Payment Classification:				
Urban hospitals	2,391	12,193	12,406	1.8
Large urban areas	1,363	12,940	13,160	1.7
Other urban areas	1,028	11,201	11,406	1.8
Rural areas	901	10,084	10,207	1.2
Teaching Status:				
Nonteaching	2,211	9,850	10,010	1.6
Fewer than 100 residents	835	11,367	11,570	1.8
100 or more residents	246	17,167	17,441	1.6
Urban DSH:				
Non-DSH	561	10,314	10,448	1.3
100 or more beds	1,563	12,565	12,785	1.8
Less than 100 beds	357	8,849	9,038	2.1
Rural DSH:				
SCH	259	9,547	9,662	1.2
RRC	271	10,639	10,842	1.9
100 or more beds	41	10,943	11,128	1.7
Less than 100 beds	240	6,977	6,754	−3.2
Urban teaching and DSH:				
Both teaching and DSH	870	13,659	13,887	1.7
Teaching and no DSH	94	11,460	11,593	1.2
No teaching and DSH	1,050	10,218	10,422	2
No teaching and no DSH	377	9,840	10,023	1.9
Special Hospital Types:				
RRC	243	10,318	10,518	1.9
SCH	317	10,781	10,886	1
SCH and RRC	129	11,225	11,374	1.3
Type of Ownership:				

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES FOR FY 2018 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM—Continued

[Payments per discharge]

	Number of hospitals (1)	Estimated average FY 2017 payment per discharge (2)	Estimated average FY 2018 payment per discharge (3)	Proposed FY 2018 changes (4)
Voluntary	1,914	12,027	12,223	1.6
Proprietary	862	10,383	10,585	1.9
Government	514	12,805	13,012	1.6
Medicare Utilization as a Percent of Inpatient Days:				
0–25	509	15,200	15,448	1.6
25–50	2,113	11,775	11,983	1.8
50–65	535	9,626	9,742	1.2
Over 65	135	7,473	7,364	−1.5
FY 2018 Reclassifications by the Medicare Geographic Classification Review Board:				
All Reclassified Hospitals	900	11,720	11,914	1.7
Non-Reclassified Hospitals	2,392	11,900	12,101	1.7
Urban Hospitals Reclassified	629	12,240	12,452	1.7
Urban Nonreclassified Hospitals	1,814	12,157	12,376	1.8
Rural Hospitals Reclassified Full Year	271	9,327	9,435	1.2
Rural Nonreclassified Hospitals Full Year	482	8,419	8,424	0.1
All Section 401 Reclassified Hospitals:	148	11,661	11,862	1.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	48	8,080	8,169	1.1

H. Effects of Other Proposed Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of Proposed Policy Relating to New Medical Service and Technology Add-On Payments

In section II.H. of the preamble to this proposed rule, we discuss six technologies for which we received applications for add-on payments for new medical services and technologies for FY 2018, as well as the status of the new technologies that were approved to receive new technology add-on payments in FY 2017. We note that three applicants withdrew their applications prior to the issuance of this proposed rule. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.H.6. of the preamble of this proposed rule, we have not yet determined whether any of these six technologies for which we received applications for consideration for new technology add-on payments for FY 2018 will meet the specified criteria. Consequently, it is premature to estimate the potential payment impact of these six technologies for any potential new technology add-on payments for FY 2018. We note that if any of the six technologies are found to be eligible for new technology add-on payments for FY 2018, in the FY 2018 IPPS/LTCH PPS final rule, we would discuss the estimated payment impact for FY 2018.

In section II.H.5. of the preamble of this proposed rule, we are proposing to discontinue new technology add-on payments for Blinatumomab (BLINCYTO™), CardioMEMS™ HF (Heart Failure) Monitoring System, the LUTONIX® Drug Coated Balloon (DCB) Percutaneous Transluminal Angioplasty (PTA) and IN.PACT™ Admiral™ Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter, and the MAGEC® Spinal Bracing and Distraction System (MAGEC® Spine) for FY 2018 because these technologies will have been on the U.S. market for 3 years. We also are proposing to continue 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 technologies would still be 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. For Defitelio®, based on the applicant's estimate from FY 2017, we currently estimate that new technology add-on payments for Defitelio® would 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 would 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 would 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™ would increase overall FY 2018 payments by $2,812,500 (maximum add-on payment of $37,500 * 75 patients).

2. Effects of Proposed 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 proposed rule, we discuss our proposed changes to the list of MS–DRGs subject to the postacute care transfer policy and the DRG special payment policy. As reflected in Table 5 listed in section VI. of the Addendum to this proposed rule (which is available via the Internet on the CMS Web site), using criteria set forth in regulations at 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 are not proposing to make any changes in these payment policies in this FY 2018 proposed rule. As a result of our proposals to revise the MS–DRG classifications for FY 2018, which are discussed in section II.F. of the preamble of this proposed rule, we are proposing to add three MS–DRGs to the list of MS–DRGs subject to the postacute care transfer policy

and the MS–DRG special payment policy. Column 4 of Table I in this Appendix A shows the effects of the proposed changes to the MS–DRGs and the relative payment weights and the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate DRG classification changes in order to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. The analysis and methods for determining the proposed changes due to the MS–DRGs and relative payment weights account for and include changes as a result of the proposed 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 proposed MS–DRG reclassification policies for FY 2018.

3. Effects of the Proposed Changes to the Volume Decrease Adjustment for Sole Community Hospitals (SCHs)

In section V.C. of the preamble of this proposed rule, we discuss our proposal to modify the methodology used to calculate volume decrease adjustments for SCHs. We are proposing to prospectively require 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 proposing that the cap will no longer be applied to the volume decrease adjustment calculation methodology in future periods. In addition, we are proposing 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 MACs to adjust the volume decrease adjustment payment amount for excess staffing. We estimate that these proposed changes to the volume decrease adjustment would 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 would qualify for the adjustment in FY 2018 that the additional amount of the volume decrease adjustment payment based on our proposed methodology would be $750,000 per hospital.

4. Effects of Proposed Changes to Low-Volume Hospital Payment Adjustment Policy

In section V.E. of the preamble of this proposed 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 parallel low-volume hospital payment adjustment regarding hospitals operated by the IHS or a Tribe. Under this proposal, an IHS hospital would be able to qualify for a low-volume hospital adjustment based on its distance to the nearest IHS 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. 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 proposed change to the low-volume payment adjustments would decrease aggregate low-volume payment adjustments from $315 million in FY 2017 to $4 million in FY 2018. This $311 million decrease in FY 2018 is based on an estimated $314 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 proposed 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 les than 200 total discharges, and were determined from the same data used in developing the quantitative analyses of proposed changes in payments per case discussed previously in section I.G. of this Appendix A.

5. Effects of the Proposed Changes to Medicare DSH and Uncompensated Care Payments for FY 2018

As discussed in section V.G. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the 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 proposing 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). We also are proposing to continue to use low-income insured patient days as a proxy for uncompensated care 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 reduction to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments to DSH eligible hospitals, which for FY 2018 is $6,962,310,946.63, or 75 percent of what otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed 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 what 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 are proposing to use 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 are proposing to calculate an individual Factor 3 for cost reporting years beginning during FYs 2012, 2013, and 2014. We will then add the individual amounts and divide the sum by three in order to calculate an average Factor 3 for FY 2018. For purposes of this proposed rule, we are using data from the December 2016 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. For modeling purposes, as the FY 2015 SSI ratios are not yet available, we are using SSI days from the FY 2013 and FY 2014 SSI ratios, which are the most recent available SSI ratios. We expect the March 2017 update of the HCRIS database as well as the FY 2015 SSI ratios to be available in time for calculating Factor 3 for the FY 2018 IPPS/LTCH PPS final rule.

The proposed 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 proposed rule, we are proposing to make several additional modifications to the Factor 3 methodology: (1) To annualize Medicaid data if a hospitals' 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, and (4) to calculate Factor 3 for Puerto Rico hospitals and Indian Health Service and Tribal hospitals by substituting data regarding low-income insured days for FY 2013 for Worksheet S–10 data from FY 2014 cost reports. We also are proposing to continue 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 proposing to continue 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 averaging the sum of three individual Factor 3s 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 proposed 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 2,418 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 February 23, 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 proposed 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 PROPOSED PAYMENTS FOR ESTIMATED FY 2018 DSHS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2017 TO FY 2018

	Number of estimated DSHs (FY 2018)	FY 2017 final rule estimated DSH $ (in millions)	FY 2018 proposed rule estimated DSH $ (in millions)	Dollar difference: FY 2017–FY 2018 (in millions)	Percent change **
	(1)	(2)	(3)	(4)	(5)
Total	2,418	$9,553	$10,931	$1,378	14.4
By Geographic Location:					
Urban Hospitals	1,921	9,113	10,355	1,241	13.6
Large Urban Areas	1,037	5,717	6,538	821	14.4
Other Urban Areas	884	3,396	3,816	420	12.4
Rural Hospitals	497	439	577	137	31.2
Bed Size (Urban):					
0 to 99 Beds	331	185	240	56	30.2
100 to 249 Beds	841	2,154	2,461	307	14.3
250+ Beds	749	6,775	7,653	878	13.0
Bed Size (Rural):					
0 to 99 Beds	370	190	291	100	52.7
100 to 249 Beds	114	193	227	34	17.6
250+ Beds	13	56	58	3	4.7
Urban by Region:					
New England	92	387	420	34	8.8
Middle Atlantic	237	1,570	1,676	106	6.8
South Atlantic	314	1,724	2,082	359	20.8
East North Central	324	1,252	1,421	169	13.5
East South Central	128	566	617	52	9.1
West North Central	103	439	497	58	13.2
West South Central	253	1,165	1,489	324	27.8
Mountain	120	448	512	64	14.4
Pacific	311	1,448	1,496	48	3.3
Puerto Rico	41	116	144	28	23.8
Rural by Region:					
New England	12	16	21	6	35.4
Middle Atlantic	27	33	34	1	1.5
South Atlantic	84	92	118	27	29.0
East North Central	66	44	59	14	32.4
East South Central	136	141	154	13	9.2
West North Central	28	19	23	4	23.5
West South Central	112	72	140	67	93.6

MODELED DISPROPORTIONATE SHARE HOSPITAL PROPOSED PAYMENTS FOR ESTIMATED FY 2018 DSHS BY HOSPITAL TYPE: MODEL DSH $ (IN MILLIONS) FROM FY 2017 TO FY 2018—Continued

	Number of estimated DSHs (FY 2018) (1)	FY 2017 final rule estimated DSH $ (in millions) (2)	FY 2018 proposed rule estimated DSH $ (in millions) (3)	Dollar difference: FY 2017–FY 2018 (in millions) (4)	Percent change ** (5)
Mountain	27	15	21	6	37.0
Pacific	5	7	6	(1)	-8.9
By Payment Classification:					
Urban Hospitals	1,912	9,106	10,346	1,239	13.6
Large Urban Areas	1,037	5,717	6,538	821	14.4
Other Urban Areas	875	3,389	3,807	418	12.3
Rural Hospitals	506	447	586	139	31.1
Teaching Status:					
Nonteaching	1,510	2,955	3,428	472	16.0
Fewer than 100 residents	665	3,213	3,571	358	11.1
100 or more residents	243	3,384	3,932	548	16.2
Type of Ownership:					
Voluntary	1,420	5,971	6,710	739	12.4
Proprietary	550	1,650	1,715	65	3.9
Government	448	1,932	2,506	574	29.7
Medicare Utilization Percent:					
Missing or Unknown	4	0.65	1.25	0.60	92.2
0 to 25	424	2,972	3,451	480	16.1
25 to 50	1,635	6,218	7,044	826	13.3
50 to 65	309	352	422	70	20.0
Greater than 65	46	11	13	2	20.1

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 $10,930 million in FY 2018.

