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Fiscal Year 2019 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Final Rule Summary

On August 2, 2018, the Centers for Medicare & Medicaid Services (CMS) released its final rule describing federal fiscal year (FY) 2019 policies and rates for Medicare's prospective payment systems for acute care inpatient hospitals (IPPS) and the long-term care hospital prospective payment system (LTCH PPS).

The payment rates and policies described in the IPPS/LTCH final rule would affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in long-term care hospitals paid under their respective prospective payment systems. The final rule also sets forth rate-of-increase limits for inpatient services provided by cancer and children's hospitals, and religious nonmedical health care institutions, which are paid based on reasonable costs.

The final rule will be published in the *Federal Register* on August 17, 2018.

Data files available to support analysis of the final rule and numbered tables that were historically included in the IPPS rule are now available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page.html

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I. IPPS Rate Updates and Impact of the Rule; Outliers

CMS estimates that policies and rates in the final rule would increase combined operating and capital payments to approximately 3,330 acute care hospitals paid under the IPPS by about $4.8 billion in FY 2019 compared to FY 2018. The rule indicates that the increase results from an additional $4.4 billion in IPPS operating and uncompensated care payments (UCP) and $0.4 billion in IPPS capital payments, new technology add-on payments and low volume hospital payments.

A. Inpatient Hospital Operating Update

The final rule would increase IPPS operating payment *rates* by 1.85 percent for hospitals which successfully participate in the Inpatient Quality Reporting (IQR) program and are meaningful users of electronic health records (EHR). The percent rate increase is the net result of a market basket update of 2.9 percent; an annual multifactor productivity (MFP) adjustment of -0.8 percentage points; an Affordable Care Act (ACA) required statutory update adjustment of -0.75 percentage points; and a documentation and coding adjustment of +0.5 percentage points. The payment rate update factors are summarized in the table below.

The IPPS "applicable percentage increase" applies to the national operating standardized amounts and also to the hospital-specific rates on which some sole community hospitals (SCHs) and Medicare Dependent Hospitals (MDHs) are paid. The documentation and coding adjustment does not apply to the hospital-specific rates resulting in a 1.35 percent increase rather than the 1.85 percent increase applicable to the national standardized operating amounts.

Factor	Percent Change
FY 2019 Market Basket	2.9
Multifactor productivity adjustment	-0.8
ACA Adjustment	-0.75
Subtotal	1.35
Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	1.85

Hospitals that fail to participate successfully in the IQR Program or are not meaningful users of EHR do not receive the full payment rate increase. The reduction is ¼ of the market basket for

hospitals failing IQR, ¾ of the market basket for hospitals failing EHR and the full market basket for hospitals failing both.

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2019 payments increasing 2.4 percent. Not all policy changes are reflected in this total. For example, increases in uncompensated care payments are not included in this total. The factors that are included in this total are:

Contributing Factor	National Percentage Change
FY 2019 increase in payment rates	+1.8[1]
Frontier hospital wage index floor and out-migration wage adjustment	+0.1[2]
Residual	+0.5[3]
Total	+2.4

[1]Weighted average of the updates of 1.35 percent for hospitals that receive payment in full or in part based on hospital-specific rates and 1.85 percent for all other hospitals.
[2]The frontier hospital wage index floor increases payments by about $62 million to 49 hospitals and the outmigration adjustment increases payments by about $42 million to 220 providers.
[3]The residual is unexplained. In the past, this residual was largely explained by the difference in the estimate of outlier payments in the prior year (i.e. FY 2018) compared to the 5.1 percent removed from the rates for the current year (i.e. FY 2019). In the outlier section of the final rule, CMS indicates because claims data for all of FY 2018 will not be available until after September 30, 2018, it cannot provide an estimate of actual FY 2018 outlier payments.

Table I Impact Analysis

Detailed impact estimates are displayed in Table I of the final rule (reproduced in the Appendix to this summary). The following table summarizes the impact by hospital category.

Hospital Type	All Changes
All Hospitals	2.4%
Large Urban	2.4%
Other Urban	2.5%
Rural	1.2%
Major Teaching	3.1%

The effects of several significant policies are shown or described separately from the rule's distributional impact table including:

- New Technology Add-On Payments. CMS approved 9 new technologies for add-on payments and is continuing add-on payments for 3 technologies for FY 2019. CMS estimates that it will spend approximately $233 million for new technology add-on payments in FY 2019. More details are provided in section II. H.

- Post-Acute Transfer Policy. CMS's implementation of section 53019 of the Bipartisan Budget Act (BBA) 2018 extends the post-acute care transfer policy to IPPS discharges to hospice prior to the geometric mean length of stay. CMS' Actuaries estimate that the BBA 2018 provision will result in annual savings of $240 million beginning in FY 2019 and up to

$540 million annually by FY 2028. Otherwise, CMS is making routine updates to the list of post-acute care transfer MS-DRGs and MS-DRGs subject to the special payment methodology when the MS-DRGs have changed. More details are provided in section IV. A.

- Low Volume Hospitals. CMS estimates its implementation of extensions and revisions to the low volume hospital adjustment required by section 50204 of BBA 2018 will increase Medicare payments by $75 million in FY 2019 compared to FY 2018. This estimate is based on 628 providers receiving approximately $426 million in FY 2019 compared to 612 providers receiving approximately $350 million in FY 2018. More details are provided in section IV. D.

- Medicare DSH and Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to increase 22.3 percent or $1.5 billion. More details are provided in section IV. F.

- Hospital Readmissions Reduction Program (HRRP). The HRRP would reduce FY 2019 payments to an estimated 2,599 hospitals or about 85 percent of the 3,062 eligible hospitals. CMS estimates savings from the HRRP will be approximately $566 million in FY 2019 or about the same as FY 2018. More details are provided in section IV. H.

- Hospital Value-Based Purchasing (HVBP) Program. The HVBP is budget neutral but will redistribute about $1.9 billion (2 percent of base operating MS-DRG payments) based on hospitals' performance scores. More details are provided in section IV. I.

- Hospital Acquired Conditions (HAC) Reduction Program. The statute requires that HAC program penalties apply to the 25 percent lowest performing hospitals on HACs. The final rule includes a table that shows 804 of 3,219 hospitals being subject to a HAC penalty. More details are provided in section IV. J.

- Capital IPPS Payments. CMS estimates that the capital payment per case will increase 2.1 percent. Of this increase, 1.4 percent is attributed to the capital payment rate update and another 0.5 percent is attributed to an increase in case mix. More details are provided in section V.

C. IPPS Standardized Amounts

The following four rate categories apply in FY 2019:

- Full Update [before adjustments] = 1.35%
- Failing IQR Only (49 hospitals): Penalty = -0.725 percentage points. Update = 0.625%
- Failing EHR Only (137 hospitals): Penalty = -2.175 percentage points. Update = -0.825%
- Failing Both (40 hospitals): Penalty = -2.9 percentage points. Update = -1.55 percent

The applicable percentage changes listed above are prior to budget neutrality factors applied to the standardized amount and other non-budget neutral adjustments pertaining to documentation and coding. The updated standardized amounts for the final rule were calculated by applying the

additional Medicare Access and CHIP Reauthorization Act (MACRA) mandated documentation and coding adjustment of +0.5 percentage points for FY 2019. Additional budget neutrality adjustments to the standardized amounts are as follows:

- MS-DRG recalibration, 0.997192 (a decrease of 0.28 percent);
- Wage index, 1.000748 (an increase of 0.08 percent);
- Geographic reclassification, 0.985932, a reduction of 1.4 percent;
- Rural floor budget neutrality, 0.993142, a reduction of 0.68 percent applied to hospital wage indices;
- Rural Demonstration Budget Neutrality Factor, 0.999467; and
- The outlier offset factor is 0.948999, the same as in prior years.

The net increase in the operating standardized amounts from FY 2018 to FY 2019 is approximately 1.38 percent and is accounted for by the following:

Update = 1.35 percent
Documentation and Coding = 0.5 percent
Reclassification Budget Neutrality Between FY 2018 and FY 2019 = -0.21 percent
All Other Budget Neutrality Factors = -0.26 percent.

Including the FY 2019 capital payment rate, which increases 1.27 percent, the operating plus capital standardized amounts will increase by approximately 1.37 percent in FY 2019 compared to FY 2018.

FY 2019 RULE TABLES 1A, 1B and 1D

Table 1A

NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS LABOR/NONLABOR (68.3 PERCENT LABOR SHARE/31.7 PERCENT NONLABOR SHARE IF WAGE INDEX > 1.0)—FY 2019							
Passed IQR and EHR Update = 1.35 Percent		**Passed IQR, Failed EHR) Update = -0.825 Percent**		**Failed IQR, Passed EHR Update = 0.625 Percent**		**Failed IQR, Failed EHR Update = -1.55 Percent)**	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$3,858.62	$1,790.90	$3,775.81	$1,752.47	$3,831.02	$1,778.09	$3,748.21	$1,739.66

Table 1B

NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX <= 1.0)—FY 2019							
Passed IQR and EHR Update = 1.35 Percent		**Passed IQR, Failed EHR) Update = -0.825 Percent**		**Failed IQR, Passed EHR Update = 0.625 Percent**		**Failed IQR, Failed EHR Update = -1.55 Percent**	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$3,502.70	$2,146.82	$3,427.53	$2,100.75	$3,477.65	$2,131.46	$3,402.48	$2,085.39

Table 1D

CAPITAL STANDARD FEDERAL PAYMENT RATE	
	Rate
National	$459.72

The standardized amounts do not include the 2 percent Medicare sequester reduction that began in 2013 and will continue until 2028 absent new legislation. The sequester reduction is applied as the last step in determining the payment amount for submitted claims and it does not affect the underlying methodology used to calculate MS-DRG weights or standardized amounts.

All areas in Puerto Rico have a wage index that is less than 1.0. The standardized amounts for all Puerto Rico hospitals are those found in Table 1B for hospitals that submit quality data and are meaningful EHR users. Puerto Rico hospitals are not required to submit quality data and therefore, are not subject to the penalties for not submitting quality data. However, section 602 of Public Law 114–113 specifies that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning with FY 2016, and also applies the adjustments to the applicable percentage increase under the statute for Puerto Rico hospitals that are not meaningful EHR users, effective FY 2022. Thus, until FY 2022, the standardized amounts for Puerto Rico hospitals will always be the same as those for hospitals with a wage index of less than 1.0 that have successfully participated in the IQR and EHR programs.

D. Outlier Payments and Threshold

To qualify for outlier payments for high cost cases, a case must have costs greater than the sum of all IPPS payments plus the "outlier threshold" or "fixed-loss" amount. To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's total covered charges billed for the case are converted to estimated costs using the hospital's cost-to-charge ratio (CCR). An outlier payment for an eligible case is then made based on a marginal cost factor, which is 80 percent of the estimated costs above the fixed-loss cost threshold.

FY 2019 outlier threshold. CMS is adopting an outlier fixed-loss cost threshold for FY 2019 of $25,769. The FY 2018 outlier threshold is $26,601. CMS projects that the final outlier threshold for FY 2019 will result in outlier payments equal to 5.1 percent of operating DRG payments and 5.06 percent of capital payments and is reducing the operating and capital standardized amounts by the same percentages that it estimates will be paid as outliers. The process CMS followed in setting the FY 2019 outlier threshold is summarized below.

FY 2019 outlier threshold methodology. CMS simulated payments by applying FY 2019 payment rates and policies using cases from the FY 2017 Medicare Provider Analysis and Review File (MedPAR), with the hospital charges on the MedPAR claims inflated by 2 years, from FY 2017 to FY 2019, to account for charge inflation.

CMS determined the 1-year average annualized rate-of-change in charges per case for FY 2019 by comparing the average covered charge per case from the 3rd quarter of FY 2016 through the 2nd quarter of FY 2017 to the average covered charge per case from the third quarter of FY 2017 through the second quarter of FY 2018 as shown in the table below. This rate-of-change was 4.3 percent (1.04338) or 8.9 percent (1.08864) over 2 years.[1] The billed charges are obtained from MedPAR claims and adjusted by 1.08864.