**Z0 Percentage change is determined as the difference between Medicare DSH payments modeled for the FY 2018 IPPS/LTCH PPS proposed rule (column 3) and Medicare DSH payments modeled for the FY 2017 IPPS/LTCH 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) proposed changes to Factor 1, which increased from $10.797 billion to $12.002 billion; (2) proposed changes to Factor 2, which increased from 55.36 percent to 58.01 percent; and (3) proposed changes to the data used to determine Factor 3. The proposed impact analysis found that, across all projected DSH eligible hospitals, FY 2018 DSH payments are estimated at approximately $10.930 billion, or an increase of approximately 14.4 percent from FY 2017 DSH payments (approximately $9.553 billion). While these proposed 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.

As seen in the above table, percent changes in DSH payments of less than 14.4 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 14.4 percent indicate a hospital type is projected to have a larger increase than the overall 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 Worksheet S–10, used in the Factor 3 computation.

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 13.6 percent increase in DSH payments, and rural hospitals are projected to receive a 31.2 percent increase in DSH payments. However, only smaller rural hospitals are projected to receive larger than average increases in DSH payments, with rural hospitals that have 0–99 beds projected to experience a 52.7 percent payment increase, and larger rural hospitals with 250+ beds projected to experience a 4.6 percent payment increase. This trend is consistent with urban hospitals, in which the smallest urban hospitals (0–99 beds) are projected to receive an increase in DSH payments of 30.2 percent. Larger hospitals (100–250 beds and 250+ beds) are projected to receive increases of 14.3 and 13.0 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 Pacific, Middle Atlantic, New England, and East South Central regions. The West South Central, Puerto Rico, and South Atlantic region hospitals are projected to receive a larger than average increase in DSH payments. Increases in remaining urban hospital regions are generally consistent with the overall average percent increase of 14.4. Regionally, rural hospitals are projected to receive a wider range of increases. Rural hospitals in the Pacific region are expected to receive a decrease in DSH payments (due to the reduction in the number of DSH hospitals in the region) while rural hospitals in the Middle Atlantic region are expected to receive virtually no change in in DSH payments, despite an estimated increase in the overall amount of DSH payments. Increases are projected to be substantially larger than the overall average in most regions, including West South Central, Mountain, New England, East North Central, South Atlantic, and West North Central regions.

Teaching hospitals with 100 or more residents are projected to receive relatively larger increases than teaching hospitals with fewer than 100 residents, although all are fairly consistent with the national average. Government hospitals are projected to receive larger than average increases, while voluntary hospitals are expected to receive increases generally consistent with the overall average. Proprietary hospitals are expected to receive smaller increases in DSH payments. Hospitals with 25 to 50 percent

Medicare utilization are projected to receive increases in DSH payments slightly below the overall average, while all other hospitals are projected to receive larger increases.

6. Effects of Proposed Reduction Under the Hospital Readmissions Reduction Program

In section V.I. of the preamble of this proposed rule, we discuss our 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 proposed rule, we estimate that 2,591 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 $564 million in FY 2018, an increase of $27 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 proposed proxy FY 2018 hospital-specific readmissions adjustment factors found in Table 15 of this proposed rule (available only through the Internet as described in section VI. of the Addendum to this proposed rule).

7. Effects of Proposed Changes Under the FY 2018 Hospital Value-Based Purchasing (VBP) Program

In section V.J. of the preamble of this proposed rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 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 proposed 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. We intend to update this estimate for the FY 2018 IPPS/LTCH PPS final rule using the March 2017 update of the FY 2016 MedPAR file.

The proposed 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 December 2016 update to the FY 2016 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the Internet on the CMS Web site 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 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.

Nonteaching 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 PROPOSED 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	1,227	0.094
Other Urban	1,048	0.152
Rural Area	680	0.392
Urban hospitals	2,275	0.121
0–99 beds	486	0.685
100–199 beds	721	0.082
200–299 beds	434	−0.039
300–499 beds	423	−0.159
500 or more beds	211	−0.159
Rural hospitals	680	0.392
0–49 beds	207	0.612
50–99 beds	276	0.398
100–149 beds	114	0.243
150–199 beds	44	0.052
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	0.025
East North Central	364	0.217
East South Central	135	0.009
West North Central	152	0.451
West South Central	320	0.194
Mountain	156	0.058

IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNT PROPOSED CHANGES RESULTING FROM THE FY 2018 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average percentage change
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	0.501
West South Central	107	0.257
Mountain	52	0.740
Pacific	22	0.504
By MCR Percent:		
0–25	424	0.125
25–50	2,017	0.167
50–65	459	0.277
Over 65	40	0.446
Missing	15	0.424
By DSH Percent:		
0–25	1,218	0.355
25–50	1,405	0.081
50–65	177	0.113
Over 65	155	−0.164
By Teaching Status:		
Non-Teaching	1,925	0.314
Teaching	1,030	−0.063

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 will be used for the updated impact analysis in that final rule.

8. Effects of Proposed Changes to the HAC Reduction Program for FY 2018

In section V.K. of the preamble of this proposed rule, we discuss the proposed changes to the HAC Reduction Program for FY 2018. The table and analysis below show the estimated cumulative effect of the proposed measures and scoring system for the HAC Reduction Program in this proposed rule. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57013 through 57025), we finalized changes to the HAC Reduction Program for FY 2018, including adoption of the modified PSI 90 Composite, defining the applicable time period, and changes to the scoring methodology (adoption of the z-score method for calculating measure scores). Based on this z-score methodology, the table below presents data on the estimated proportion of hospitals in the worst-performing quartile of the Total HAC Scores by hospital characteristic. We note that because scores will undergo a 30-day review and correction period by the hospitals that will not conclude until after the publication of the FY 2018 IPPS/LTCH PPS final rule, we are not providing hospital-level data or a hospital-level payment impact in conjunction with this FY 2018 IPPS/LTCH PPS proposed rule.

To estimate the impact of the FY 2018 HAC Reduction Program, we used, as previously finalized, AHRQ PSI 90 measure results based on Medicare FFS discharges from July 2014 through September 2015 and version 6.0 (recalibrated) of the AHRQ software. For the CLABSI, CAUTI, Colon and Abdominal Hysterectomy SSI, MRSA Bacteremia, and CDI measure results, we used standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the NHSN for infections occurring between January 1, 2014 and December 31, 2015. We noted that actual FY 2018 HACRP results will be calculated using CDC NHSN data from CYs 2015 and 2016 and will use the re-baselined values and expansion to non-ICU wards but could not be presented here due to data timelines.

We note that, at this time, we are unable to provide the estimated impact of the FY 2018 HAC Reduction Program due to an error in the version 6.0 (recalibrated) AHRQ software. We anticipate that we will be able to provide this information in the FY 2018 final rule. We have provided the final impacts from the FY 2017 final rule as estimated impacts for FY 2018.

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2017 HAC REDUCTION PROGRAM

[By hospital characteristic]

Hospital characteristic	Number of hospitals [a]	Number of hospitals in the worst-performing quartile [b]	Percent of hospitals in the worst-performing quartile [c]
Total [d]	3,215	771	24.0
By Geographic Location:			
All hospitals:			
Urban	2,404	653	27.2
Rural	796	107	13.4
Urban hospitals:			
1–99 beds	592	91	15.4

ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORE FOR THE FY 2017 HAC REDUCTION PROGRAM—Continued

[By hospital characteristic]

Hospital characteristic	Number of hospitals [a]	Number of hospitals in the worst-performing quartile [b]	Percent of hospitals in the worst-performing quartile [c]
100–199 beds	734	166	22.6
200–299 beds	440	134	30.5
300–399 beds	276	101	36.6
400–499	150	61	40.7
500 or more beds	212	100	47.2
Rural hospitals:			
1–49 beds	303	48	15.8
50–99 beds	289	29	10.0
100–149 beds	118	11	9.3
150–199 beds	45	9	20.0
200 or more beds	41	10	24.4
By Region:			
New England	134	42	31.3
Mid-Atlantic	365	131	35.9
South Atlantic	519	133	25.6
East North Central	494	96	19.4
East South Central	295	45	15.3
West North Central	259	38	14.7
West South Central	511	104	20.4
Mountain	226	55	24.3
Pacific	397	116	29.2
By DSH Percent: [e]			
0–24	1,387	321	23.1
25–49	1,454	324	22.3
50–64	181	58	32.0
65 and over	178	57	32.0
By Teaching Status: [f]			
Non-teaching	2,160	381	17.6
Fewer than 100 residents	790	237	30.0
100 or more residents	250	142	56.8
By Type of Ownership:			
Voluntary	1,868	478	25.6
Proprietary	825	154	18.7
Government	485	121	24.9
By MCR Percent:			
0–24	472	148	31.4
25–49	2,106	481	22.8
50–64	518	104	20.1
65 and over	80	18	22.5

Source: FY 2018 HAC Reduction Program Proposed Rule preliminary results are based on AHRQ PSI 90 data from July 2014 through September 2015 and CDC CLABSI, CAUTI, SSI, CDI, and MRSA results from January 2014 to December 2015. Hospital Characteristics are based on the FY 2017 Final Rule Impact File updated on October 3, 2016.

[a] The total number of non-Maryland hospitals with a Total HAC Score with hospital characteristic data (3,200 for geographic location, bed size, and teaching status; 3,178 for type of ownership; and 3,176 for MCR) does not add up to the total number of non-Maryland hospitals with a Total HAC Score for the FY 2018 HAC Reduction Program (3,215) because 15 hospitals are not included in the FY 2017 Final Rule Impact File and not all hospitals have data for all characteristics.

[b] 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.

[c] This column is the percent of 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.

[d] Total excludes 47 Maryland hospitals and 64 non-Maryland hospitals without a Total HAC Score for FY 2017.