[1] In a communication with CMS, the agency indicated that the charge figures in the table are incorrect and should be $556,685,469,198 for 2016/2017 changing the average charge to $57,124 and $541,126,488,108 for 2017/2018

Quarter	Covered Charges (April 1, 2016, through March 31, 2017)	Cases (April 1, 2016, through March 31, 2017)	Covered Charges (April 1, 2017, through March 31, 2018)	Cases (April 1, 2017, through March 31, 2018)
April – June	$133,106,496,424	2,356,775	$137,726,975,443	2,319,109
July – September	$139,415,422,805	2,413,871	$142,676,638,337	2,363,685
October – December	$151,053,166,855	2,559,371	$121,360,081,623	1,983,155
January – March	$136,264,070,864	2,415,120	$142,121,633,027	2,407,887
Total	$559,839,156,948	9,745,137	$543,885,328,430	9,073,836
Avg. Charge/Case		$57,448		$59,939
% Change				4.338%
% Change Squared				8.864%

CMS is using hospital CCRs from the March, 2018 update to the Provider-Specific File (PSF) and applying an adjustment factor to account for cost and charge inflation. The adjustment methodology compares the national average case-weighted operating and capital CCRs from the most recent (March 2018) update of the PSF to the national average case-weighted operating and capital CCRs from the same period of the prior year (March 2017). The methodology uses total transfer-adjusted cases from FY 2017 to determine the national average case-weighted CCRs for both sides of the comparison. The CCR adjustment is illustrated in the below table.

	March, 2017	March, 2018	% Change/Adj.
Operating	0.265819	0.260874	-1.86% (0.981397)
Capital	0.022671	0.021554	-4.93% (0.950793)

For estimating the outlier threshold for FY 2019, CMS adjusts the wage index of eligible hospitals in frontier states; includes estimated uncompensated care payments; and makes no adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled at cost report settlement.

CMS had proposed to use a CCR of 1.0 rather than the hospital specific CCR to determine the costs associated with CAR-T products—two of which are on the market and have costs of several hundreds of thousands of dollars. CMS is not finalizing that policy. The final rule indicates that it would be premature to adopt such a policy given other ongoing initiatives described in the President's Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs and a comment solicitation on a potential Center for Medicare and Medicaid Innovation (Innovation Center) model in the CY 2019 OPPS/ASC proposed rule. The Innovation Center model would test private market strategies and introduce competition to improve quality of care for beneficiaries, while reducing both Medicare expenditures and beneficiaries' out of pocket spending.

changing the average charge to $59,636 for an increase of 1.04396 or 8.9 percent (1.04396 * 1.04396) over two years.

FY 2017 Outlier Payments. CMS' current estimate, using available FY 2017 claims data, is that actual outlier payments for FY 2017 were approximately 5.57 percent of actual total MS-DRG payments or 0.47 percent higher than the amount CMS removed from IPPS rates to fund the outlier pool. Following long-standing policy, the agency will not make retroactive adjustments to ensure that total outlier payments for FY 2017 are equal to the projected 5.1 percent of total MS-DRG payments.

FY 2018 Outlier Payments. CMS indicates that it is unable to provide an estimate of actual outlier payments for FY 2018 based on FY 2018 claims data because complete claims for all of FY 2018 will be unavailable until after September 30, 2018. CMS will provide an estimate of actual FY 2018 outlier payments in the FY 2020 IPPS/LTCH PPS proposed rule.

CMS received similar comments as in prior rules concerned about the public's ability to replicate the proposed rule outlier calculations. As it has done previously, CMS responded by: 1) referring to prior responses to public comments it has given previously on these issues; 2) indicating additional information that it has made available in response to these concerns; and 3) describing additional work it is considering undertaking to address this issue. At this time, CMS is taking no further action.

II. MS-DRG Classifications and Relative Weights

A. Background
B. MS-DRG Reclassifications
C. Adoption of MS-DRGs in FY 2008

The FY 2019 rule continues the Medicare severity diagnosis-related group (MS-DRG) classification system used beginning in FY 2008. For information on the adoption of the MS-DRGs in FY 2008, CMS refers readers to the FY 2008 IPPS final rule (72 FR 47140 through 47189). For general information about the MS-DRG system, including yearly reviews and changes to the MS-DRGs, the rule refers readers to previous discussions in these IPPS/LTCH PPS final rules: FY 2010 (74 FR 43764 through 43766) and the FYs 2011 through 2018 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; 81 FR 56787 through 56872; and 82 FR 38010 through 38085, respectively).

D. MS-DRG Documentation and Coding Adjustment

CMS adopted the MS-DRGs in FY 2008 to better recognize severity of illness in Medicare payment rates for acute care hospitals. By increasing the number of MS-DRGs and more fully accounting for patient severity of illness, the rule indicates that MS-DRGs provide incentives for hospitals to improve their documentation and coding of patient diagnoses. CMS indicates that coding and documentation improvements have led to increases in aggregate payments without a corresponding increase in actual patient severity of illness. As a result, CMS exercised its authority to maintain budget neutrality in its original implementation of the MS-DRGs 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.

The rule refers readers to CMS' implementation of statutory enactments since 2008 that have changed CMS' documentation and coding adjustments and required a retrospective review of IPPS spending. These statutory enactments required CMS to make rate adjustments to recoup additional spending in FY 2008 and FY 2009 attributed to documentation and coding.

The American Tax Relief Act (ATRA) later required an $11 billion recoupment of the increase in spending due to documentation and coding that included FY 2010 through FY 2012 IPPS rates that CMS was not previously authorized to recoup. The rule refers readers to prior rulemaking (most recently, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38008 through 38009)) for its implementation of section 631 of ATRA.

CMS planned to implement this statutory $11 billion recoupment through a series of one-time adjustments to IPPS rates in successive years and then, once the recoupment was completed, make a single positive adjustment (3.2 percentage points) to IPPS rates. However, MACRA required CMS to make the positive adjustment over several years (six adjustments of 0.5 percentage points) and did not allow CMS to fully restore the recoupment adjustments it made to IPPS rates (3.0 percentage points instead of 3.2 percent percentage points). After the enactment of MACRA, CMS changed its estimate of the amount necessary to make the full $11 billion recoupment (3.9 percentage points instead of 3.2 percentage points). However, CMS contends that the statute only allows restoring 3.0 percentage points to the rates, not the full 3.9 percentage points in recoupment adjustments. The 21st Century Cures Act later changed the first-year adjustment to 0.4588 percentage points rather than 0.5 percentage points.

As has been addressed in three consecutive rules, commenters believe that Congress only intended that 0.2 percentage points of a 3.2 percent recoupment adjustment be credited as savings to Medicare, not 0.9 percentage points of the 3.9 percent cumulative adjustment CMS later made after MACRA was enacted. The commenters ask CMS to restore the additional 0.7 percentage point adjustment for FY 2019. CMS disagrees noting that in the 21st Century Cures Act, Congress reduced the FY 2018 adjustment from 0.5 percentage points to 0.4588 percentage points after it was known that the CMS had changed its estimates of the cumulative reduction needed to recoup $11 billion from 3.2 percent to 3.9 percent. CMS sees no evidence that Congress intended for the agency to make an additional 0.7 percentage point adjustment in FY 2018 or any later year to compensate for the higher than expected final ATRA adjustment made in FY 2017.

E. Refinement of the MS-DRG Relative Weight Calculation

Since FY 2009, the MS-DRG relative weights have been fully cost-based. CCRs are used to estimate costs from charges for 19 distinct cost centers. For FY 2019, CMS calculated the MS-DRG weights for FY 2019 using national averages for the 19 CCRs. Accompanying the rule, CMS posted the version of the HCRIS cost report data file which it used to calculate the 19 CCRs for FY 2019 on the CMS website at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

Click on File #4 (FY 2019 Final Rule: HCRIS Data File).

CMS received one comment requesting that it use a single diagnostic radiology CCR to set weights, rather than using separate CT and MRI cost centers. The commenter furnished data showing that the CCRs for CT and MRI are incorrect and are inappropriately reducing payments under the IPPS. The commenter indicated that the charge compression hypothesis underlying the creation of these and other additional cost centers has been shown as false for separate CT and MRI cost centers. CMS responded that it did not make a proposal on this issue and referred to prior rules for its analysis of CMS' basis for establishing distinct CCRs for MRIs and CT scans: FY 2017 IPPS/LTCH PPS final rule (81 FR 56785) and FY 2014 IPPS/LTCH PPS final rule (78 FR 50518 through 50523). CMS will continue to explore ways in which it can improve the accuracy of the cost report data and calculated CCRs used in the cost estimation process.

F. Changes to Specific MS-DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2019 MS-DRG Updates

CMS encourages input from stakeholders concerning the annual IPPS updates. **To be considered for any updates or changes in FY 2020, comments should be submitted by November 1, 2018**. Comments for FY 2020 should be sent to the CMS MS-DRG Classification Change Request Mailbox at: MSDRGClassificationChange@cms.hhs.gov.

This section of the preamble discusses changes that CMS finalizes to the MS-DRGs for FY 2019. For this final rule, CMS did not do any additional analysis of claims data from the proposed rule. CMS' MS-DRG analysis is based on ICD-10 claims data from the September 2017 update of the FY 2017 MedPAR file, which contains hospital bills received through September 30, 2017 for discharges occurring through September 30, 2017.

In deciding on modifications to the MS-DRGs for particular circumstances, CMS considers whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients in the MS-DRG (discussed in greater detail in previous rulemaking, 76 FR 51487). CMS evaluates patient care costs using average costs and lengths of stay. CMS uses its clinical advisors to decide whether patients are clinically distinct or similar to other patients in the MS-DRG. In addition, CMS considers the number of patients who will have a given set of characteristics and notes it generally prefers not to create a new MS-DRG unless it would include a substantial number of cases.
CMS uses the 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. In order to warrant the creation of a CC or MCC subgroup within a base MS-DRG, the subgroup must meet all five of the following criteria:

- 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.

The FY 2019 ICD-10 MS-DRG GROUPER and Medicare Code Editor (MCE) Software Version 36, the ICD-10 MS-DRG Definitions Manual files 36 and the Definitions of Medicare Code Edits Manual 36 are available on the CMS Web site at: https://www.cms.gov/Medicare/Medicare/Medicare-Fee-for-Service-Paymet/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html.

CMS discusses specific changes to the MS-DRGs for FY 2019. **Highlights of CMS' discussion are summarized below; the reader is referred to the final rule for more specific details.**

2. Pre-MDC

a. Heart Transplant or Implant of Heart Assist System

In the FY 2018 IPPS final rule, CMS stated it planned to review the current ICD-10 logic for Pre-MDC MS-DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC respectively), MS-DRG 215 (Other Heart Assist System Implant), and MS-DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively), where procedures involving the heart assist devices are assigned. CMS invited comments on restructuring the MS-DRGs for heart assist system procedures.

MS-DRG 001 and 002 (Heart Transplant or Implant of Heart Assist System with and without MCC respectively). The logic for MS-DRG 001 and 002 is comprised of two lists: the first list includes procedure codes identifying a heart transplant procedure and the second list includes procedures identifying the implantation of a heart assist system (ICD-10-PCS codes: 02HA0QZ, 02HA3QZ, and 02HA4QZ). In addition to the three procedure codes for implantation of a heart assist system there are 33 pairs of code combinations or procedure code (or procedure code clusters) that when reported together satisfy the logic for assignment to MS-DRGs 001 and 002.

Commenters recommended that CMS maintain the current logic under the MS-DRGs 001 and 002. Commenters also recommended that CMS continue to monitor the data and requested that coding guidance be issued for assignment of the correct ICD-10-PCS procedure codes describing LAVD to encourage accurate reporting of these procedures. Based on data analysis, CMS proposed to maintain the current logic for MS-DRGs 001 and 002.

Commenters supported CMS' proposal. CMS finalizes its proposal to maintain the current log of MS-DRGs 001 and 002 for FY 2019. CMS will continue to analyze claims data for consideration of future modifications.

MS-DRG 215 (Other Heart Assist System Implant). Commenters also suggested CMS maintain the current logic for MS-DRG 215 and recommended CMS continue to analyze the data. Based on data analysis, CMS proposed to maintain the current logic for MS-DRG 215. Commenters supported CMS' proposal and finalizes its proposal to maintain the current log of MS-DRG 215 for FY 2019. CMS will continue to analyze claims data for consideration of future modifications.

Extracorporeal Membrane Oxygenation (ECMO). CMS also received a request to review cases reporting the use of ECMO in combination with the insertion of a percutaneous short-term external heart assist device. The commenter noted that there is not a specific procedure code to identify percutaneous ECMO, which is less invasive and less expensive than traditional ECMO. The commenter submitted a separate request to create a new procedure code for percutaneous ECMO. The requestor suggested that cases reporting a procedure code for ECMO (5A15223) in combination with the insertion of a percutaneous short-term external heart assist device (02HA3RZ and 02HA4RZ) could be reassigned MS-DRG 003 (ECMO or Tracheostomy with Mechanical Ventilation > 96 Hours) to MS-DRG 215.

CMS did analyses for both MS-DRG 003 and 215. For MS-DRG 003, CMS found the average LOS and average costs were lower when ECMO is combined with the insertion of a percutaneous short-term external heart assist system. CMS, however, was unable to determine if the ECMO procedures were performed percutaneously in the absence of a unique ICD-10 PCS procedure code. CMS proposed not to reassign these cases until there is a way to specifically identify percutaneous ECMO in the claims.

Some commenters supported CMS' proposal. Other commenters acknowledged the new ICD-10-PCS procedure codes that identify percutaneous ECMO procedures (effective October 1, 2018) and suggested that CMS assign the new procedure codes to MS-DRG 215. In response, CMS notes that because these codes were not finalized at the time of the proposed rule, there were no proposed MDC, MS-DRG, or O.R. non-O.R. designation for these new procedure codes. Consistent with its annual process of assigning new procedure codes, which includes review by CMS' clinical advisors, the new procedure codes for percutaneous ECMO procedures have been designated as non-O.R. procedures (additional information is available in Table 6B –New Procedure Codes associated with this final rule and is available at https://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.)

CMS finalizes its proposal not to reassign cases reporting ICD-10-PCS procedure code 5A15223 when reported with ICD-10-PCS procedure codes 02HA3RZ or 02HA4Z for FY 2019. Consistent with its policy for determining MS-DRG assignments for new codes, the two new procedure codes describing percutaneous ECMO procedures are designated as no-O.R. procedures impacting the MS-DRG assignment of MS-DRGs 207, 291, 296, and 870. The MS-DRG assignment for the central procedure remains in MS-DRG 003. CMS will continue to analyze claims data for consideration of future modifications.

MS-DRG 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with and without MCC, respectively). A commenter also suggested CMS maintain the current logic for MS-DRGs 268 and 269 and recommended CMS continue to monitor the data. Based on analysis of data, CMS proposed not to make any changes to MS-DRGs 268 and 269. Commenters supported CMS' proposal. CMS finalizes its proposal to maintain the current log of MS-DRGs 268 and 269 for FY 2019. CMS will continue to analyze claims data for consideration of future modifications.

b. Brachytherapy

CMS received a request to create a new MS-DRG for all procedures involving the CivaSheet® technology, an implantable, planar brachytherapy source designed to enable delivery of radiation to the site of the cancer tumor excision or debulking, while protecting neighboring tissue. The requestor indicated the technology is used for a number of cancer indications. Procedures involving the CivaSheet® technology are reported using ICD-10-PCS Section D-Radiation Therapy codes, with the root operation "Brachytherapy". These codes are non-O.R. codes and group to the MS-DRG to which the principal diagnosis is assigned.

Based on data analysis, CMS identified only four cases reporting one of the brachytherapy procedure codes across all MS-DRGs. CMS believes that creating a new MS-DRG based on a small number of cases could lead to distortion in the relative payment weights for the MS-DRGs. A larger number of clinically cohesive cases within the MS-DRG provides greater stability for annual updates. CMS did not propose to create a new MS-DRG for procedures involving the CivaSheet® technology.

Some commenters supported CMS' proposal. Several commenters, including the manufacturer of CivaSheet® technology disagreed and stated that the current payment does not allow widespread adoption and use of the technology. CMS acknowledges these concerns and as part of its ongoing analysis of the MS-DRGs under ICD-10, it will continue to explore mechanisms to address rare diseases and low volume DRGs. In response to a comment about errors in the tables in the proposed rule, CMS acknowledges these inadvertent errors but notes they have no bearing on its final decision.

CMS finalizes its proposal to maintain the current MS-DRG structure for procedures involving the CivaSheet® technology for FY 2019.

c. Laryngectomy

CMS proposed to reorder the lists of diagnosis and procedure codes for MS-DRGs 11, 12, and 13 (Tracheostomy for Face, Mouth and Neck Diagnoses with MCC, with CC, and without CC/MCC, respectively). The list of principal diagnosis codes for face, mouth, and neck would be sequenced first followed by the list of the tracheostomy procedure codes, and lastly the list of laryngectomy procedure codes. To reflect that laryngectomy procedures may be assigned to these MS-DRGs, CMS also proposed to revise the titles of MS-DRGS 11, 12, and 13 to Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with MCC, with CC, and without CC/MCC, respectively.

CMS finalizes the above proposals.

d. Chimeric Antigen Receptor (CAR) T-Cell Therapy

CAR T-cell therapy is a cell-based gene therapy in which a patient's T-cells are genetically engineered resulting in the addition of a chimeric antigen receptor on the T cells that will bind to a certain protein on the patient's cancerous cells. The CAR T-cells are then administered to the

patient by infusion. Procedures involving the CAR T-cells therapy drugs are currently identified with ICD-10-PCS procedure codes XW033C3 (Induction of engineered autologous CAR T-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3) and XW043C3 (Induction of engineered autologous CAR T-cell immunotherapy into central, percutaneous approach, new technology group 3).

Two CAR T-cell therapy drugs received FDA approval in 2017. KYMRIAH™ (manufactured by Novartis Pharmaceutical Corporation) was approved for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. In May 2018, KYMRIAH received FDA approval for a second indication, treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. YESCARTA™ (manufactured by Kite Pharma, Inc.) was approved for use in the treatment of adult patients with relapsed or refractory large B-cell lymphoma and have not responded to or who relapsed after at least two other kinds of treatment. Both manufacturers submitted applications for new technology add-on payments for FY 2019. CMS approved a new technology add-on payment for KYMRIAH and YESCARTA for FY 2019 (see section II.H.5.a of this summary).

CMS examined the existing MS-DRGs to identify cases most similar to CAR T-cell therapy procedures. Given the CAR T-cell procedures involve a type of autologous immunotherapy in which the patient's cells are genetically transformed and then returned to the patient, CMS' clinical advisors believed that patients receiving treating with CAR T-cell therapy would have similar clinical characteristics and comorbidities to patients receiving treatment for other hematopoietic carcinomas treated with autologous bone marrow transplant. For FY 2019, CMS proposed to assign cases reporting the use of CAR T-cell therapy (ICD-10-PCS procedure codes XW033C3 and XW043C3) to MS-DRG 016. CMS proposed to revise the title of MS-DRG 016 to "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy".

CMS also discussed an alternative suggestion to create a new MS-DRG for procedures involving the utilization of CAR T-cell therapy. CMS was interested on how the administration of the CAR T-cell therapy drugs and associated services meet the criteria for the creation of a new MS-DRG. Given that a new MS-DRG must be established in a budget neutral manner, CMS was concerned with the redistributive effects away from core hospital services over time toward specialized hospitals and how that may affect payment for core services.

CMS also invited comments on alternative approaches, including alternatives in the context of the pending new technology add-on payment applications for KYMRAIAH™ and YESCARTA™. Based on feedback that hospitals would be unlikely to set charges different from the cost of CAR T-cell therapy drugs, CMS mentioned another suggestion to allow hospital to use a CCR of 1.0 for charges associated with XW033C3 and XW043C3 for determining outlier payments and for the purposes of a new technology add-on payment. This change would result in a higher outlier payment, higher new technology add-on payment or the determination of higher costs for IPPS-excluded cancer hospital cases. Another payment alternative suggested taking into account an appropriate portion of the average sales price (ASP) for these drugs. CMS also

received suggestions that payment should be established to promote comparability between the inpatient and outpatient setting.

Many commenters stated that the existing payment mechanisms under the IPPS do not allow for accurate payment of the unprecedented high cost of CAR T-cell therapy. Commenters also stated that payment for CAR T-cell therapy should avoid inappropriate financial incentives for care to be provided in the outpatient instead of the inpatient setting. Commenters requested a permanent solution to ensure accurate payment for CAR T-cell therapy that also limited any redistributive effects within the IPPS. In response, CMS notes the various solicitations for public comment the Administration has made related to drug pricing, including the solicitation for public comment in the 2019 OPPS/ASC proposed rule on key design considerations for developing a potential model that would test private market strategies to improve quality and reduce costs. CMS believes it would be premature to adopt changes to the existing payment mechanisms before reviewing comments from all the solicitations. CMS stated it needs more comprehensive clinical and cost data before developing new payment models for CAR T-cell therapy.

As an interim payment policy, commenters recommended a range of options. Some commenters recommended CMS finalize the proposed assignment of the therapy to MS-DRG 016, approve the new technology add-on payment, and/or allow a CCR of 1.0 for CAR T-cell therapy. Other commenters disagreed with the proposed assignment of CAR T-cell therapy because of differences between CAR T-cell therapy and autologous bone marrow transplants, including the lengths of stay and the level of associated toxicity. Some of these commenters suggested a new MS-DRG for CAR T-cell therapy and recommended for determining the payment based on the cost of CAR T-cell therapy instead of historical claims data. Some commenters thought the separate DRG for drug eluting stents was a possible payment model for CAR T-cell therapy. Another group of commenters requested that the costs of CAR T-cell therapy should be carved out from the IPPS and paid on a pass-through basis reflecting the cost of the therapy to the hospital; commenters indicated some state Medicaid programs use this approach.

CMS acknowledges the differences between autologous bone marrow transplant and CAR T-cell therapy but it believes this MS-DRG is the most appropriate match. It believes it is premature to create a new MS-DRG for CAR T-cell therapy. CMS also acknowledges the comments suggesting technical and operational recommendations for changes to the existing IPS and will consider them for future rulemaking as appropriate.

CMS finalizes its proposal to assign CAR T-cell therapies (identified by ICD-10-PCS procedure codes XW033C3 and XW043C3 to MS-DRG 016 for FY 2019. CMS will revise the title of MS-DRG 016 from "Autologous Bone Marrow Transplant with CC/MCC" to "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy." CMS will consider requests for alternative MS-DRG assignments and/or creation of a new MS-DRG for CAR T-cell therapy after reviewing public comment on a potential model and it gains experience with CAR T-cell therapy.

3. MDC 1 (Diseases and Disorders of the Nervous System)

a. Epilepsy with Neurostimulator

CMS agrees with a requestor that ICD-10-CM diagnosis codes G40.109 and G40.111 are also representative of epilepsy diagnoses and should be added to the list of epilepsy diagnosis codes for cases assigned to MS-DRG 023 (Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator). CMS finalizes its proposal to add these diagnosis codes to MS-DRG 023, effective October 1, 2018.

b. Neurological Conditions with Mechanical Ventilation

CMS received two separate but related requests to create new MS-DRGs for cases that identify patient diagnosed with neurological conditions and who require mechanical ventilation in the absence of an O.R. procedure. The requestors stated that the ICD-10-CM Official Guidelines for Coding and Reporting allows sequencing of acute respiratory failure as the principal diagnosis when it is jointly responsible with an acute neurologic event for admission and when a patient requires mechanical ventilation it would result in assignment MS-DRGs 207 (Respiratory System Diagnoses with Ventilator Support > 96 Hours) and 208 (Respiratory System Diagnoses with Ventilator Support < 96 Hours).

The first request was to specifically identify patients presenting with intracranial hemorrhage or cerebral infarction with mechanical ventilation and create two new MS-DRGs based on the duration of mechanical ventilation (>96 hours and <96 hours). The second request was to consider any principal diagnosis under the current GROUPER logic for MDC 1 with mechanical ventilation and create two new MS-DRGS also based on the duration of mechanical ventilation. Based on the analyses and consultation with its clinical advisors, CMS believed the findings do not support the creation of two additional MS-DRGs. CMS did not perform separate claims analysis for other conditions classified under MDC 1.