[e] A hospital is considered to be a DSH hospital if it has a DSH patient percentage greater than zero.

[f] A hospital is considered to be a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

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 proposed rule, we discuss our proposed 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 proposed rule, we describe our proposals for implementation of the extension under section 15003 of Public Law 114–255, the proposed budget neutrality methodology for the extension period authorized by the legislation, and the proposed reconciliation of actual and estimated costs of the demonstration for previous years (2011 through 2016). Our proposal for budget neutrality would adopt the general methodology used in previous years for the demonstration. As discussed in section V.L. of the preamble of this proposed rule, in the IPPS final rules from FYs 2005 through 2016, we have estimated the additional payments for each of the participating hospitals as a result of the demonstration. In order to achieve budget neutrality, we have 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 Public Law 108–173), 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 added subsection (g)(5) to section 410A of Public Law 108–173 which provides for participation 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, but that were participating in the demonstration as of December 30, 2014, unless the hospital makes an election to discontinue participation.

We are proposing 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 are proposing 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 is 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 second 5 years of the 10-year extension period.

We are proposing that if the selection of the additional hospitals under the solicitation is not 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 section V.L. of the preamble of this proposed rule, we also describe an alternative approach that we considered, under 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. In addition, we describe the methodology that we considered for calculating the budget neutrality offset amount under this alternative approach. We are inviting public comments on this alternative approach and calculation methodology.

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 are proposing to continue this general procedure. Specifically, we are proposing 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 expect that this will occur in FY 2019. We also are proposing 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 estimated amounts included in the budget neutrality offset amounts for these fiscal years in a future final rule.

As discussed in section V.L. of the preamble of this proposed rule, depending on when the selection of additional hospitals as authorized by section 15003 of Public Law 114–225 is finalized, the estimate of the cost of the demonstration for FY 2018 will be formulated and included in the budget neutrality offset amount in either the FY 2018 final rule or the FY 2019 proposed and final rules. Therefore, although this FY 2018 IPPS/LTCH PPS proposed rule sets forth our proposed budget neutrality offset methodology, it does not include a specific budget neutrality offset amount.

10. Effects of the Proposed Changes Relating to Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations

In section V.N. of the preamble of this proposed rule, we discuss our proposals 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, we are proposing 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 are proposing 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. We do not expect any significant payment impact because these proposals 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 the Proposed Changes Relating to Hospital-within-Hospital (HwH) Policy

In section VII.B. of the preamble of this proposed rule, we discuss our proposal 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 proposal 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 proposing to revise 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 proposed revision would 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 proposals 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 section VIII.C.2. of the preamble of this proposed 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. 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, 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 were not implemented. Furthermore, section 123(i) of Public Law 110–275 states that the Secretary may waive the requirements of Titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. Budget neutrality estimates for the demonstration will be based on the demonstration period of 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 services, and ambulance services. These waivers are being implemented with the goal of increasing access to care with no net increase in costs. (We initially addressed this demonstration in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065).)

We specified waivers and payment enhancements for the demonstration and selected 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, in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57064 through 57065), we adopted a contingency plan 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, 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. 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 CAHs. Therefore we will make the reduction to payments to all CAHs, not just those participating in the demonstration, because the FCHIP demonstration is specifically designed to test innovations that affect delivery of services by this provider category. As we explained in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57065), we believe 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, we plan to recoup any excess costs over a period of three cost report periods, beginning in CY 2020. Therefore, this policy has no impact for any national payment system for FY 2018.

I. Effects of Proposed Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented below, we used data from the December 2016 update of the FY 2016 MedPAR file and the December 2016 update of the Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2016 update of the most recently available hospital cost report data (FYs 2013 and 2014) 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 December 2016 update of the FY 2016 MedPAR file, we simulated payments under the capital IPPS for FY 2017 and proposed 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 proposed 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 11.1 million in FY 2017 and 11.3 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 proposed rule, the proposed update is 1.2 percent for FY 2018.
- In addition to the proposed FY 2018 update factor, the proposed FY 2018 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality

adjustment factor of 0.9992, a proposed outlier adjustment factor of 0.9434, 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 proposed rule as it relates to the capital Federal rate. As also discussed in section V.C. of the preamble of this proposed rule, we are not proposing to make an additional MS–DRG documentation and coding adjustment to the capital IPPS Federal rate for FY 2018.

2. Results

We used the actuarial model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of our proposed 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 December 2016 update of the FY 2016 MedPAR file, the December 2016 update to the PSF, and the most recent cost report data from the December 2016 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2017 and estimated proposed total payments per case for FY 2018 based on the proposed FY 2018 payment policies. Column 2 shows estimates of payments per case under our model for FY 2017. Column 3 shows estimates of proposed 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 proposed 1.2 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) Geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, proposed capital payments per case in FY 2018 are expected to increase as compared to capital payments per case in FY 2017. This expected increase overall is due to the proposed approximately 1.2 percent update to the capital Federal rate for FY 2018, as well as the proposed outlier adjustment of 0.9434 which is a 0.51 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, as are changes in the DRGs. The expected increase in capital payments per case as a result of MS–DRG changes is somewhat larger for hospitals in rural areas than for hospitals in rural areas. (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 proposed rule.) Over all hospitals, the proposed changes to the GAFs have no effect on capital payments per case. However, by region, hospitals within both rural and urban regions may experience an increase or a decrease in capital payments per case due to proposed changes in the GAFs. These regional effects of the proposed changes to the GAFs on capital payments are consistent with the projected changes in payments due to proposed changes in the wage index (and policies affecting the wage index) as shown in Table I in section I.G. of this Appendix A.

The net impact of these proposed changes is an estimated 2.4 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) would 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 would increase by an estimated 2.8 percent, while hospitals in rural areas, on average, are expected to experience a 2.6 percent increase in capital payments per case from FY 2017 to FY 2018. Capital IPPS payments per case for other urban hospitals are estimated to increase 1.7 percent.

The comparisons by region show that the estimated increases in capital payments per case from FY 2017 to FY 2018 in urban areas would range from a 3.6 percent increase for the West South Central urban region to a 1.1 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 5.0 percent, while the South Atlantic rural region is projected to experience an increase in capital IPPS payments per case of 1.4 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 proposed increase in capital payments for voluntary hospitals is estimated to be 2.0 percent and for government hospitals, the increase is estimated to be 3.4 percent. Proprietary hospitals are expected to experience an increase in capital IPPS payments of 3.0 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 proposed 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 2.8 percent. The estimated percentage increase for rural reclassified hospitals is 2.4 percent, and for rural nonreclassified hospitals, the estimated increase is 2.6 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 1.8 percent, while capital payments for other reclassified hospitals are expected to increase an estimated 6.1 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	921	943	2.4
Large urban areas (populations over 1 million)	1,349	1,016	1,044	2.8
Other urban areas (populations of 1 million of fewer)	1,142	886	902	1.7
Rural areas	801	625	642	2.6
Urban hospitals	2,491	955	977	2.3
0–99 beds	638	769	799	4.0
100–199 beds	765	826	848	2.7
200–299 beds	445	877	892	1.8
300–499 beds	431	969	993	2.4
500 or more beds	212	1,141	1,166	2.2
Rural hospitals	801	625	642	2.6
0–49 beds	313	522	541	3.5
50–99 beds	285	585	598	2.2
100–149 beds	117	621	636	2.4
150–199 beds	46	668	689	3.1

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
200 or more beds	40	745	764	2.5
By Region:				
Urban by Region	2,491	955	977	2.3
New England	114	1,037	1,052	1.4
Middle Atlantic	315	1,059	1,082	2.1
South Atlantic	404	850	867	2.0
East North Central	385	918	937	2.1
East South Central	147	801	813	1.5
West North Central	160	932	953	2.3
West South Central	378	863	895	3.6
Mountain	162	1,005	1,016	1.1
Pacific	375	1,211	1,254	3.5
Puerto Rico	51	436	449	3.0
Rural by Region	801	625	642	2.6
New England	20	861	905	5.0
Middle Atlantic	53	603	618	2.4
South Atlantic	125	584	593	1.4
East North Central	115	645	659	2.1
East South Central	154	575	591	2.7
West North Central	97	666	686	3.0
West South Central	154	554	570	2.9
Mountain	59	697	717	2.9
Pacific	24	807	836	3.6
By Payment Classification:				
All hospitals	3,292	921	943	2.4
Large urban areas (populations over 1 million)	1,363	1,014	1,043	2.8
Other urban areas (populations of 1 million of fewer)	1,028	885	907	2.4
Rural areas	901	730	733	0.3
Teaching Status:				
Non-teaching	2,211	779	799	2.6
Fewer than 100 Residents	835	893	910	1.9
100 or more Residents	246	1,288	1,321	2.6
Urban DSH:				
100 or more beds	1,563	982	1,007	2.6
Less than 100 beds	357	692	720	4.1
Rural DSH:				
Sole Community (SCH/EACH)	259	623	632	1.5
Referral Center (RRC/EACH)	271	772	775	0.4
Other Rural:				
100 or more beds	41	862	834	−3.3
Less than 100 beds	240	507	516	1.8
Urban teaching and DSH:				
Both teaching and DSH	870	1,054	1,082	2.6
Teaching and no DSH	94	928	941	1.4
No teaching and DSH	1,050	822	844	2.6
No teaching and no DSH	377	833	865	3.8
Rural Hospital Types:				
Non special status hospitals	2,601	953	977	2.6
RRC/EACH	243	801	804	0.3
SCH/EACH	317	716	731	2.0
SCH, RRC and EACH	129	756	773	2.2
Hospitals Reclassified by the Medicare Geographic Classification Review Board:				
FY 2018 Reclassifications:				
All Urban Reclassified	629	956	971	1.6
All Urban Non-Reclassified	1,814	956	983	2.8
All Rural Reclassified	271	660	675	2.4
All Rural Non-Reclassified	482	580	595	2.6
All Section 401 Reclassified Hospitals	148	873	857	−1.8
Other Reclassified Hospitals (Section 1886(d)(8)(B))	42	600	637	6.1
Type of Ownership:				
Voluntary	1,914	938	957	2.0
Proprietary	862	823	848	3.0
Government	514	960	993	3.4
Medicare Utilization as a Percent of Inpatient Days:				
0–25	509	1,096	1,129	3.1
25–50	2,113	927	948	2.2
50–65	535	756	772	2.1
Over 65	135	582	639	9.8

J. Effects of Proposed Payment Rate Changes and Proposed Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2018. In the preamble of this proposed rule, we specify the statutory authority for the provisions that are presented, identify the proposed policies, and present rationales for our decisions as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 415 LTCHs included in this impacts analysis, which includes data for 72 nonprofit (voluntary ownership control) LTCHs, 328 proprietary LTCHs, and 15 LTCHs that are government-owned and operated. (We note that, although there are currently approximately 425 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the proposed FY 2018 MS–LTC–DRG relative weights (discussed in section VIII.B.3.c. of the preamble of this proposed rule). Moreover, in the claims data use for this proposed rule, 3 of these 415 LTCHs only have claims for site neutral payment rate cases and are therefore not included in our impact analysis for LTCH PPS standard Federal payment rate cases.) In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed 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 proposed 1.0 percent annual update to the LTCH PPS standard Federal payment rate required by section 411 of Public Law 114–10, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, the proposed change to the SSO payment methodology (discussed in VIII.E. of the preamble of this proposed rule), our proposal to adopt a 1-year regulatory delay of the full implementation of the 25-percent threshold policy for FY 2018, and our proposals to implement certain provisions of the 21st Century Cures Act, and the best available claims and CCR data to estimate the proposed 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).