CMS' clinical advisors noted that all patients requiring mechanical ventilation (in the absence of an O.R. procedure) are known to be more resource intensive and stated it would not be practical to create new MS-DRGs specifically for every diagnosis requiring mechanical ventilation. To evaluate the frequency in which the use of mechanical ventilation is reported for different clinical scenarios, CMS examined claims data across each of the 25 MDCs to determine the number of cases reporting the use of mechanical ventilation ≤ 96 hours and >96 hours. The claims data for both scenarios reflected a wide variance with regard to the number of cases and average costs.

In response to comments disagreeing with its proposal, CMS states it will consider additional analysis in its efforts to refine the MS-DRGs for cases of patients requiring mechanical ventilation across the MDCs.

CMS finalizes its proposal not to create new MS-DRGs for cases that identify patients diagnosed with neurologic conditions classified under MDC 1 who require mechanical ventilation with or without a thrombolytic in the absence of an O.R. procedure.

4. MDC 5 (Diseases and Disorders of the Circulatory System)

a. Pacemaker Insertions

CMS received a request to assign all procedures involving the insertion of pacemaker devices to surgical MS-DRGs, regardless of the principal diagnosis. The requestor recommended that pacemaker insertions be grouped to surgical MS-DRGs within the MDC to which the principal diagnosis is assigned or grouped to MS-DRGs 981, 982, and 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC and without CC/MCC, respectively). Based on analyses of claims data and recommendations of its clinical advisors, CMS proposed to create pairs of procedure code combinations involving both the insertion of a pacemaker device with the insertion of a pacemaker lead that act as a procedure code combination pair or "cluster" in the GROUPER logic for designation as O.R. procedures outside of MDC 5 when the codes are reported together.

Commenters supported this proposal. One commenter disagreed with the proposal and suggested that it would be more appropriate to designate each pacemaker device and pacemaker lead procedure code as an O.R. procedure to allow initial insertions and placement of individual components to group to surgical MS-DRGs within all MDCs. CMS did additional analyses and found only 10 cases where a stand-alone code for insertion of a pacemaker device procedure or a stand-alone code for insertion of a pacemaker lead was reported; these 10 cases grouped to 10 different medical MS-DRGs.

CMS finalizes its proposal to create pairs of procedure code combinations involving both the insertion of a pacemaker device with the insertion of a pacemaker lead that act as a procedure code combination pair or "cluster" in the GROUPER logic for designation as O.R. procedures outside of MDC 5 when the codes are reported together.
CMS also proposed to designate all procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual code.

Some commenters supported this proposal and others opposed this proposal. One commenter disagreed with the proposal and stated that the placement of a lead or generator still require the use of an operating room, sterile field, anesthesiology, ad preparing the patient. CMS responds that its clinical advisors continue to support the non-O.R. designation because the complexity of these procedures is less than inserting a full pacemaker system and that a sterile field, anesthesia and preparation of the patient can be performed in other settings, such as a cardiac catheterization laboratory.

CMS finalizes its proposal to designate all procedure codes describing the insertion of a pacemaker device or the insertion of a pacemaker lead as non-O.R. procedures when reported as a single, individual stand-alone code outside of MDC 5.

Table's 6P.1d, 6P.1e and 6P.1f in the proposed rule provide specific list of the proposed combination pairs and the lists of pacemaker devices and pacemaker leads. (The tables are available at http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.)

CMS also proposed to maintain the current GROUPER logic for MS-DRGs 258 and 259 (Cardiac Pacemaker Replacement with MCC and without MCC, respectively) and for MS-DRGs 260, 261 and 262 (Cardiac Pacemaker Revision Except Device Replacement with MCC, with CC, and without CC/MCC, respectively). CMS noted that procedure codes describing the removal or revision of a cardiac lead or revision of a cardiac rhythm related (pacemaker) device (listed in the proposed rule) are currently designated as O.R. procedures and are assigned to MS-DRGs 260, 261, and 262 under MDC 5. CMS solicited comments on whether these codes should be designated as non-O.R. procedure codes when reported as a single, individual code with a principal diagnosis of MDC 5.

CMS appreciates commenters' support and agrees with the comment to add two additional ICD-10-PCS procedure codes (02H63MZ and 02H73MZ) to the pacemaker insertion code pairs and as stand-alone codes for the insertion of a pacemaker lead.

CMS finalizes the list of procedure codes in Table's 6P.1d, 6P.1e and 6P.1f with the addition of ICD-10 PCS procedure codes 02H63MZ and 02H73MZ to the pacemaker insertion code pairs and as stand-alone codes for the insertion of a pacemaker lead. CMS also finalizes maintaining the current GROUPER logic for MS-DRGs 258 and 259 and for MS-DRGs 260, 261, and 262.

In the proposed rule, CMS also solicited comments on whether ten procedure codes (listed in the rule) that describe the removal or revision of a cardiac lead and removal or revision of a cardiac rhythm related (pacemaker) device should also be designated as non-O.R. procedure codes when reported as a single, individual stand-alone code with a principal diagnosis outside of MDC 5. CMS agrees with commenters that removal or revision of a cardiac lead or pacemaker generator can be more complex and require greater resources than an initial insertion procedure. CMS maintains the O.R. designation of these codes and will continue to analyze these procedures. In the proposed rule, CMS also identified twenty-one procedure codes (listed in the rule) that describe an intracardiac or "leadless" pacemaker that are designated as O.R. procedures and assigned to MS-DRGs 228 and 229 (Other Cardiothoracic Procedures with MCC and without MCC, respectively) under MDC 5. CMS solicited comments on whether these procedure codes should also be considered for classification into all surgical unrelated MS-DRGs outside of MDC 5. Commenters supported the current classification of these procedure codes. CMS maintains the current designation of these procedure codes. CMS notes if one of the procedure codes is reported with a principal diagnosis outside of MDC 5, the case will group to one of the unrelated surgical MS-DRGs.

b. Drug-Coated Balloons in Endovascular Procedures

CMS received a request to reassign cases utilizing a drug-coated balloon in an endovascular procedure involving the treatment of superficial femoral arteries for peripheral arterial disease from the lower severity level MS-DRG 254 (Other Vascular Procedures without CC/MCC) and

MS-DRG 253 (Other Vascular Procedures with CC) to the highest severity level MS-DRG 252 (Other Vascular Procedures with MCC). CMS also received a request to revise the title of MS-DRG to "Other Vascular Procedures with MCC or Drug-Coated Balloon Implant".
CMS examined claims data reporting any 1 of the 36 ICD-10-PCS procedure codes for drug-coated balloons (see list in the final rule) in MS-DRGs 252, 253, and 254. CMS noted that the analysis show that there is not a high volume of cases reporting the use of a drug-coated balloon in endovascular procedures (2,890 cases) compared to all the cases (71,641 cases) in the MS-DRGs. The data showed that the average LOS for cases reporting use of a drug-coated balloon in MS-DRGs 253 and 254 is lower than all the cases, while the LOS is slightly higher compared to cases in MS-DRG 252. The average costs for cases reporting the use of a drug-coated balloon were higher compared to all of the cases in all three MS-DRGs.

Across all the assigned MS-DRGs (252, 253, and 254) the combination of all the cases (71,641) had an average LOS of 6 and average costs of $24,569. CMS noted that the use of a drug-coated balloon has higher costs than all other cases assigned to these MS-DRGs but it does not think it is a significant amount. In addition, the clinical advisors did not think it would be clinically appropriate to reassign cases for patients from the lowest severity level to the highest severity level without additional data to better determine the resource utilization for these patients. Because 24 of the 36 ICD-10-PCS procedure codes describing the drug-coated balloon also include the use of an intraluminal device, CMS conducted additional analysis using the combined cases in MS-DRGs 252, 253, and 254 to determine the number of cases reporting an intraluminal device with a drug-coated balloon versus the number of cases reporting only the use of a drug-coated balloon. The data showed that the use of a drug-coated balloon alone have lower average costs ($24,553) than the use or an intraluminal device or a drug-eluting intraluminal device with a drug-coated balloon ($28,418 and $26,098, respectively). The average LOS was comparable across all scenarios.

CMS did not propose any changes in the assignment of drug-coated balloons in an endovascular procedure involving the treatment of superficial femoral arteries for peripheral arterial disease. A number of commenters supported maintain the current classification of cases involving the use of a drug-coated balloon used in endovascular procedures. CMS agrees with a comment that continued analysis of cases reporting the use of a drug-coated balloon is important. CMS disagrees with a commenter that cases with the drug-coated balloons should be assigned to MS-DRG 252 or 253, and not to MS-DRG 254. CMS notes that its clinical advisors continue to believe it would not be clinically appropriate to reassign cases from the lowest severity level to the highest severity level in the absence of better data to determine the resource use for this subset of patients. CMS notes the new ICD-10-PCS procedure codes describing the use of a drug-coated balloon in the upper extremity and effective October 1, 2018 will provide additional information.

CMS finalizes its proposal to not reassign cases reporting the use of a drug-coated balloon in the performance of endovascular procedures from MS-DRG 253 and MS-DRG 254 to MS-DRG 252. CMS will continue to evaluate the differences in cases where a procedure utilizes a drug-coated balloon alone versus cases when a procedure utilizes an intraluminal device or a drug-eluting intraluminal device in addition to a drug-coated balloon.

5. MDC 6 (Diseases and Disorders of the Digestive System)

a. Benign Lipomatous Neoplasm of Kidney

CMS agrees with a request to reassign ICD-10-CM diagnosis code D17.71 from MDC 06 to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). CMS also identified another related diagnosis code that should be reassigned. CMS finalizes its proposals to reassign ICD-10 diagnosis code D17.71 from MS-DRGS 393, 394, and 395 under MDC 06 to MS-DRGs 686, 687, and 688 under MDC 11 and also reassign ICD-10-CM diagnosis code D17.72 from MS-DRGs 606 and 607 to MS-DRGs 686, 687, and 688.

b. Bowel Procedures

CMS received a request to reassign eight ICD-10-PCS procedure codes (listed in the proposed rule) for the reposition of the colon and takedown of end colostomy from MS-DRGs 344, 345, and 336 (Minor Small and Large Bowel Procedures with MCC, with CC and without CC/MCC, respectively) to MS-DRGs 329, 339, and 331 to MS-DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC and without CC/MCCC, respectively).
Based on analysis of claims data and input from its clinical advisors, CMS proposed maintaining the current assignments of the eight specific bowel repositioning procedures. Commenters agreed and CMS finalizes its proposal.

CMS also examined a subset of cases reporting one of the 12 repair and repositioning procedures (listed in the proposed rule) assigned to MS-DRGs 329, 330, and 331. Based on analysis of clinical data and input from its clinical advisors, CMS proposed to reassign the 12 procedures from MS-DRGs 329, 330, and 331 to MS-DRGs 344, 345, and 346.
Commenters disagreed with this proposal and recommended that any changes be delayed under additional data analysis was conducted. CMS agrees and does not finalize its proposal to reassign the 12 repair and repositioning codes.

6. MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Spinal Fusion

In the FY 2018 IPPS final rule, CMS announced plans to review the ICD-10 logic for the MS-DRGs where procedures involving spinal fusion are currently assigned for FY 2019. CMS received a comment suggesting it publish findings from this review and discuss future actions. The commenter agreed on the need to fully evaluate the MS-DRGs with spinal fusion procedure with additional claims data, particularly because of the 33 clinically invalid codes identified through the FY 2018 rulemaking process and the 87 codes identified from the ICD-10-PCS classification discussed at the September 2017 ICD-10 Coordination and Maintenance Committee meeting and proposed to be deleted effective October 1, 2018. The commenter noted that the problem with procedure codes describing clinically invalid spinal fusion procedures will not be fully resolved until FY 2019 claims are available for FY 2021 ratesetting. The commenter also provided evidence that a significant number of claims from the FY 2016 MedPAR data report one of the clinically invalid codes.

CMS did not propose any changes to the MS-DRGs involving spinal fusion procedures for FY 2019.