Based on the best available data for the 415 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2018 would decrease by approximately 5.2 percent (or approximately $238 million) based on the proposed rates and factors presented in section VIII. of the preamble and section V. of the Addendum to this proposed rule. (We note that this estimate does not reflect our proposal 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 proposals regarding the implementation of certain provisions of the 21st Century Cures Act. As discussed in greater detail below, our actuaries estimate these proposals would increase spending by approximately $65 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 proposed 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 would 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 41 LTCHs whose cost reporting period will begin in the first quarter of FY 2018 so that, for purposes of this estimate, we assume all 41 LTCH 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 6.3 percent of all FY 2018 site neutral payment rate cases and therefore, we estimate that group of LTCHs will discharge 6.3 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 December 2016 update of the PSF and the LTCH claims from the December 2016 update of the FY 2016 MedPAR files for the 415 LTCHs in our database used for this proposed rule, we found the following: 6.3 percent of site neutral payment rate cases are from 41 LTCHs whose cost reporting periods will begin during the first quarter of FY 2018; 23.7 percent of site neutral payment rate cases are from 106 LTCHs whose cost reporting periods will begin in the second quarter of FY 2018; 9.3 percent of site neutral payment rate cases are from 55 LTCHs whose cost reporting periods will begin in the third quarter of FY 2018; and 60.7 percent of site neutral payment rate cases are from 213 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: 6.3 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 93.7 percent of site neutral payment rate discharges are eligible to be paid under the transitional payment method.
- Second Quarter FY 2018: 30.0 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 70.0 percent of site neutral payment rate second quarter discharges are eligible to be paid under the transitional payment method.
- Third Quarter FY 2018: 39.3 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 60.7 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 proposed 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 would 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 would decrease by approximately 22 percent (or approximately $252 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 would be paid based on the proposed 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 would increase approximately 0.4 percent (or approximately $15 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2018 is primarily due to the combined effects of 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 proposed rule) and an estimated proposed decrease in HCO payments for these cases (discussed in section V.D. of the Addendum to this proposed rule). (We note that because our proposed SSO payment methodology discussed in VIII.E. of the preamble of this proposed rule incorporates a proposed budget neutrality adjustment, this proposal does not increase or decrease aggregate payments, and therefore does not factor into the 0.4 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 proposed rule presented in Table IV in section I.J.4. of this Appendix, we estimate that aggregate FY 2018 LTCH PPS payments would be approximately $4.371 billion, as compared to estimated aggregate FY 2017 LTCH PPS payments of approximately $4.609 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $238 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 $65 million for our proposal to delay full implementation of the 25-percent threshold policy for FY 2018 and our proposed implementation of certain provisions of the 21st Century Cures Act. Therefore, in total we project an overall decrease in LTCH PPS payments of approximately $173 million (−$238 million + $65 million) or approximately a 3.75 percent decrease in LTCH PPS payments in FY 2018 as compared to FY 2017. Because the proposed combined distributional effects and estimated payment changes exceed $100 million, this proposed rule is a major economic rule. We note that the estimated $238 million decrease in LTCH PPS payments in FY 2018 (which includes proposed estimated payments for LTCH PPS standard Federal payment rate cases and site neutral payment rate cases, but does not include estimated payments for our proposal 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 would also affect the overall payment effects of the policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2017 is $42,476.41. For FY 2018, we are proposing to establish an LTCH PPS standard Federal payment rate of $41,497.20, which reflects the proposed 1.0 percent annual update to the LTCH PPS standard Federal payment rate, the proposed area wage budget neutrality factor of 1.000077 to ensure that the changes in the wage indexes and labor-related share do not influence aggregate payments, and the proposed budget neutrality adjustment of 0.9672 to ensure that our proposed changes to the SSO payment methodology (discussed in VIII.E. of the preamble of this proposed 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 proposing to establish an LTCH PPS standard Federal payment rate of $40,675.49. This proposed reduced LTCH PPS standard Federal payment rate reflects the proposed 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 proposed 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 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 proposed 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 would be paid using special methodologies that are not affected by the proposed annual update to the LTCH PPS standard Federal payment rate (without incorporating our proposed SSO payment methodology as discussed in VIII.E. of the preamble of this proposed rule),

as well as the proposed 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 proposed 1.0 percent annual update for FY 2018 required under section 411 of Public Law 114–10.

For FY 2018, we are proposing to update the wage index values based on the most recent available data, and we are proposing to continue to use labor market areas based on the OMB CBSA delineations (as discussed in section V.B. of the Addendum to this proposed rule). In addition, we are proposing to reduce the labor-related share from 66.5 percent to 66.3 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 are proposing to apply a proposed area wage level budget neutrality factor of 1.000077 to ensure that the proposed changes to the wage data and labor-related share do not result in a change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

As we discuss in VIII.E. of the preamble of this proposed rule, we are proposing to simplify 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 are proposing to apply a proposed budget neutrality factor of 0.9672 to ensure the proposed 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 would decrease from FY 2017 to FY 2018. Based on the FY 2016 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2017 HCO threshold of $21,943 (as established in the FY 2017 IPPS/LTCH PPS final rule) would 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 would be approximately 8.6 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2017. Combined with our estimate that proposed FY 2018 HCO payments for LTCH PPS standard Federal payment rate cases would 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 would result in the estimated decrease in HCO payments of approximately 0.6 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 our proposed SSO payment methodology, this increase in estimated costs would 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 would increase total payments for LTCH PPS standard Federal payment rate cases by approximately 0.2 percent.

Table IV shows the estimated impact of the proposed payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2018 by comparing estimated FY 2017 LTCH PPS payments to estimated proposed FY 2018 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) The proposed projected increase in payments from FY 2017 to FY 2018 for LTCH PPS standard Federal payment rate cases of 0.4 percent is attributable to the impacts of the proposed change to the LTCH PPS standard Federal payment rate (0.9 percent in Column 6) and the effect of the proposed estimated decrease in HCO payments for LTCH PPS standard Federal payment cases (−0.6 percent), and the proposed estimated increase in payments for SSO cases (0.2 percent) prior to incorporation of our proposed 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 proposed rule, based on the most recent available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, and the resulting LTCH PPS payment amounts would result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 0.4 percent increase 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 Proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed rule), does not impact FY 2018 LTCH PPS payments.) In addition, if adopted, our actuaries estimate that our proposal to further delay the full implementation of the 25-percent threshold policy for FY 2018 would increase aggregate Medicare spending by $50 million.

As discussed in section VIII.E. of the preamble of this proposed 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 Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003

standard Federal 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 $238 million based on Table IV. This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $15 million and the projected decrease in payments to site neutral payment rate cases of approximately $252 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 proposal 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 proposed rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate 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 proposed 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 proposed 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 proposed 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 proposed LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the proposed changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

Under the 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 proposed changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 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 proposed rates, factors, and the policies in this FY 2018 IPPS/LTCH PPS proposed rule (as discussed in section VIII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed 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 Proposed LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our proposed policies on proposed payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2017 and proposed 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 proposed FY 2018 LTCH PPS standard Federal payment rate, we used the proposed FY 2018 standard Federal payment rate of $41,497.20 (or $40,675.49 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 proposed FY 2018 LTCH PPS payments, we used the proposed FY 2018 LTCH PPS labor-related share (66.3 percent), the proposed FY 2018 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the Internet on the CMS Web site), the proposed FY 2018 fixed-loss amount for LTCH PPS standard Federal payment rate cases of $30,081 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2018 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the FY 2018 nonlabor-related share (33.7 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 proposed 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 proposed SSO payment methodology and for HCO cases for LTCH PPS standard Federal payment rate cases, we applied a proposed inflation factor of 5.6 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 proposed payment rates and proposed policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the proposed 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 proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 for proposed changes to the area wage level adjustment (that is, the wage indexes and the labor-related share), including the application of the proposed area wage level budget neutrality factor (as discussed in section V.B. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for changes resulting from our proposed 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 proposed changes (and includes the effect of estimated changes to HCO and SSO payments).

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND PROPOSED 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 proposed FY 2018 LTCH PPS payment per standard payment rate [1]	Proposed percent change due to change to the proposed annual update to the standard federal rate [2]	Proposed percent change due to proposed changes to area wage adjustment with wage budget neutrality [3]	Proposed percent change due to proposed change to the short stay outlier payment methodology change [4]	Proposed percent change due to all proposed standard payment rate changes [5]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
All Providers	415	73,231	$46,947	$47,149	0.9	0.0	0.0	0.4
By Location:								
Rural	21	2,214	37,951	37,702	0.9	−0.3	0.1	−0.7
Urban	394	71,017	47,227	47,443	0.9	0.0	0.0	0.5
Large	200	40,843	49,951	50,249	0.9	0.1	0.1	0.6
Other	194	30,174	43,541	43,645	0.9	−0.1	−0.2	0.2
By Participation Date:								
Before Oct. 1983	16	2,509	42,228	43,135	0.9	−0.5	2.0	2.1
Oct. 1983–Sept. 1993	45	9,580	52,603	52,668	0.8	−0.1	−0.2	0.1
Oct. 1993–Sept. 2002	169	30,469	45,835	46,061	0.9	0.0	−0.1	0.5
After October 2002	185	30,673	46,671	46,834	0.9	0.0	0.0	0.3
By Ownership Type:								
Voluntary	72	9,536	49,476	49,458	0.9	−0.1	−0.3	0.0
Proprietary	328	62,236	46,393	46,647	0.9	0.0	0.0	0.5
Government	15	1,459	54,034	53,468	0.9	−0.2	−1.0	−1.0
By Region:								
New England	12	2,748	44,003	44,457	0.9	−0.3	0.3	1.0
Middle Atlantic	25	5,845	51,781	52,133	0.9	−0.2	0.4	0.7
South Atlantic	66	13,245	46,739	47,089	0.9	−0.1	0.4	0.7
East North Central	68	11,419	46,589	46,717	0.9	0.0	−0.1	0.3
East South Central	34	5,209	43,878	44,214	0.9	0.0	0.6	0.8
West North Central	27	4,325	45,735	45,380	0.9	0.2	−1.2	−0.8