In response to the commenter's suggestion and findings, CMS provided (in the proposed and final rules) the results from its analysis of the September 2017 update of the FY 2017 MedPAR claims data for the MS-DRGs involving spinal fusion procedures. The results of the data analysis demonstrated that the invalid spinal fusion procedures represent approximately 12 percent of all discharges across the spinal fusion MS-DRGs. CMS does not understand why providers assign procedure codes for spinal fusion procedures with the device value "Z". CMS will continue to monitor the claims data for resolution of the coding issues and will work with the AHA to provide further education on spinal fusion procedures and the proper reporting of the ICD-10-PCS spinal fusion procedures codes.

CMS agrees with commenters that accurate coding of spinal fusion procedures has been confusing and it will continue to monitor the claims data of these procedures. It will review the ICD-10-PSC spinal fusion coding guidelines to determine where additional clarifications may be made.

7. MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast): Cellulitis with Methicillin Resistant Staphylococcus aureus (MRSA) Infection

CMS received a request to reassign ICD-10 diagnosis codes reported with a primary diagnosis of cellulitis and a secondary diagnosis of B95.62 (MRSA as the cause of disease classified elsewhere) or A49.02 (MRSA, unspecified site) from MS-DRGs 602 and 603 (Cellulitis with MCC, without MCC, respectively) to MS-DRGs 867, 868 and 869 (Other Infectious and Parasitic Disease Diagnoses with MCC, CC, without CC/MCC, respectively). The requestor stated that patients diagnosed with cellulitis and MRSA are entirely different from patients diagnosed only with cellulitis.

Based on analyses and input from its clinical advisors, CMS proposed not to reassign cellulitis cases reported with ICD-10-CM diagnosis code of B95.62 or A49.02 to MS-DRG 867, 868, or 869. CMS finalizes this proposal.

8. MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders): Acute Intermittent Porphyria

CMS received a request to revise the MS-DRG classification for cases of patients diagnosed with porphyria (a rare disorder that interferes with the production of hemoglobin) and reported with ICD-10-CM diagnosis code E80.21 (Acute intermittent (hepatic) porphyria). Treatment for patients consists of an intravenous injection of Panhematin®. ICD-10-CM diagnosis code E80.21 is currently assigned to MS-DRG 642 (Inborn and Other Disorders of Metabolism).[2] CMS' analysis showed that the average LOS for this subset of cases (183 cases) was 5.6 days and the average costs were $19,244. This average LOS was lower than the average for all cases in MS-DRG 643 but higher than the average for all cases in MS-DRGs 644 and 645. The

[2] This issue has been previously discussed in the FY 2013 and FY 2015 IPPS/LTCH PPS proposed and final rules.

average costs for the subset of cases are much higher than the average costs for all cases in MS-DRGs 643, 644, and 645.

CMS stated it was unable to identify a MS-DRG that would more closely parallel these cases with respect to average costs and LOS that would also be clinically aligned. Given the small number of porphyria cases, CMS did not believe there is a justification for creating a new MS-DRG and did not propose to revise the MS-DRG classification for porphyria cases.
Some commenters supported CMS' proposal but others disagreed stating that patients with acute porphyria attacks have difficulties obtaining treatment with Panhematin® as an inpatient because of the financial disincentives. Commenters were concerned that instead of treating patients with an acute porphyria attack with Panhematin®, facilities are attempting to provide symptomatic relief and transferring patients to an outpatient setting to receive the drug. Commenters stated this was not the appropriate standard of care for acute porphyria attacks and can result in long-term health consequences.

CMS acknowledges the commenters' concerns and reiterates it is not appropriate for facilities to deny treatment to beneficiaries that involves increased costs. CMS is concerned about the commenters' statements about access to treatment and will continue to explore mechanisms to address appropriate payment for rare diseases and low volume DRGs. For FY 2019, CMS finalizes its proposal to maintain the MS-DRG classification for porphyria cases.

9. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Admit for Renal Dialysis

CMS received a request to review the codes (Z49.01, Z49.02, Z49.31, and Z49.32) assigned to MS-DRG 685 (Admit for Renal Dialysis) to determine if the MS-DRG should be deleted, or if it should remain as a valid MS-DRG. The requestor noted that three of the four ICD-10 diagnosis codes currently assigned to MS-DRG 685 are on the "Unacceptable Principal Diagnosis" edit codes listed in the Medicare Code Editor (MCE).

Based on analysis and input from its clinical advisors, CMS proposed to delete MS-DG and reassign the ICD-10-CM diagnosis codes to MS-RDGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses with MCC, with CC, and without CC/MCC). CMS finalizes this proposal.

10. MDC 14 (Pregnancy, Childbirth and the Puerperium)

In the FY 2018 IPPS proposed and final rules, CMS noted that the code list in the ICD-10-MS-DRG Version 33 Definitions Manual for MS-DRG 774 (Vaginal Delivery with Complication Diagnoses) required further analysis to clarify what constitutes a vaginal delivery to satisfy the ICD-10 MS-DRG logic. After reviewing this issue and obtaining input from its clinical advisors, CMS was concerned the MS-DRG logic involving a vaginal delivery under MDC 14 needed additional review. CMS solicited comments on the following:

- Refinements to four MS-DRGs related to vaginal deliveries: MS-DRGs 767, 768, 774, and 775.

- 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.

CMS discussed the recommendations it received and provides extensive analyses of possible refinements to the MS-DRGs related to vaginal deliveries. Based on its review, CMS proposed deleting 10 MS-DRGs and creating 18 new MS-DRGs. These proposals were intended to simply the vaginal delivery procedure logic by eliminating the extensive diagnosis and procedure lists for several conditions that must be met for assignment to the vaginal delivery MS-DRGs. In general, commenters supported CMS' proposal. In the final rule, CMS responds to specific comments about MS-DRGs and GROUPER logic. After consideration of comments, CMS finalizes its proposals:

- Reassign ICD-10-PCS procedure codes 0UDB72X, 0UDB7ZZ, 0UDB8ZX, and 0UDB8ZZ that describe dilation and curettage procedures from MS-DRG 767 under MDC 14 to MS-DRGs 744 and 745 under MDC 13.
- Finalizing its proposed list of diagnosis and procedure codes for assignment to the revised MDC 14 MS-DRGs including the deletion of 10 MS-DRGs and the creation of 18 new MS-DRGs.

11. MDC 18 (Infectious and Parasitic Diseases (Systematic or Unspecified Sites): Systematic Inflammatory Response Syndrome (SIRS) of Non-Infectious Origin

CMS' clinical advisors recommended that ICD-10-CM diagnosis codes for R65.10 and R65.11 (SIRS of non-infectious origin without and with acute organ dysfunction, respectively) should be reassigned from MS-DRGs 870, 871, and 872 (Septicemia or Severe Sepsis with Mechanical Ventilation > 96 Hours, with MCC, and without MCC, respectively) to more appropriate MS-DRGs for diagnosis codes describing conditions of non-infectious origins. CMS examined the claims data in this MS-DRG and found a total of 1,392 cases reporting a principal data code of R65.10 or R65.11. CMS noted that these cases have been coded inaccurately according to the Coding Guidelines, which indicates R65.10 and R65.11 should not be reported as the principal diagnosis on an inpatient claim. CMS reviewed alternative options under MDC 18 and proposed to reassign diagnosis codes R65.10 and R65.11 to MS-DRG 864 and revise the title of this MS-DRG to "Fever and Inflammatory Conditions". CMS finalizes this proposal.

12. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): Corrosive Burns

CMS received a request to reassign cases with a primary diagnosis of toxic effects (ICD-10-CM codes T51 through T65) and a secondary diagnosis of corrosive burns (ICD-10-CM T21.40 through T21.79) from 13 MS-DRGs including MS-DRGs for injuries, skin grafts for injuries, poisoning and toxic effects, extensive burns, and nonextensive burns. Based on CMS' analyses of the claims data and the advice of its clinical advisors, CMS proposed not to reassign these cases. CMS finalizes this proposal.

13. 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, procedures, and demographic information are entered into the Medicare claims processing systems and 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. The link to the MCE manual file are posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html through the FY 2019 IPPS Final Rule home page.
CMS discussed requests it received by November 1,2017 to examine specific code edit lists that requestors believed were incorrect and that affected claims processing functions. The interested reader is referred to the final rule for discussion of the following edits:

- Age conflict,
- Sex conflict,
- Manifestation code as principal diagnosis,
- Questionable admission, and
- Unacceptable principal diagnosis.

Future Enhancements. CMS engaged a contractor to assist in the review of the limited coverage and noncovered procedure edits in the MCE that may also be in the claims processing systems utilized by the MACs. The review is designed to identify where duplicate edits may exist and to determine the impact if these edits were removed from the MCE.

CMS encourages comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to MSDRGClassificationChange@cms.hhs.gov by November 1, 2018 for FY 2020.

14. Changes to Surgical Hierarchies

The surgical hierarchy is an ordering of surgical classes from most resource-intensive to least resource-intensive. It ensures that cases involving multiple surgical procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class. 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. CMS notes 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. This can occur when the difference between the average costs for two surgical classes is very small and when the surgical class is "the other O.R." procedures which is uniformly ordered last in the surgical hierarchy in each appropriate MDC.
Based on the changes finalized for MDC 14 (Pregnancy, Childbirth and the Puerpeium) CMS finalizes its proposed corresponding changes to the surgical hierarchy for MDC 14. CMS encourages commenters to submit requests to examine ICD-10 claims pertaining to the surgical

hierarchy via the CMS MS-DRG Classification Change Request Mailbox at MSDRGClassificationChange@cms.hhs.gov by November 1, 2018 for FY 2020 consideration.

15. Changes to the MS-DRG Diagnosis Codes for FY 2019

A substantial complication or comorbidity is 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. CMS notes that 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 the FY 2008 IPPS final rule (72 FR 47152 through 47171), CMS 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.

Proposed Additions and Deletions to the Diagnosis Code Severity Levels. CMS posted the proposed additions and deletions to the MCC severity list and the CC severity list for FY 2019 on the CMS web site. CMS also invited comments on its proposed severity level designations for the diagnosis codes listed in Tables 6I.1 and 6J.1. CMS noted, the proposed deletions are a result of code expansions, with the exception of diagnosis codes B20 and J80, which are the results of proposed severity level designation changes. Effective with FY 2019, these diagnosis codes will not be valid codes.

In the final rule, CMS responds to comments it received about the proposed severity level for specific diagnosis codes. After consideration of these comments, CMS finalizes its proposal to designate diagnosis codes K35.20 and T81.44XA as CC severity levels. CMS also finalizes its other proposed additions and deletions with their corresponding severity level designations for FY 2019. The following tables identify the additions and deletions to the MCC and the CC severity list for FY 2019:

- Table 6I.1 – Additions to the MCC List
- Table 6I.2 – Deletions to the MCC List
- Table 6J.1 – Additions to the CC List
- Table 6J.2 – Deletions to the CC List

The tables are available on the CMS web site at: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

Principal Diagnosis Is Its Own CC or MCC. CMS stated that its initial goal in developing the ICD-10 MS-DRG was to ensure that a case was signed to the same MS-DRG, regardless of whether the record was coded in ICD-9 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 the 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. CMS states that ICD-10 data can now be used to evaluate the effectiveness of the special logic for assigning a severity level as an indicator of resource data. CMS conducted analysis of the

ICD-10 coded data combined with clinical review to determine whether or not to keep or remove the special logic for assigning a complex principal diagnosis to the appropriate MS-DRG.

CMS estimated the overall financial impact of removing the special logic from the GROUPER. Before removing the special logic in the Version 35 GROUPER, the cases impacted by the special logic had an estimated average payment of $58 million above the average costs for all MS-DRGs to which the claims were originally assigned. After removing the special logic, the 18,596 cases impacted by the special logic had an estimated average payment of $39 million below the average costs for the newly assigned MS-DRGs. Additional analyses are discussed in the final rule.

CMS also examined 32 subsets of cases that utilized the special logic and had 100 or more cases. A table in the final rule contains examples of four subsets of cases that utilize the special logic, comparing average LOS and average costs between two MS-DRGs within a base DRG, corresponding to the MS-DRG assigned when the special logic is removed and the MS-DRG assigned when the special logic is utilized. For all subset of cases, CMS used the principal diagnosis E11.52 (Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene). The MS-DRG pairs evaluated are MS-DRGs 240 and 241, 253 and 254, 256 and 257, and 300 and 301.