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND PROPOSED POLICY CHANGES TO LTCH PPS PAYMENTS FOR STANDARD PAYMENT RATE CASES FOR FY 2018—Continued

[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 proposed FY 2018 LTCH PPS payment per standard payment rate [1]	Proposed percent change due to change to the proposed annual update to the standard federal rate [2]	Proposed percent change due to proposed changes to area wage adjustment with wage budget neutrality [3]	Proposed percent change due to proposed change to the short stay outlier payment methodology change [4]	Proposed percent change due to all proposed standard payment rate changes [5]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)
West South Central	127	18,398	41,960	41,929	0.9	0.2	−0.6	−0.1
Mountain	31	4,184	49,112	49,256	0.9	−0.2	−0.2	0.3
Pacific	25	7,858	58,479	59,128	0.8	0.0	0.3	1.1
By Bed Size:								
Beds: 0–24	26	1,753	46,440	46,297	0.9	0.5	−0.7	−0.3
Beds: 25–49	193	25,450	43,767	43,898	0.9	−0.1	0.0	0.3
Beds: 50–74	117	20,112	48,449	48,509	0.9	0.0	−0.2	0.1
Beds: 75–124	47	13,018	50,260	50,681	0.9	0.1	0.0	0.8
Beds: 125–199	23	8,013	48,199	48,375	0.9	0.0	−0.1	0.4
Beds: 200+	9	4,885	46,633	47,363	0.8	0.1	0.7	1.6

[1] Estimated FY 2018 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed 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 proposed 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 proposed changes to the area wage level adjustment under § 412.525(c) (as discussed in section V.B. of the Addendum to this proposed rule).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2017 to FY 2018 for proposed 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 proposed changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the proposed percent change in estimated payments per discharge for all proposed changes, does not equal the sum of the proposed percent changes in estimated payments per discharge for the proposed annual update to the LTCH PPS standard Federal payment rate (Column 6) and the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in both estimated payments to SSO cases (prior to accounting for the proposed 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 proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the proposed LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 0.4 percent, on average, for all LTCHs from FY 2017 to FY 2018 as a result of the proposed payment rate and proposed policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 0.4 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2018 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed 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 proposing to update 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 proposing to apply an area wage level budget neutrality factor to the proposed FY 2018 LTCH PPS standard Federal payment rate of 1.000077, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed 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 payment rate payments. Finally, we are proposing a budget neutrality adjustment of 0.9672 for our proposed changes to the SSO payment methodology (discussed in VIII.E.2.d. of the preamble of this proposed 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 proposed 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 proposed changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also reflects estimated payments for SSO cases that 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 proposed 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 proposed 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 proposed 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 0.4 percent. However, for rural LTCHs, the proposed overall percent change for LTCH PPS standard Federal payment rate cases is estimated to be a 0.7 percent decrease. This projected decrease is primarily driven by a projected decrease resulting from changes to the proposed changes to the FY 2018 MS–LTC–DRGs and relative weights as well as from the projected 0.3 percent decrease resulting from the proposed changes to the area wage index adjustment. For urban LTCHs, we estimate an increase of 0.5

percent from FY 2017 to FY 2018. Among the urban LTCHs, large urban LTCHs are projected to experience an increase of 0.6 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 0.2 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 42 percent) are in LTCHs that began participating in the Medicare program after September 2002, and they are projected to experience a 0.3 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 4 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience an average percent increase of 2.1 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 2.0 percent increase resulting from our proposed SSO payment method. Approximately 11 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 0.1 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 42 percent of all LTCH PPS standard Federal payment rate cases, are projected to experience a 0.5 percent increase in estimated payments from FY 2017 to FY 2018. Lastly, LTCHs that began participating in Medicare program after October, 2002 also treat approximately 42 percent of all LTCH PPS standard Federal payment rate cases and are projected to experience a 0.3 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 79 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 4 percent of LTCHs. Based on ownership type, voluntary LTCHs are expected to experience no change in payments to LTCH PPS standard Federal payment rate cases, while proprietary LTCHs are expected to experience an average increase of 0.5 percent in payments to LTCH PPS standard Federal payment rate cases. Government owned and operated LTCHs, meanwhile, are expected to experience a 1.0 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 experience a decrease from FY 2017 for LTCHs located in the West South Central and West North Central regions, 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 would have the largest positive impact on LTCHs in the Pacific and New England regions (1.1 percent and 1.0 percent, respectively, as shown in Table IV), which is largely attributable to the proposed changes in the proposed changes to the SSO payment method. In contrast, LTCHs located in the East North Central and Mountain regions 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.

(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 would experience a decrease in payments for LTCH PPS standard Federal payment rate cases of 0.3 percent, and LTCHs with 25–49 beds would experience an increase in payments for LTCH PPS standard Federal payment rate cases of 0.3 percent. LTCHs with 50–74 beds would experience an increase in payments for LTCH PPS standard Federal payment rate cases of 0.1 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 woud experience an increase in payments for LTCH PPS standard Federal payment rate cases of 0.8 percent while LTCHs with 125–199 beds would experience an increase in payments for LTCH PPS standard Federal payment rate cases of 0.4 percent. Finally, LTCHs with 200 or more beds would experience the largest increase in payments for LTCH PPS standard Federal payment rate cases of 1.6 percent mostly due to estimated increase in payments from proposed changes to the FY 2018 MS–LTC–DRG classifications and relative weights and our proposed SSO payment method.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule would result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2018 relative to FY 2017 of approximately $15 million (or approximately 0.4 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 proposed rule would 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 $252 million (or approximately 22 percent) for the 415 LTCHs in our database. Therefore, we project that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments to all LTCH cases in FY 2018 relative to FY 2017 of approximately $238 million (or approximately 5.2 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 $65 million for our proposal to delay full implementation of the 25-percent threshold policy for FY 2018 and our proposed implementation of certain provisions of the 21st Century Cures Act. Therefore, in total, we project an overall decrease in LTCH PPS payments of approximately $173 million ($238 million decrease + $65 million increase) or approximately a 3.75 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 proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program.

K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

1. Background

In section IX.A. of the preamble of this proposed 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 proposed rule, we are proposing to: (1) Update the electronic clinical quality measure (eCQM) reporting requirements with regard to the number of eCQMs and quarters of data for the FY 2019 and FY 2020 payment determinations; (2) update the eCQM certification requirements for the FY 2019 and FY 2020 payment determinations; (3) update our previously finalized eCQM validation processes for the FY 2020 payment determination and subsequent years; (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 new Hybrid Hospital-Wide 30-Day Readmission 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 NIH stroke scale for the FY 2023 payment determination and subsequent years; (8) provide confidential reports of measure data stratified by dual eligible status for the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization and Hospital 30-day, All-Cause, Risk Standardized Mortality Rate (RSRR) for Pneumonia measures; and (9) update the Extraordinary Circumstances Exceptions (ECE) Policy for the FY 2020 payment determination and subsequent years.

As further explained in section XIII.B.6. of the preamble of this proposed rule, we believe that there will be an overall decrease in burden for hospitals due to the proposals discussed above. We refer readers to section XIII.B.6. of the preamble of this proposed rule for a summary of our burden estimates.

2. Impact of the Proposed Updates to the eCQM Reporting Requirements

(a) Impact for the CY 2017 Reporting Period/FY 2019 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 eCQMs (81 FR 57157) for both the FY 2019 and FY 2020 payment determinations. In section IX.A.8. of the preamble of this proposed rule, we are proposing the following changes to this finalized policy: (1) Revise the CY 2017 reporting period/FY 2019 payment determination eCQM reporting requirements, such that hospitals are required to report six eCQMs and to submit two, self-selected, calendar quarters of data; and (2) revise the CY 2018 reporting period/FY 2020 payment determination eCQM reporting requirements such that hospitals are required to report six eCQMs for the first three quarters of CY 2018. As described in section XIII.B.6.b. of the preamble of this proposed rule, we believe that the reduction in the required number of eCQMs for the CY 2017 reporting period/FY 2019 payment determination will result in a reduction of 200 minutes per hospital per year, or 3 hours and 20 minutes per hospital per year, for the FY 2019 payment determination.

In total, for the FY 2019 payment determination, we expect our proposal to require hospitals to report data on six eCQMs for two quarters (as compared to our previously finalized requirements to report data on eight eCQMs for four quarters) to represent an annual burden reduction of 11,000 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program. Using the wage estimate described in section XIII.B.6.a. of the preamble of this proposed rule, we expect this to represent a cost reduction of $361,240 across all 3,300 IPPS hospitals participating in the Hospital IQR Program.

(b) Impact for the CY 2017 Reporting Period/FY 2019 Payment Determination

Using the same estimate as described above of 10 minutes per record per quarter, we note that if our proposed updates to the CY 2018 reporting period/FY 2020 payment determination are finalized as proposed, we anticipate our proposal to require: (1) Reporting on six of the available eCQMs; and (2) submission of the first three quarters of CY 2018 eCQM data, will result in a burden reduction of 2 hours and 20 minutes (140 minutes) per hospital for the FY 2020 payment determination as compared to the previously finalized requirements to report eight eCQMs for four quarters for the FY 2020 payment determination (81 FR 57157 through 57159). In total, this would represent an annual burden reduction of 7,700 hours across all 3,300 IPPS hospitals participating in the Hospital IQR Program and a cost reduction of $252,868 ($32.84 hourly wage × 7,700 annual hours reduction) across all 3,300 IPPS hospitals.

3. Impact of the Proposed Modifications to eCQM Certification Requirements for the FY 2019 and FY 2020 Payment Determinations and Subsequent Years

In section IX.10.d. of the preamble of this proposed rule we discuss our proposed changes to the Hospital IQR Program eCQM submission requirements to align with the Medicare EHR Incentive Program for eligible hospitals and CAHs. Specifically, for the CY 2017 reporting period/FY 2019 payment determination, we are proposing that: (1) A hospital using EHR technology certified to the 2014 or 2015 Edition, 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 does not need to be recertified each time it is updated to a more recent version of the eCQM specifications. For the CY 2018 reporting period/FY 2020 payment determination, we are proposing that: (1) A hospital using EHR technology certified to the 2015 Edition, but such EHR technology is not certified to all available eCQMs, would be required to have its EHR technology certified to all of the eCQMs that are available to report; and (2) an EHR certified for all available eCQMs under the 2015 Edition of CEHRT would not need to be recertified each time it is updated to a more recent version of the eCQM specifications.