CMS proposed to remove the special logic in the GROUPER for processing claims containing a diagnosis code form the Principal Diagnosis Is Its Own CC or MCC List.
Commenters supported the proposed deletion of the Principal Diagnosis Is Its Own CC or MCC logic. In response to a few commenters who disagreed with the proposal and recommended additional analysis consistent with the comprehensive CC/MCC analysis, CMS notes that an additional analysis would not be conclusive because the purpose of the comprehensive CC.MCC analysis is to evaluate the impact in resource use for patients with conditions reported as secondary diagnoses. CMS believes the methodology it used is appropriate for assessing it should maintain the special logic currently used.

As an initial step in the first phase of CMS' comprehensive review of the CC and MCC list, CMS finalizes its proposal to remove the special logic in the GROUPER for processing claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists. CMS also finalizes its proposal to delete the following tables:

- Table 6L – Principal Diagnosis Is Its Own MCC List and
- Table 6M – Principal Diagnosis Is Its Own CC List

Proposed Complications or Comorbidity (CC) Exclusions List. A substantial complication or comorbidity is 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. CMS created a CC Exclusions List to: (1) preclude coding of CCs for closely related conditions; (2) preclude duplicative or inconsistent coding from being treated as CCs; and (3) ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair. CMS posted the proposed additions and deletions FY 2019 on the CMS web site.

In the final rule, CMS responds to comments it received about the proposed severity level for specific diagnosis codes. After consideration of public comments, CMS finalizes its proposed severity level assignments under the ICD-10 MSG-DRGs Version 36, effective October 1, 2018. The following tables identify the final changes to the ICD-10 MS-DRGs Version 36 CC Exclusion List:

- Table 6G.1 – Secondary Disorders Order Additions
- Table 6G.2 – Principal Disorders Order Additions
- Table 6H.1 – Secondary Disorders Order Deletions
- Table 6H.2 – Secondary Disorders Order Deletions
-

The additional tables, associated with this final rule are available, effective October 1, 2018 for FY 2019:

- Table 6A (New Diagnosis Codes)
- Table 6B (New Procedure Codes)
- Table 6C (Invalid Diagnosis Codes)
- Table 6D (Invalid Procedure Codes)
- Table E (Revised Diagnosis Code Titles)
- Table 6F (Revised Procedure Code Titles)

All the above tables are available on the CMS web site at: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

16. Comprehensive Review of CC List for FY 2019

CMS discussed the statistical algorithm it uses to determine the impact on resource use of each secondary diagnosis. Each diagnosis with available Medicare data is evaluated to determine its impact on resource use and to determine the most appropriate subclass (non-CC, CC or MCC) assignment. In order to make this determination, the average costs for each subset of cases are compared to the expected costs for cases in that subset.

Requested Changes to Severity Levels. CMS received four requests for changes to severity levels of ICD-10-CM diagnosis codes. CMS proposed to change the severity levels of ICD-10-diagnosis codes B20 (Human immunodeficiency virus disease) from a MCC to a CC and J80 (Acute respiratory distress syndrome) from a CC to a MCC. CMS proposed not to change the severity level for G39.40 (Encephalopathy, unspecified).

In response to comments opposing the proposed severity level for ICD-10-diagnosis code B20, CMS notes that the data did not support maintaining a severity level of an MCC and its clinical advisors did not believe that the secondary diagnosis of HIV would be expected to result in the additional resources associated with an MCC. After consideration of comments, CMS finalizes its proposals related to severity level.

17. Review of Procedure Codes in MS-DRGs 981 through 983 and 987 through 989

Each year CMS reviews MS-DRGs 981, 982, and 983 (Extensive OR Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS- DRGs 987, 988, and 989 (Nonextensive OR Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC) to determine whether it would be appropriate to change the procedures assigned to these MS-DRGs. These MS-DRGs are reserved for those atypical cases in which none of the O.R. procedures performed are related to the principal diagnosis.
Moving Procedure Codes. For FY 2019, CMS finalizes its proposal not to remove any procedure codes from these MS-DRGs into one of the surgical MS-DRGs for the MDC into which the principal diagnosis is assigned. In response to a commenter raising specific grouping issues, CMS notes it will review these issues for FY 2020 as part of its ongoing analysis of the unrelated procedure MS-DRGs. CMS reminds reads, that comments about MS-DRG classification should be submitted no later that November 1 of each year for possible inclusion in the annual proposed rule.

Reassignment of Procedure Codes. CMS finalizes its proposal to maintain the current structure of MS-DRGs 981 through 983 and MS-DRGs 987 through 989.

Adding Diagnosis or Procedure Codes to MDCs. CMS received requests for reassigning cases for congenital pectus excavatum, sternal fracture repair, and rib fracture repair. CMS finalizes its proposals to reassign ICD-10 diagnosis codes for pectus excavatum from MCD 4 to MDC 8; reassign diagnosis codes for sternum fracture from MCD 4 to MDC 8; and rib fracture from MDC 8 into MDC 4. The interested reader is referred to the final rule to learn about the specific ICD-10-CM procedure codes and their MS-DRG reassignments.

18. Changes to the ICD-10-CM and ICD-10-PCS Coding Systems

The ICD-10-CM Coordination and Maintenance Committee is responsible for approving coding changes, and developing errata, addenda, and other modifications to the ICD-10-CM to reflect newly developed procedures and technologies and newly identified diseases. The NCHS has lead responsibility for the ICD-10-CM diagnosis codes and CMS has lead responsibility for the ICD-10-PCS procedure codes.

The official list of ICD-10-CM and ICD-10-PCS codes can be found on the CMS website at http://www.cms.gov/Medicare/Coding/ICD10/index.html.
CMS provides the following contact information for questions and comments concerning coding issues:

- For diagnosis codes contact Donna Pickett, Co-Chairperson, ICD-10 Coordination and Maintenance Committee, NCHS, Room 2402, 3311 Toledo Road, Hyattsville, MD 20782. Comments can also be sent by: mailto:nchsicd10@cdc.gov.
- For procedure codes send questions and comments to: ICDProcedureCodeRequest@cms.hhs.gov.

19. Replaced Devices Offered Without Cost or With a Credit

In the FY 2008 final rule with comment period (72 *FR* 47246 through 47251), CMS discussed Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. CMS specified that if a hospital received a credit for a recalled device equal to 50 percent or more of the cost of the device, CMS would reduce a hospital's IPPS payment for those MS-DRGs. In the FY 2012 IPPS/LTCH final rule (76 *FR* 51556 and 51557), CMS 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.
For FY 2019, CMS finalizes its proposal not to add any MS-DRGs to the IPPS policy for replaced devices without cost or with a credit. The list that CMS is finalizes is below.

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit

MDC	MS-DRG	MS-DRG Title
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC
MDC 01	025	Craniotomy & Endovascular Intracranial Procedures with MCC
MDC 01	026	Craniotomy & Endovascular Intracranial Procedures with CC
MDC 01	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC
MDC 03	129	Major Head & Neck Procedures with CC/MCC or Major Device
MDC 03	130	Major Head & Neck Procedures without CC/MCC
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC
MDC 05	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC
MDC 05	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC
MDC 05	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC
MDC 05	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC
MDC 05	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC
MDC 05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC
MDC 05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC
MDC 05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC
MDC 05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
MDC 05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
MDC 05	242	Permanent Cardiac Pacemaker Implant with MCC
MDC 05	243	Permanent Cardiac Pacemaker Implant with CC
MDC 05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
MDC 05	245	AICD Generator Procedures
MDC 05	258	Cardiac Pacemaker Device Replacement with MCC
MDC 05	259	Cardiac Pacemaker Device Replacement without MCC
MDC 05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
MDC 05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
MDC 05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
MDC 05	265	AICD Lead Procedures
MDC 05	266	Endovascular Cardiac Valve Replacement with MCC
MDC 05	267	Endovascular Cardiac Valve Replacement without MCC
MDC 05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
MDC 05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
MDC 05	270	Other Major Cardiovascular Procedures with MCC
MDC 05	271	Other Major Cardiovascular Procedures with CC
MDC 05	272	Other Major Cardiovascular Procedures without CC/MCC
MDC 08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
MDC 08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
MDC 08	466	Revision of Hip or Knee Replacement with MCC
MDC 08	467	Revision of Hip or Knee Replacement with CC
MDC 08	468	Revision of Hip or Knee Replacement without CC/MCC
MDC 08	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC
MDC 08	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC

20. Other Policy Changes: Other Operating Room (O.R.) and Non-O.R. Issues

CMS received 11 requests to change the designation of specific ICD-10-PCS from non-O.R. to O.R procedures or vice versa. As discussed in the proposed rule, if CMS proposes to change the designation of codes from non-O.R. procedures, it also proposes MS-DRGs for assignment of the procedure codes.

a. Percutaneous and Percutaneous Endoscopic Excision of Brain and Cerebral Ventricles

CMS agreed with a request to move 22 ICD-10-PCS procedure codes (listed in the proposed rule) from the non-O.R. designation. CMS finalizes its to add these procedure codes to MS-DRGs 25, 26, and 27 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 1 (Diseases and Disorders of the Nervous System).

b. Open Extirapation of Subcutaneous Tissue and Fascia

CMS disagreed with a request to move 23 ICD-10-PCS procedure codes (listed in the proposed rule) from the non-O.R. designation. CMS finalizes its proposal to maintain these procedure codes as non-O.R. procedures.

c. Open Scrotum and Breast Procedures.

CMS agreed with a request to move 13 ICD-10-PCS procedure codes that describe procedures involving open draining, open extirpation, and open debridement/excision of the scrotum and breast (listed in the proposed rule). CMS finalizes its proposal to add the scrotal procedure codes to MS-DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy with CC/MCC and without CC/MCC, respectively) and MS-DRGs 717 and 718 (Other Male Reproductive System O.R. Procedures Except Malignancy with CC/MCC and without CC/MCC, respectively). CMS also finalizes its proposal to add the breast procedure codes to MS-DRGs 584 and 585 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

d. Open Parotid Gland and Submaxillary Gland Procedures

CMS agreed with a request to move eight ICD-10-PCS procedure codes that describe procedures involving open drainage and open extirpation of the parotid or submaxillary glands (listed in the proposed rule). CMS finalizes its proposal to add these procedures to MS-DRG 139 (Salivary Gland Procedures).

e. Removal and Reinsertion of Spacer; Knee Joint and Hip Joint

CMS agreed with a request to move four sets of ICD-10-PCS procedure code combinations (eight codes) that describe procedures involving open removal and insertion of spacers into the knee or hip joints (listed in the proposed rule). CMS agreed with the requestor but it also proposed to reassign these codes when reported as stand-alone procedures. CMS finalizes its proposal to add the four knee procedure codes to MS-DRGs 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively) or MS-DRGs 488 and 489 (Knee Procedures without Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively). For the hip procedures, CMS proposes to add these procedures to MS-DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively).

f. Endoscopic Dilation of Ureter(s) with Intraluminal Device

CMS agreed with a request to reassign three ICD-10-PCS procedure codes (listed in the proposed rule). CMS finalizes its proposal to add these procedures to MS-DRGs 656, 657, and 658 (Kidney and Ureter Procedures for Neoplasm with MCC, with CC, and without CC/MCC, respectively), MS-DRGs 659, 660, and 661 (Kidney and Ureter Procedures for Non-Neoplasm with MCC, with CC, and without CC/MCC, respectively), MS-DRGs 907, 908 and 909 (Injuries, Poisonings and Toxic Effects of Drugs) and MS-DRGs 957, 958, and 959 (Multiple Significant Trauma).

g. Thoracoscopic Procedures of Pericardium and Pleura

CMS agreed with a request to reassign seven ICD-10-PCS procedure codes involving thorascoscopic drainage of the pericardial cavity or pleural cavity, or extirpation of matter from

the pleura. Based on its review, CMS added two related procedure codes. CMS finalizes its proposal to add these procedure codes to the 18 MS-DRGs listed in the final rule.

h. Open Insertion of Totally Implantable and Tunneled Vascular Access Devices (VAD)

CMS received a request to reassign 20 ICD-10-PCS procedure codes (listed in the proposed rule). CMS agreed that open insertion of totally implantable VAD procedures typically require the resources of an operating room but it does not believe that the tunneled VAD procedures typically require the resources of an operating room. Therefore, CMS finalized its proposal to designate these procedures as O.R. procedures but if the procedure is unrelated to the principal diagnosis, it will be assigned to MS-DRGs 981, 982, and 983 instead of a medical MS-DRG. CMS also maintains the non-O.R. designation for tunneled VAD procedures.

i. Percutaneous Joint Reposition with Internal Fixation Device

CMS disagreed with a request to move 20 ICD-10-PCS procedure codes from the non-O.R. designation. CMS finalizes its proposal to maintain these procedure codes as non-O.R. procedures.

j. Endoscopic Destruction of Intestine

CMS agreed with a request to reassign four codes (listed in the proposed rule) and finalizes its proposal to remove these four codes from the O.R. procedure lists and add them to the non-O.R. procedure list.

k. Drainage of Lower Lung Via Natural or Artificial Opening Endoscopic Diagnostic

CMS agreed with a request to remove two procedure codes (0B9J8ZX and 0B9F8ZX) from the list of O.R. procedure codes. CMS identified three additional related codes (0B9D8ZX, 0B9C8ZX, and 0B9G8ZX) to remove from the list of O.R. procedure list. CMS finalizes its proposal to add these five codes to the non-O.R. procedure list.

l. Endobronchial Valve Procedures

In response to the proposed rule, a commenter requested 8 ICD-10-PCS procedure codes to be placed on the O.R. procedure list. CMS disagrees and maintains these non-O.R. designation of these codes.

G. Recalibration of the MS-DRG Relative Weights

The Secretary is required by statute to revise the MS-DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. In developing relative weights for the FY 2019 rule, CMS used two data sources:

- FY 2017 MedPAR data for discharges occurring on October 1, 2016, through September 30, 2017, based on bills received by CMS through March 31, 2018, 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 2017 MedPAR file used to calculate the relative weights includes data for approximately 9.7 million Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from the analysis. The data also exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. To the extent possible, all the claims were regrouped using the FY 2019 MS-DRG classifications discussed in section II.F.

- Medicare cost report data files from HCRIS, principally for FY 2016 cost reporting periods, using the December 31, 2017 update of the FY 2016 HCRIS. As in the past, CMS uses the HCRIS dataset that is three years prior to the applicable IPPS fiscal year.

Following the process used to calculate the relative weights for FY 2019, hospitals' FY 2017 billed charges were converted to costs using national average CCRs calculated by CMS for the 19 cost centers. The cost report lines used to create the 19 cost center CCRs and their corresponding revenue codes for each of the 19 cost centers are shown in the final rule (see unnumbered tables on pp. 427-440 of the display copy). The FY 2019 CCRs are shown in the table below and compared to FY 2018.

Group	FY 2018 CCR	FY 2019 CCR
Routine Days	0.458	0.442
Intensive Days	0.373	0.368
Drugs	0.194	0.191
Supplies & Equipment	0.297	0.299
Implantable Devices	0.332	0.309
Therapy Services	0.321	0.304
Laboratory	0.120	0.113
Operating Room	0.191	0.179
Cardiology	0.112	0.103
Cardiac Catheterization	0.117	0.110
Radiology	0.153	0.145
MRIs	0.079	0.074
CT Scans	0.038	0.035
Emergency Room	0.171	0.159
Blood and Blood Products	0.322	0.296
Other Services	0.365	0.345
Labor & Delivery	0.412	0.382
Inhalation Therapy	0.169	0.156
Anesthesia	0.089	0.078

The cost-based relative weights were normalized by an adjustment factor of 1.761194774 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself

does not increase or decrease total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act.

Using data from the FY 2017 MedPAR file, there were 7 MS-DRGs, all related to newborns, which contain fewer than 10 cases, the minimum number CMS has established to assure accurate and stable cost weights. For these 7 MS-DRGs, CMS is computing FY 2019 relative weights by adjusting their FY 2018 weights by the percentage change in the average weight of the cases in other MS-DRGs – the same procedure used previously.

Several commenters expressed concern about reductions of greater than 20 percent in relative weights from FY 2018 with suggestions to either the retain the FY 2018 weight or establish policies that mitigate the reduction in weights from one year to the next. CMS does not believe it is normally appropriate to address relative weight fluctuations that appear to be driven by changes in the underlying data. Nevertheless, CMS has observed significant reductions in relative weights for each of the 2 years since CMS began using the ICD-10 data in calculating the relative weights. CMS is adopting a temporary one-time measure for FY 2019 that will set the FY 2019 relative weight equal to the FY 2018 relative weight where the FY 2018 relative weight declined by 20 percent from the FY 2017 relative weight and the FY 2019 relative weight would have declined by 20 percent or more from the FY 2018 relative weight without this intervention.

H. Add-On Payments for New Services and Technologies

1. Background

Section 1886(d)(K) and (L) of the Act establish a process for identifying and ensuring adequate payment for new medical services and technologies under the IPPS. The regulations at 42 CFR 412.87 specify three criteria for a new medical service or technology to receive add-on payments under the IPPS: (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.

CMS notes that even if a technology receives a new FDA approval, it may not necessarily be considered "new" for purposes of new technology add-on payments if it is "substantially similar" to a technology that was approved by FDA and has been on the market for more than 2 or 3 years. CMS uses three criteria for evaluating whether a new technology is substantially similar to an existing technology (74 FR 43813 -43814):

1. Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome;
2. Whether a product is assigned to the same or a different MS-DRG; and
3. Whether the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population.

If a technology meets all three of the criteria, CMS considers it substantially similar to an existing technology and for purposes of the new technology add-on payments, CMS would not consider the medical service or technology "new". CMS first determines whether a medical service or technology is new; if CMS determines that medical service or technology is considered new, then it will make a determination as to whether the cost threshold and substantial clinical improvement criteria are met.

For purposes of the cost criterion, Table 10 released with the FY 2018 IPPS/LTCH PPS final rule contains the final thresholds that will be used to evaluate applications for new technology add-on payments for FY 2019.[3] Beginning with FY 2020, CMS proposed it would no longer include the thresholds applicable to the next fiscal year in the IPPS rule associated with the prior fiscal year (in this case FY 2019). Instead, it proposed to provide the thresholds as one of the data files posted on the CMS website where the impact data files associated with the rulemaking for the applicable fiscal year (in this case FY 2019) are posted. CMS did not receive any comments on this proposal. Thus, CMS **finalizes** the thresholds applicable to FY 2020 would be included in the data files associated with FY2019 and not included as a Table within the IPPS. CMS believes this will clarify for the public that the listed thresholds will be used for new technology add-on payment applications for the next fiscal year.
Under the new technology add-on payment policy, Medicare will make an add-on payment equal to the lesser of: (1) 50 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed Medicare's payment); or (2) 50 percent of the difference between the full DRG payment and the hospital's estimated cost for the case. Further, 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. Add-on payment for new medical services or technologies for FY 2005 and later years have not been subjected to budget neutrality.

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. CMS also notes that for FY 2020, complete application information, along with final deadlines for submitting an application, will be posted as it becomes available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. This web site will also post the tracking forms completed by each applicant and will be available before the publication of the proposed rule for FY 2020.

CMS invites any product developers or manufacturers of new medical technologies to contact the agency early in the process of product development if they have questions or concerns about the evidence needed in the agency's coverage decisions. In addition, stakeholders with questions about Medicare's coverage, coding, and payment processes, or questions about how to navigate

[3] Table 10 is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2018-IPPS-Final-Rule-Home-Page-Items/FY2018-Ipps-Final-Rule-Tables.html.

these processes, can contact the Council on Technology and Innovation (CTI) at CTI@cms.hhs.gov.[4]

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

On February 13, 2018, CMS held a town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" relating to pending new technology applications. CMS live-streamed the meeting and also posted the town hall on the CMS YouTube web page.

In their evaluation of individual applications, CMS considered the applicants' presentation made at the town hall meeting and written comments received by February 23, 2018. Where applicable, CMS summarized comments related to "substantial clinical improvement" at the end of each discussion of the individual applications in the proposed rule. Comments unrelated to the "substantial clinical improvement" criterion were not summarized.

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) a new section was created within the ICD-10-PCS codes, labeled Section "X" codes, to identify new medical services and technologies that are not usually captured by coders, or do not have the desired specificity within the current ICD-10-PCS structure required for new technology. Information regarding "X" codes can be found on the CMS web site at https://www.cms.gov/Medicare/Coding/ICD10/2016-ICD-10-CM-and-GEMs.html.

CMS notes that after section "X" codes have served their purpose, proposals to delete them and create new codes in the body of ICD-10-PCS would be addressed at ICD-10 Coordination and Maintenance Committee meetings. CMS also notes that codes for new technologies that are consistent with the current ICD-10-PCS codes may still be created within the current ICD-10-PCS structure.

4. FY 2019 Status of Technologies Approved for FY 2018 Add-On Payments

CMS' policy is that a medical service or technology may be considered new within 2 or 3 years after the point at which data becomes available which reflects the inpatient hospital code assigned to the new service or technology. CMS' practice has been to begin and end new technology add-on payments on the basis of a FY and it generally follows a guideline that uses a 6-month window before and after the start of the FY to determine whether to extend an add-on payment for an additional fiscal year. In general, CMS extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the US market occurs in the later half of the FY.

[4] The CTI was established under section 942(a) of Pub. L. 108-173 and oversees the agency's cross-cutting priorities on coordinating coverage, coding and payment processes for new technologies, including drug therapies. CTI's "Innovator's Guide" is available at https://www.cms.gov/Medicare/Coverage/CouncilonTechnology/Downloads/Innovatiors-Guide-Master-7-23-15.pdf.

For FY 2019, CMS **finalizes** its proposal to discontinue new technology add-on payments for:

- EDWARDS INTUITY Elite™ Valve System (INTUITY) and LivaNova Perceval Valve (Perceval),
- GORE®EXCLUDER® Iliac Branch Endoprosthesis (IBE),
- Praxbind® (Idarucizumab), and
- Vistogard™ (Uridine Triacetate).

CMS disagrees with comments that the new-technology add-on payment should continue and that the duration of the new technology add-on payment should be different for INTUITY and Perceval, based on their individual dates of market entry. In response to comments, CMS cites section 412.87(b)(2) that states a medical service or technology may be considered "new" within 2 or 3 years after which data begins to become available reflecting the inpatient hospital code assigned to the new service or technology. This section also specifies that after CMS has recalibrated the DRGs based on available data, to reflect the costs of an otherwise new medical service or technology, the medical service will no longer be considered "new" under the criterion of this section. Additionally, CMS reiterates it determined that the Perceval and INTUITY valves are substantially similar to each other and therefore, it used the earliest date when data became available for the technology to determine the beginning of the newness period. CMS also notes that consistent with the statute and its implementing regulations, a technology is no longer considered "new" once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349).

The manufacturer of the GORE IBE recommended that CMS continue the new technology add-on payment for an additional year to obtain additional claims data to reflect the cost of the technology. The manufacturer believed that the procedure might have been under-reported due to ICD-10-PCS procedure code changes in FY 2018 and the Medicare Administrative Contractors' (MAC) non-coverage of the Category III CPT code (0254T) for the identification of GORE IBE procedures. CMS acknowledges these concerns, but as stated above, CMS' policy for determining whether to extend new technology add-on payments for an additional year generally apply regardless of the volume of claims. CMS also notes that coding changes or local coverage determinations typically do not delay the beginning of the newness period.

For FY 2019, CMS **finalizes** its proposal to continue new technology add-on payments for:

- Defitelio® (Defibrotide) with the maximum new technology add-on payments increased from $75,900 to $80,500 for FY 2019. This increase in the add-on payment incorporates the applicant's updated cost information. CMS estimates the FY 2019 add-on payments for this technology at approximately $5.474 million (based on 68 patients).
- *Ustekinumb (Stelara®)* with the maximum new technology add-on payment for a case involving Stelara® remaining at $2,400 for FY 2019. CMS estimates the FY 2019 add-on payments for this technology at approximately $400,800 (based on 167 patients).
- Bezlotozumab (ZINPLAVA™) with the maximum new technology add-on payment for a case involving ZINPLAVA™ remaining at $1,900 for FY 2019. CMS estimates the FY 2019 add-on payments for this technology at approximately $2.858 million (1,504 patients).