Further, we are proposing that: (1) For the CY 2017 reporting period/FY 2019 payment determination, hospitals would be required to use the most recent version of the CQM electronic specifications; Spring 2016 version of the eCQM specifications and any applicable addenda; and (2) for the CY 2018 reporting period/FY 2020 payment determination, hospitals be required to use the most recent version of the CQM electronic specifications; 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 for eligible hospitals and CAHs, we believe that these proposals will have no effect on burden for hospitals under the Hospital IQR Program.

4. Impact of the Proposed Modifications to the Existing Validation Processes for the FY 2020 Payment Determination and Subsequent Years

(a) Impact of the Proposed Modifications to the Validation of eCQM Data for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.11. of the preamble of this proposed rule, we discuss our proposal to adopt a modification to the existing eCQM data validation process for the Hospital IQR Program data beginning with validation for the FY 2020 payment determination. First, we are proposing to require eight cases to be submitted per quarter for eCQM validation for the FY 2020 payment determination and subsequent years. We are making this proposal in conjunction with our proposal to require two quarters of data for the CY 2017 eCQM reporting period and our proposal to require three quarters of data for the CY 2018 eCQM reporting period. Accordingly, if those eCQM reporting proposals are finalized, we are proposing that the number of required case files for validation would be 16 records (eight cases per quarter over two quarters) for the FY 2020 payment determination and 24 records (eight cases per quarter over three quarters) for the FY 2021 payment determination. Second, we are proposing to add additional exclusion criteria to our hospital and case selection process for eCQM validation for the CY 2018 reporting period/FY 2020 payment determination and subsequent years. Third, we are proposing to extend to the FY 2021 payment determination and subsequent years our previously finalized medical record submission policy for eCQM 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 are proposing to extend to the FY 2021 payment determination our previously finalized medical record submission policy for eCQM 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 are also proposing to clarify our finalized policy.

We believe the updates to the exclusions and maintaining previously finalized medical record submission requirements will have no effect on burden for hospitals. We believe that the changes associated with the proposed eCQM validation process will result in a burden reduction of approximately 4,333 hours across up to 200 hospitals selected for eCQM validation. Using the estimated hourly labor cost of $32.84, we estimate an annual cost reduction of $142,296 (4,333 hours × $32.84 per hour) across the 200 hospitals selected for eCQM validation due to our proposal to decrease the number of records collected for validation from 32 records to 16 records for the FY 2020 payment determination. We refer readers to section XIII.B.6.d.(1) of the preamble of this proposed rule for more detail on these calculations.

(b) Impact of the Proposed Modifications to the Validation of eCQM Data for the FY 2021 Payment Determination and Subsequent Years

Applying the time per individual submission of 1 hour and 20 minutes (or 80 minutes) per record for the 24 records we are proposing that hospitals submit for eCQM validation for the FY 2021 payment determination, we estimate a burden reduction of approximately 2,133 hours across up to 200 hospitals selected for eCQM validation for the FY 2021 payment determination. Using the estimated hourly labor cost of $32.84, we estimate an annual cost reduction of $70,048 (2,133 hours × $32.84 per hour) across the 200 hospitals selected for eCQM validation due to our proposal to reduce the number of records collected from 32 records as finalized in the FY 2017 IPPS/LTCH PPS final rule to 24 records for the FY 2021 payment determination. We refer readers to section XIII.B.6.d.(2) of the preamble of this proposed rule for more detail on these calculations.

(c) Impact of the Proposed Modifications to the Validation Exclusions for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.11.b. of the preamble of this proposed rule, we are proposing a new eCQM validation exclusion criterion. Specifically, hospitals that do not have at least five discharges for at least one reported measure (among the six required eCQMs proposed for the CY 2017 and CY 2018 eCQM reporting periods) included in their QRDA I file submissions would be excluded from the random sample of up to 200 hospitals selected for eCQM validation for the FY 2020 payment determination and subsequent years. We also are proposing, for the FY 2020 payment determination and subsequent years, to exclude hospitals meeting the newly proposed exclusion criterion discussed above and/or either of the two exclusion criteria finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57178). Lastly, we are proposing that the three exclusions would be applied before the random selection of 200 hospitals for eCQM validation, such that hospitals meeting any of these exclusions would not be eligible for selection.

In section IX.A.11.b. of the preamble of this proposed rule, we also are proposing to exclude the following cases from validation for those hospitals that are chosen to participate in eCQM 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 proposals will impact the burden experienced by hospitals because, while they influence which hospitals and cases would be selected, they would not change the number of hospitals that must participate in eCQM validation, the number of records that would be collected for validation, or the validation reporting requirements for the hospitals selected.

(d) Impact of the Proposed Modifications to the Medical Record Submission Requirements for the FY 2021 Payment Determination and Subsequent Years

In section IX.A.11.b. of the preamble of this proposed rule, we are proposing that for hospitals participating in eCQM validation we: (1) Require submission of at least 75 percent of sampled eCQM measure medical records in a timely and complete manner; and (2) that the accuracy of eCQM data submitted for validation would not affect a hospital's validation score (81 FR 57180). We do not expect these proposals to impact the burden experienced by hospitals, as we are continuing existing policies.

(e) Impact of the Proposed Educational Review Process for Chart-Abstracted Measures for the FY 2020 Payment Determination and Subsequent Years

In section IX.A.11.c. of the preamble of this proposed rule, we are proposing to formalize the process of allowing hospitals to use an educational review process to correct validation results for the first three quarters of validation for chart-abstracted measures. Second, we are proposing 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. As stated in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49762), we estimate a burden of 15 minutes per hospital to report structural measure data and to complete all forms, including the reconsideration request form and the educational review form. We refer readers to the FY 2017 IPPS/LTCH PPS final rule for more detailed information on the burden associated with the chart-abstracted validation requirements (81 FR 57260). Although this proposal may allow hospitals to avoid the formal reconsideration process, we do not expect this proposal to change our previously finalized burden estimates for the chart-abstracted measures validation process or add any additional burden, as it would not change the requirements for selecting hospitals for validation of chart-abstracted measures nor change the chart-abstracted validation reporting requirements for the selected hospitals.

5. Impact of the Proposed Voluntary Reporting on the Hybrid Hospital-Wide 30-Day Readmission Measure for the CY 2018 Reporting Period

In section IX.A.7.a. of the preamble of this proposed rule, we are proposing voluntary reporting on the Hybrid Hospital-Wide 30-Day Readmission measure for the 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 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 proposed rule, we are proposing that hospitals 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 voluntarily reporting this measure to be similar to our estimates for eCQM reporting (that is 10 minutes per measure, per quarter). We anticipate that approximately 100 hospitals would voluntarily report the Hybrid Hospital-Wide 30-Day Readmission measure. As such, this proposal represents an annual burden increase of 67 hours across up to 100 hospitals voluntarily participating. Using the wage estimate described above, we estimate this to represent a cost increase of $2,200 ($32.84 hourly wage × 67 annual hours) across up to 100 hospitals voluntarily reporting data for this measure. We refer readers to section XIII.B.6.e. of the preamble of this proposed rule for more detail on these burden calculations.

6. Impact of the Proposed 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 proposed rule, we are proposing to refine and update the HCAHPS Survey measure by replacing the set of three current Pain Management questions with the ''Communication About Pain'' composite measure beginning with the FY 2020 payment determination. There is no additional burden associated with the refinement of these questions because we are rewording the existing questions to include language that focuses on communication about pain. In addition, consistent with previous years (81 FR 57261), the burden estimate for the Hospital IQR Program excludes the burden associated with the HCAHPS Survey measure, which is submitted under a separate information collection request and approved under OMB control number 0938–0981.

7. Impact of the Proposed Update to 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 proposed rule, we are proposing to update 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 proposed update would 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 would result from the update to the stroke mortality measure.

8. Impact of Confidential and Potential Future Public Reporting of Readmission Measure Data Stratified by Social Risk Factors

In section IX.A.13. of the preamble of this proposed rule we discuss our intent to provide confidential reports to hospitals that include measure data stratified by dual eligible status for the Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate Following Pneumonia Hospitalization and Hospital 30-day, All-Cause, Risk Standardized Mortality Rate (RSRR) for Pneumonia measures. Because this proposal is related to the way we would display data, and not the methods of data collection implemented by the hospitals, we believe no additional burden on hospitals would result from the confidential reporting of stratified measure data using social risk factor indicators. We note that all measures for which we might consider confidential reporting or public display of stratified measure data would already be included in the Hospital IQR Program, and as claims-based measures, we do not expect any additional burden because these data are already reported to the Medicare program for payment purposes.

9. Impact of 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 proposed rule we discuss our intent to align the naming of this exception policy and update 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 proposals, we believe the updates will have no effect on burden for hospitals.

10. 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 new requirements for reporting we are proposing for the FY 2020 payment determination, the number of hospitals not receiving the full annual percentage increase may increase, due to the changes in policy described above. At this time, information is not available to determine the precise number of hospitals that will not meet the requirements to receive the full annual percentage increase for the FY 2020 payment determination. If the number of hospitals failing to receive the full annual percentage increase does increase because of the new 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 Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.B. of the preamble of this proposed rule, we discuss our proposed policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act, which was added by section 3005 of the Affordable Care Act. 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 proposed rule, we are proposing 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 proposal in section IX.B.4. of the preamble of this proposed rule to 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))—if finalized, the PCHQR Program measure set would consist of 18 measures for the FY 2020 program.

As further explained in section XIII.B.7. of the preamble of this proposed rule, we anticipate that these proposed new requirements would reduce overall burden on participating PCHs. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53667), we estimated a burden of 2.5 hours to abstract the information from medical records and submit it for each case, which equates a reduction in burden of 40,910 hours total across the 11 centers. 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 proposed 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, or a total of 41,536 hours across all 11 PCHs. Our proposal to remove three chart-abstracted measures would 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 proposal to adopt 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 proposal.

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.C.1. of the preamble of this proposed 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 would receive the reduction for FY 2018 as LTCHs become more familiar with the requirements. In addition, 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 our proposals will have a negligible impact on overall LTCH payments for FY 2018.

In section IX.C.7. of the preamble of this proposed rule, we are proposing 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 proposing 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 proposing that data for these measures will be collected and reported using the LTCH CARE Data Set (LTCH CARE Data Set Version 4.00, effective April 1, 2018).

We also are proposing to remove the All-Cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs (NQF #2512). 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.

In addition, 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), would 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 proposed measure would be reduced from the burden and cost to report the current measure.

We also are proposing to remove the program interruption items from the LTCH

CARE Data Set. Specifically, we are proposing 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 would be reduced.

In section IX.C.10. of the preamble of this proposed rule, we are proposing requirements related to the reporting of standardized patient assessment data beginning with the FY 2019 LTCH QRP. Some of the proposed data elements are already included on the LTCH CARE Data Set and are already included in current burden estimates. However, we are proposing 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.

In summary, the 4.5-minute increase in burden for the two proposed ventilator weaning quality measures is offset with the 3 minute reduction in burden for the proposed 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. In addition, we are proposing that data for the new standardized data elements will be collected by LTCHs and reported to CMS using the LTCH CARE Data Set (LTCH CARE Data Set Version 4.00, effective April 1, 2018) for the purpose of fulfilling the requirements of the IMPACT Act. This results in an additional 12.6 minutes of burden for the proposed standardized data elements, with a net burden of 10.5 minutes. Overall, the cost associated with the proposed changes to the LTCH QRP is estimated at an additional $3,187.15 per LTCH annually, or $1,357,726 for all LTCHs annually.

While the reporting of data on quality measures and standardized patient assessment data involves collecting information, we believe that the burden associated with modifications to the LTCH CARE Data Set discussed in this proposed rule fall under the PRA exceptions provided in section 1899B(m) of the Act. Section 1899B(m) of the Act, which was added by the IMPACT Act, states that the PRA requirements do not apply to section 1899B of the Act. However, the PRA requirements and burden estimates will be submitted to OMB for review and approval when modifications to the LTCH CARE Data Set or other applicable PAC assessment instruments are not used to achieve standardized patient assessment data.

For a detailed discussion of information collection requirements related to our proposals, we refer readers to section XIII.B.9. of the preamble of this proposed rule.

N. Effects of Proposed Updates to the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

As discussed in section IX.D. of the preamble of this proposed rule and in accordance with section 1886(s)(4)(A)(i) 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 proposed 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 would 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 help facilitate successful reporting outcomes through ongoing stakeholder education, national trainings, and a technical help desk.

We are proposing provisions that impact the FY 2018 procedural requirements and subsequent years, and the FY 2020 payment determinations and subsequent years. We refer readers to section XIII.B.10. of the preamble of this proposed rule for details discussing information collection requirements for the IPFQR Program.

O. Effects of Proposed Requirements Regarding the Electronic Health Record (EHR) Incentive Programs and Meaningful Use

In section IX.E. of the preamble of this proposed rule, we discuss proposed policies for eligible hospitals and CAHs reporting CQMs electronically under the Medicare and Medicaid EHR Incentive Programs in 2017. As outlined in this proposed rule, we are proposing 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 2 self-selected quarters of data; and (2) revise the number of CQMs eligible hospitals and CAHs are required to report electronically for CY 2017 to 6 (self-selected) available CQMs. In addition, we are proposing the following CQM reporting requirements for CY 2018: (1) 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 data of 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 would be required to report at least 6 (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, would 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 would have a submission period that would be the 2 months following the close of the CY 2018 CQM reporting period, ending February 28, 2019.

Because the proposed reporting requirements for data collection regarding the reporting of CQMs electronically under the Medicare and Medicaid EHR Incentive Programs would 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 are not proposing modifications for the CQMs reporting requirements by attestation. Therefore, there would be no change in burden associated with attestation of CQMs.

In section IX.F. of the preamble of this proposed rule, we discuss proposed 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 proposed policies. State attestation systems would 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 proposals, 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 proposed CQM 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.

In section IX.G.1. of the preamble of this proposed rule, we discuss our proposals to change the EHR reporting period in 2018 from the full CY 2018 to any continuous 90-day period within CY 2018 for all returning EPs, eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs. We do not believe that modifying the EHR reporting period would cause an increase in cost as the reporting requirements for a 90 day reporting period are virtually the same for a full calendar year reporting period as the requirements for a full year calendar year reporting period and 90 day EHR reporting period requires the same number of objectives and measures to be met.

In section IX.G.2. of the preamble of this proposed rule, as required by the 21st Century Cures Act (Pub. L. 114–255), we are proposing 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 this proposed rule, as required by the 21st Century Cures Act, we are proposing 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 would cause an increase in burden as CMS would identify the EPs who might meet this requirement.

For the information collection requirements relating to the above proposals, we refer readers to section XIII.B.11. of the preamble of this proposed rule.

P. Effects of Proposed Electronic Signature and Electronic Submission of the Certification and Settlement Summary Page of Medicare Cost Reports

In section X.A. of the preamble of this proposed rule, we discuss 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 proposal would 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 proposal would 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 Proposed Changes Relating to Survey and Certification Requirements

In section XI.A. of the preamble of this proposed rule, we discuss our proposals to revise the application and reapplication procedures for national accrediting organizations (AOs) to require them to post final survey results and acceptable plans of corrections (PoCs) to the Web sites. The AO programs consist of 10 provider-supplier AO programs and 4 Advanced Diagnostic Imaging (ADI) AO programs. All of these AO programs would be affected by the proposal. As of the end of FY 2016, there were a total of 12,434 deemed providers and suppliers divided among 10 CMS provider/supplier-approved AO programs. Accreditation surveys for deemed provider and suppliers are conducted on a triennial basis, with a varying number of surveys conducted annually by the AO, based on the provider's or supplier's entry into the AO program. It is estimated that approximately 5,492 survey reports and corresponding PoCs would need to be posted annually across the 10 provider/supplier AOs. In addition to the provider/supplier-approved AO programs, there were 16,873 ADI suppliers divided among 4 CMS-approved ADI AOs. It is estimated that approximately 2,128 survey reports and corresponding PoCs would need to be posted annually across the 4 ADI AOs. We are not able to estimate the cost associated with the proposed requirement for posting of the surveys reports and corresponding PoCs at this time. We are seeking public comments, particularly from AOs, regarding the potential initial cost of modifications to the AOs' existing public Web sites and the ongoing cost associated with uploading survey reports and PoCs. We recommend that AOs provide public comments in response to this proposed rule on their estimated costs for posting survey reports and corresponding PoCs. We will consider any public comments received and address them in the final rule.

There is no financial impact of the proposal on deemed facilities as the survey reports and associated PoCs would not be posted by the facilities, but would be posted by the AOs affiliated with the providers or suppliers or ADIs. The overall impact would be determined based on the total costs for posting of the survey reports for the 10 provider-supplier AO programs and the 4 ADI AOs.

In section XI.B. of the preamble of this proposed rule, we discuss our proposals 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'' would allow greater flexibility for the CMS Regional Offices in publishing public notices and would 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 would 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 would be at no cost to CMS. In addition, the use of Regional Press Officers to convey termination of a provider would 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 preamble of this proposed rule, we discuss 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 proposing 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 proposed rule contains a range of proposed policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

As discussed in section III.H. of the preamble of this proposed rule, we are not proposing to extend the imputed floor policy for developing the hospital wage index. We note that if the imputed floor policy were not to expire at the end of FY 2017, we estimate that IPPS payments would increase by approximately $19 million in New Jersey, $19 million in Rhode Island, and $9 million in Delaware. Because the imputed floor policy is budget neutral nationally, these additional IPPS payments as a result of the imputed floor policy not expiring would reduce payments to all IPPS hospitals by approximately $47 million.

T. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled ''Reducing Regulation and Controlling Regulatory Costs,'' was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise promulgates, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations. OMB's implementation guidance, issued on April 5, 2017, explains that ''Federal spending regulatory actions that cause only income transfers between taxpayers and program beneficiaries (for example, regulations associated with . . . Medicare spending) are considered 'transfer rules' and are not covered by EO 13771. . . . However . . . such regulatory actions may impose requirements apart from transfers. . . . In those cases, the actions would need to be offset to the extent they impose more than *de minimis* costs. Examples of ancillary requirements that may require offsets include new reporting or recordkeeping requirements. . . . Analogously, if an action reduces the stringency of requirements or conditions . . . the action may qualify as an EO 13771 deregulatory action.'' Table I of section I.G., Table III of section I.I., and Table IV of section I.J. of this Appendix show the IPPS operating and capital costs and LTCH PPS costs, respectively, on affected entities. The implications of the rule's costs and cost savings will be further considered in the context of our compliance with Executive Order 13771.

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 proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB. Table I also shows a projected overall increase of 1.7 percent in operating payments before accounting for the impact of the proposed changes in Medicare DSH payments and uncompensated care payments. When combined with the impact of those proposed changes, consistent with our policy discussed in section V.G. of the preamble of this proposed rule, we estimate that operating payments would increase by approximately 2.9 percent in FY 2018, or approximately $3.2 billion. We also currently estimate that the proposed changes in new technology add-on payments for FY 2018 would decrease spending by approximately $52 million and the proposed changes to the volume decrease adjustment would increase in 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 would decrease spending by approximately $311 million in FY 2018. These estimates, combined with our estimated increase in FY 2018 operating payment of $3.2 billion, would result in an estimated increase of approximately $2.8 billion for FY 2018. We estimate that hospitals would experience a 2.4 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there would be a $212 million increase in capital payments in FY 2018 compared to FY 2017. The cumulative operating and capital payments would result in a net increase of approximately $3.1 billion to IPPS providers. The discussions presented in the previous pages, in combination with the rest of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments per discharge in FY 2018. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed 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 2017 LTCH PPS payments would decrease approximately $173 million relative to FY 2017 as a result of the proposed payment rates and factors presented in this proposed rule.

V. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review this proposed rule, we assume that the total number of commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this 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 these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any public comments on the approach in estimating the number of entities that will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule. Therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of the proposed rule. We are seek public comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this proposed rule is $90.16 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/2015/may/naics4_621100.htm*). Assuming an average reading speed, we estimate that it would take approximately 16 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $1,442.56 (16 hours × $90.16). Therefore, we estimate that the total cost of reviewing this proposed rule is $2,071,516 ($1,442.56 × 1,436 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in the following Table V, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

The costs to the Federal Government associated with the proposed policies in this proposed rule are estimated at $3.1 billion.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2017 TO FY 2018

Category	Transfers
Annualized Monetized Transfers	$3.1 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 proposed payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2018 relative to FY 2017 of approximately $173 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 *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table VI, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to the changes to the LTCH PPS. Table VI provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the proposed payment rates and factors and other provisions presented in this proposed rule based on the data for the 415 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

The savings to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $173 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	−$173 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

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 proposed rule relating to acute care hospitals will have a significant impact on small entities as explained in this Appendix. For example, we refer readers to ''Table I—Impact Analysis of Proposed 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 we acknowledge that many of the affected entities are small entities, the analysis discussed throughout the preamble of this proposed rule constitutes our regulatory flexibility analysis. This proposed rule contains a range of proposed policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

In this proposed rule, we are soliciting public comments on our estimates and analysis of the impact of our proposals on those small entities. Any public comments that we receive and our responses will be presented in the final rule.

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 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals. (We refer readers to Table I in section I.G. of this Appendix for the quantitative effects of the proposed policy changes under the IPPS for operating costs.)

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 proposed rule would not mandate any requirements for State, local, or tribal governments, nor would 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 proposed 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 will consult with Tribal officials on these Indian-specific provisions of the proposed rule prior to the formal promulgation of this rule.

VII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Executive Office of Management and Budget reviewed this proposed rule.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules, respectively. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the 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. Proposed FY 2018 Inpatient Hospital Update

As discussed in section V.B. of the preamble to this proposed rule, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the

applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a 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 proposed rule, we are proposing to replace the FY 2010-based IPPS operating and capital market baskets with the revised and rebased 2014-based IPPS operating and capital market baskets for FY 2018.

For this FY 2018 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2018 market basket update used to determine the applicable percentage increase for the IPPS on the IHS Global Insight, 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 is estimated to be 2.9 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 proposed rule, we are proposing 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), there are four possible applicable percentage increases that can be applied to the standardized amount. Below we provide a table summarizing the four proposed applicable percentage increases.

FY 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
Proposed Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.725	−0.725
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.175	0.0	−2.175
Proposed MFP Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.4	−0.4	−0.4	−0.4
Statutory Adjustment under Section 1886(b)(3)(B)(xii) of the Act	−0.75	−0.75	−0.75	−0.75
Proposed Applicable Percentage Increase Applied to Standardized Amount	1.75	−0.425	1.025	−1.15

B. Proposed 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 proposed 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 proposed 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 proposing the same four possible applicable percentage increases in the table above for the hospital-specific rate applicable to SCHs.

C. Proposed 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 propose 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 proposed rule. Accordingly, for FY 2018, we are proposing an applicable percentage increase of 1.75 percent to the standardized amount for hospitals located in Puerto Rico.

D. Proposed 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 proposed rule, we are proposing to use 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 proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2018 is 2.9 percent.

E. Proposed 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 proposed rule, we are proposing to 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 proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to apply an update factor of 1.01 percent in determining the LTCH PPS standard Federal rate for FY 2018. For LTCHs that fail to submit quality data for FY 2018, we are proposing to apply an annual update to the LTCH PPS standard Federal rate of −1.0 percent (that is, the proposed 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 a proposed update factor of 0.99 percent in determining the LTCH PPS standard Federal rate for FY 2018.

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 2.9 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 proposing an applicable percentage increase for FY 2018 of 1.75 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 proposed rule.

[FR Doc. 2017–07800 Filed 4–14–17; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 82 Friday,

No. 81 April 28, 2017

Part III

The President

Proclamation 9594—Days of Remembrance of Victims of the Holocaust, 2017

Executive Order 13790—Promoting Agriculture and Rural Prosperity in America

Federal Register
Vol. 82, No. 81
Friday, April 28, 2017

Presidential Documents

Title 3—

The President

Proclamation 9594 of April 24, 2017

Days of Remembrance of Victims of the Holocaust, 2017

By the President of the United States of America

A Proclamation

On Yom HaShoah—the day of Holocaust Remembrance—and during this Week of Remembrance, we honor the victims of the Holocaust and Nazi persecution.

The Holocaust was the state-sponsored, systematic persecution and attempted annihilation of European Jewry by the Nazi regime and its collaborators. By the end of World War II, six million Jews had been brutally slaughtered. The Nazis also targeted other groups for persecution and murder, including Roma (Gypsies), persons with mental and physical disabilities, Soviet prisoners of war, Jehovah's Witnesses, Slavs and other peoples of Europe, gays, and political opponents.

The United States stands shoulder to shoulder with the survivors of the Holocaust, their families, and the descendants of those who were murdered. We support the Jewish diaspora and the State of Israel as we fulfill our duty to remember the victims, honor their memory and their lives, and celebrate humanity's victory over tyranny and evil. Holocaust survivors, despite scars from history's darkest days, continue to inspire us to remember the past and learn from its lessons. By sharing their experiences and wisdom, they continue to fuel our resolve to advance human rights and to combat antisemitism and other forms of hatred.

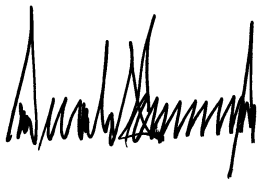
During this week in 1945, American and Allied forces liberated the concentration camp at Dachau and other Nazi death camps, laying bare to the world the unconscionable horror of the Holocaust. We must remain vigilant against hateful ideologies and indifference. Every generation must learn and apply the lessons of the Holocaust so that such horror, atrocity, and genocide never again occur. It is our solemn obligation to reaffirm our commitment to respecting the fundamental freedoms and inherent dignity of every human being.

Let us join together to remember and honor the victims of the Holocaust and Nazi persecution. We express our eternal gratitude to the liberators who selflessly risked their lives to save those of others, and we pledge to never be bystanders to evil.

We must never forget.

NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, do hereby ask the people of the United States to observe the Days of Remembrance of Victims of the Holocaust, April 23 through April 30, 2017, and the solemn anniversary of the liberation of Nazi death camps, with appropriate study, prayers and commemoration, and to honor the memory of the victims of the Holocaust and Nazi persecution by internalizing the lessons of this atrocity so that it is never repeated.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-fourth day of April, in the year two thousand seventeen, and of the Independence of the United States of America the two hundred and forty-first.



[FR Doc. 2017–08817
Filed 4–27–17; 11:15 am]
Billing code 3295–F7–P

Presidential Documents

Executive Order 13790 of April 25, 2017

Promoting Agriculture and Rural Prosperity in America

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to ensure the informed exercise of regulatory authority that affects agriculture and rural communities, it is hereby ordered as follows:

Section 1. *Policy.* A reliable, safe, and affordable food, fiber, and forestry supply is critical to America's national security, stability, and prosperity. It is in the national interest to promote American agriculture and protect the rural communities where food, fiber, forestry, and many of our renewable fuels are cultivated. It is further in the national interest to ensure that regulatory burdens do not unnecessarily encumber agricultural production, harm rural communities, constrain economic growth, hamper job creation, or increase the cost of food for Americans and our customers around the world.

Sec. 2. *Establishment of the Interagency Task Force on Agriculture and Rural Prosperity.* There is hereby established the Interagency Task Force on Agriculture and Rural Prosperity (Task Force). The Department of Agriculture shall provide administrative support and funding for the Task Force to the extent permitted by law and within existing appropriations.

Sec. 3. *Membership.* (a) The Secretary of Agriculture shall serve as Chair of the Task Force, which shall also include:

(i) the Secretary of the Treasury;

(ii) the Secretary of Defense;

(iii) the Attorney General;

(iv) the Secretary of the Interior;

(v) the Secretary of Commerce;

(vi) the Secretary of Labor;

(vii) the Secretary of Health and Human Services;

(viii) the Secretary of Transportation;

(ix) the Secretary of Energy;

(x) the Secretary of Education;

(xi) the Administrator of the Environmental Protection Agency;

(xii) the Chairman of the Federal Communications Commission;

(xiii) the Director of the Office of Management and Budget;

(xiv) the Director of the Office of Science and Technology Policy;

(xv) the Director of the Office of National Drug Control Policy;

(xvi) the Chairman of the Council of Economic Advisers;

(xvii) the Assistant to the President for Domestic Policy;

(xviii) the Assistant to the President for Economic Policy;

(xix) the Administrator of the Small Business Administration;

(xx) the United States Trade Representative;

(xxi) the Director of the National Science Foundation; and

(xxii) the heads of such other executive departments, agencies, and offices as the President or the Secretary of Agriculture may, from time to time, designate.

(b) A member of the Task Force may designate a senior-level official who is a full-time officer or employee of the member's department, agency, or office to perform the member's functions on the Task Force.

Sec. 4. *Purpose and Functions of the Task Force.* (a) The Task Force shall identify legislative, regulatory, and policy changes to promote in rural America agriculture, economic development, job growth, infrastructure improvements, technological innovation, energy security, and quality of life, including changes that:

(i) remove barriers to economic prosperity and quality of life in rural America;

(ii) advance the adoption of innovations and technology for agricultural production and long-term, sustainable rural development;

(iii) strengthen and expand educational opportunities for students in rural communities, particularly in agricultural education, science, technology, engineering, and mathematics;

(iv) empower the State, local, and tribal agencies that implement rural economic development, agricultural, and environmental programs to tailor those programs to relevant regional circumstances;

(v) respect the unique circumstances of small businesses that serve rural communities and the unique business structures and regional diversity of farms and ranches;

(vi) require executive departments and agencies to rely upon the best available science when reviewing or approving crop protection tools;

(vii) ensure access to a reliable workforce and increase employment opportunities in agriculture-related and rural-focused businesses;

(viii) promote the preservation of family farms and other agribusiness operations as they are passed from one generation to the next, including changes to the estate tax and the tax valuation of family or cooperatively held businesses;

(ix) ensure that water users' private property rights are not encumbered when they attempt to secure permits to operate on public lands;

(x) improve food safety and ensure that regulations and policies implementing Federal food safety laws are based on science and account for the unique circumstances of farms and ranches;

(xi) encourage the production, export, and use of domestically produced agricultural products;

(xii) further the Nation's energy security by advancing traditional and renewable energy production in the rural landscape; and

(xiii) address hurdles associated with access to resources on public lands for the rural communities that rely on cattle grazing, timber harvests, mining, recreation, and other multiple uses.

(b) The Task Force shall, in coordination with the Deputy Assistant to the President for Intergovernmental Affairs, provide State, local, and tribal officials—and farmers, ranchers, foresters, and other rural stakeholders—with an opportunity to suggest to the Task Force legislative, regulatory, and policy changes.

(c) The Task Force shall coordinate its efforts with other reviews of regulations or policy, including those conducted pursuant to Executive Order 13771 of January 30, 2017 (Reducing Regulation and Controlling Regulatory Costs), Executive Order 13778 of February 28, 2017 (Restoring the Rule of Law, Federalism, and Economic Growth by Reviewing the ''Waters of the United States'' Rule), and Executive Order 13783 of March 28, 2017 (Promoting Energy Independence and Economic Growth).

Sec. 5. *Report.* Within 180 days of the date of this order, the Secretary of Agriculture, in coordination with the other members of the Task Force, shall submit a report to the President, through the Assistant to the President for Economic Policy and the Assistant to the President for Domestic Policy, recommending the legislative, regulatory, or policy changes identified pursuant to section 4 of this order that the Task Force considers appropriate. The Secretary of Agriculture shall provide a copy of the final report to each member of the Task Force.

Sec. 6. *Revocation.* Executive Order 13575 of June 9, 2011 (Establishment of the White House Rural Council), is hereby revoked.

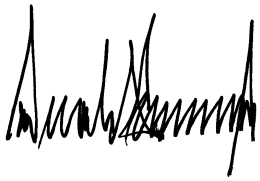
Sec. 7. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
April 25, 2017.

[FR Doc. 2017–08818
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