5. FY 2019 Applications for New Technology Add-On Payments

CMS received fifteen applications for new technology add-on payments for FY 2019. CMS notes that all applicants for new technology add-on payments must have FDA approval by July 1 of each year prior to the beginning of the FY that the application is being considered.

Three applicants withdrew their applications: Progenics Pharmaceuticals (the applicant for Azedra®), Somahlution, Inc. (the applicant for DURAGRAFT®), and TherOx, Inc. (the applicant for Supersaturated Oxygen (SSO_2). One applicant, IsoRay Medical, Inc. and GT Medical Technologies, Inc. (the applicant for GammaTile™) did not receive FDA approval for its technology by July 1, 2018 and is not eligible for consideration for new technology add-on payments for FY 2019.

The summary below provides a high-level discussion of the eleven remaining applications. **CMS approves ten of the remaining applications for new technology add-on payments for FY 2019:** KYMRIAH™ (Tisagenleclucel) and YESCARTA™ (Axicabtagene Ciloleucel), VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection), VABOMERE™ (meropenem-vaborbactam), remedē® System, ZEMDRI™ Plazomicin, Giapreza™, Cerebral Protection System (Sentinel® Cerebral Protection System), the AQUABEAM System, and AndexXa™ (andexanet alfa).

a. KYMRIAH™ (Tisagenleclucel) and YESCARTA™ (Axicabtagene Ciloleucel)

Two manufacturers, Novartis Pharmaceuticals Corporation and Kite Pharma submitted applications for new technology add-on payments for KYMRIAH™ and YESCARTA™, respectively.[5] Both of these technologies are CD-19 directed T-cell immunotherapies used for treating patients with aggressive variants of non-Hodgkin lymphoma (NHL). The indications and status of FDA approval for these technologies are summarized below (this updated table is from the final rule).

Comparison of Indication and FDA Approval for KYMRIAH™ and YESCARTA™		
FY 2019 Application Technology Name	**Description of Indication for New-Technology Add-on Payment**	**FDA Approval Status**
KYMRIAH™ (Novartis)	Autologous T-cell immune therapy indicated for use in the treatment of patients with relapsed/refractory (r/r) after two or more lines of systemic therapy including Diffuse Large B Cell Lymphoma (DLBCL) not eligible for autologous stem cell transplant (ASCT)	FDA approval received 5/1/2018

[5] Kite Parma previously submitted an application for FY2018 for KTE-C19 for use as an autologous T-cell immune therapy for treatment of adult patients with relapsed/refractory (R/R) B-cell NHL who are ineligible for ASCT. Kite Pharma withdrew its application prior to publication of the FY 2018 IPPS final rule. Kite Pharma resubmitted an application for approval for FY 2019 for KTE-C19 under a new name, YESCATA™ for the same indication.

Comparison of Indication and FDA Approval for KYMRIAH™ and YESCARTA™		
YESCARTA™ (Kite Pharma)	Autologous T-cell immune therapy indicated for use in the treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy, including DLBCL not otherwise specified, primary mediastinal large B-cell, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.	FDA approval received 10/18/2017
Technology Approved for Other Indications	**Description of Other Indication**	**FDA Approval of Other Indication**
KYMRIAH™	CD-19-directed T-cell immunotherapy indicated for use in the treatment of patients up to 25 years of age with B-cell precursor ALL that is refractory or in second or later relapse.	FDA approval received 8/30/2017
YESCARTA™	None	N/A

CMS notes that procedures involving the KYMRIAH and YESCARTA therapies are both reported using the following ICD-10-PCS procedure codes: XW033C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 3); and XW043C3 (Introduction of engineered autologous chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 3). As discussed above in section II.F, CMS finalizes its proposal to assign cases reporting these ICD-10-PCS procedure codes to Pre-MDC MS-DRG 016 for FY 2019. CMS also revises the title of MS-DRG 016 to "Autologous Bone Marrow Transplant with CC/MCC or T-cell immunotherapy".

Novartis described KYMRIAH™ as a CD-19 directed genetically modified autologous T-cell immunotherapy, which utilizes peripheral blood T-cells, reprogrammed with a transgene encoding a chimeric antigen receptor (CAR) to identify and eliminate malignant and normal cells expressing CD-19. The transduced T-cells expand in vivo to engage and eliminate CD-19 expressing cells and may exhibit immunological endurance to help support long-lasting remission. In the new technology add-on payment application, the applicant stated that no other agent currently used in the treatment of patients with r/r DLBCL employs gene modified autologous cells to target and eliminate malignant cells.

Kite Pharma described YESCARTA as a CD-19 directed genetically modified autologous T-cell immunotherapy that binds to CD-19 expressing cancer cells and normal B-cells. After anti-CD-19 CAR-T cells engage with CD-19-expressing target cells, a series of events occur leading to T-cell activation and elimination of CD-19-expressing tumor cells. According to the applicant, studies demonstrate that following anti-CD CAR t-cell engagement with CD-19-expressing target cells, a sequence of events leads to the elimination of CD-19-expressing tumor cells.

YESCARTA™ received FDA approval on October 18, 2017 and the first commercial shipment was received by a certified treatment center on November 22, 2017. KYMRIAH received FDA approval on May 1, 2018 for use in the treatment of patients with r/r DLBCL who are not eligible for ASCT. KYMRIAH was previously granted Breakthrough Therapy designation by the FDA.

Newness. For the first criterion, both applicants stated that their technology is the first treatment of its kind for the targeted adult population and that their technology is new and does not use a substantially similar mechanism of action or involve the same treatment indication as any other currently FDA-approved technology. For the second and third criteria, although the applicants for KYMRIAH™ and YESCARTA™ submitted different findings for the most common MS-DRGs to which potential cases would map, in the proposed rule CMS stated that potential cases for either treatment would map to the same MS-DRG because the same ICD-10 diagnosis and procedure codes are used for both treatments.

With respect to the second and third criteria, Kite Pharma indicated that the mechanism of action for YESCARTA™ is not the same or similar to the mechanism for KYMRIAH™ because YESCARTA™ is comprised of a CD-28 co-stimulatory domain and KYMRIAH™ has a 4-1BB co-stimulatory domain. In addition, the manufacturing processes are different.
As discussed in the proposed rule, CMS considered the two treatments as substantially similar because both technologies are CD-19 directed T-cell immunotherapies used for treating patient with aggressive variants of NHL. CMS was also concerned that there may be an age overlap between the two different patient populations for the currently approved KYMRIAH™ technology and YESCARTA™. CMS noted that if the technologies are not substantially similar, it may be necessary to use alternative coding mechanisms to distinguish between the two therapies for determining new technology add-on payments and invites comments on alternative coding mechanisms.

The applicants for YESCARTA and KYMRIAH each provided comments regarding whether the technologies were substantial similar to each other, or any existing technology. Commenters' both disagreed and agreed with CMS' proposal that the treatments were substantially similar. The applicant for YESCARTA stated it believes that each technology consists of notable differences in the construction and manufacturing processes that may lead to differences in activity and encouraged CMS to evaluate each as a separate new-technology add-on payment. The applicant discussed the differences between the co-stimulatory domains of YESCARTA and KYMRIAH may be responsible for differences in activity. The applicant stated that if CMS decides to establish one new technology add-on determination payment, the add-on payments should ensure that payment does not hinder access for patients to receive the most appropriate cell therapy. Other commenters discussed why the two CAR T-cell technologies should be considered as separate applications, including the fact that each therapy received separate FDA Breakthrough designation. Other commenters' raised concerns that combining these technologies for evaluation would make it unlikely for future CAR T-cell therapies to be considered distinct from existing CAR T-cell therapies. Some commenters believed that section 1866(d)(5)(K) of the Act does not clearly authorize CMS to jointly evaluate these two technologies.

The applicant for KYMRIAH stated in its new technology add-on payment application that it believed the two technologies were not substantially similar. Based on FDA's recent approval, however, as detailed in the final rule, the applicant for KYMRIAH agrees with CMS that KYMRIAH is substantially similar to YESCARTA, as defined by the new technology add-on payment application evaluation criteria. Other commenters', generally, agreed that KYMRIAH and YESCARTA are substantially similar technologies.

CMS **finalizes** that KYMRIAH and YESCARTA are substantially similar to one another because potential cases representing patients who may be eligible for either treatment would group to the same MS-DRGs because the same ICD-10-CM diagnosis and ICD-10-PCS procedure codes are used to report either treatment. CMS also believes that these technologies are intended to treat the same or similar disease in the same or similar patient population and use the same or similar mechanism of action using genetically modified autologous T-cells immunotherapies. CMS recognizes the technologies are not completely the same in terms of their manufacturing process, co-stimulatory domains, and clinical profiles but it concludes that in both treatments, T-cells transmit a signal to promote T-cell expansion, activation, and ultimately cancer cell elimination to produce a targeted cellular therapy that may persist in the body even after the malignancy is eradicated.

With respect to CMS' policy for evaluating substantially similar technologies, CMS believes its current policy is consistent with the authority and criteria in section 1886(d)(5)(K) of the Act. CMS notes that it is authorized by the Act to develop criteria for evaluating new technology add-on payment applications and it believes it is appropriate to evaluate technologies substantially similar to each other as one application (see discussion in 82 FR 38120). CMS notes that for FY 2019, there is no payment impact regarding the determination that the two technologies are substantially similar because the cost of the technologies are the same.

CMS welcomes additional comments in future rulemaking whether KYMRIAH and YESCARTA are substantially similar and it intends to revisit this issue in next year's proposed rule.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes that both KYMRIAH and YESCARTA meet the cost criterion.

Substantial Clinical Improvement. Novartis asserted that KYMRIAH™ represents a substantial clinical improvement over existing technologies and provides a treatment option for patients unable to receive standard of care treatment. The applicant discussed historical control data (SCHOLAR-1) and evidence from currently available treatment options and concludes that KYMRIAH™ significantly improves the clinical outcome for patients with R/R DLBCL who are not eligible for ASCT. The applicant provided evidence from the KYMRIAH™ clinical trails to demonstrate improved clinical outcomes, including the Objective Response Rate (ORR), the Complete Response (CR) rate, Overall Survival (OS), and durability of response. The applicant also asserted that KYMRIAH™ provided a manageable safety profile when treatment is performed by trained medical personnel and as opposed to ASCT, KYMRIAH™ mitigates the need for high-dose chemotherapy prior to treatment. Adverse events included the Cytokine Relapse Syndrome (CRS), which occurred in 58 percent of patients; no deaths were attributed to

the treatment. After reviewing the studies, CMS raised some concerns about the analysis based on the SCHOLAR-1 data and the high discontinuance rate of patients prior to the infusion of KYMRIAH™ in the JULIET trial. In addition, CMS noted that the rate of CRS following infusion was high.

Kite Pharma stated that YESCARTA™ represents a substantial clinical improvement over existing technologies when used in the treatment of patients with aggressive B-cell NHL. The therapy can benefit patients with R/R after failure of first-line or second-line therapy and patients who have failed or are ineligible for ASCT. According to the applicant, based on meta-analysis of outcomes in chemorefractory DLBCL, there are no curative options. The applicant also provided updated data from ongoing clinical trails provided in the FY 2018 new technology add-on payment application for the KTE-C19 technology. Adverse events included CRS, which occurred in 93 percent of patients; two deaths were from YESCARTA™ related adverse events. CMS was concerned that the data provided as part of the FY 2019 application does not include patient mortality data that was part of the FY 2018 application. CMS was also concerned that there are few published results showing any survival benefits from the use of this treatment and that only a limited number of patients (108) were studied after YESCARTA™ infusion. In addition, CMS noted the high rate of CRS.

As discussed in the final rule, each applicant provided additional information to address the concerns presented in the proposed rule. After reviewing this additional information, CMS concludes that both KYMRIAH and YESCARTA represent a substantial clinical improvement over existing technologies by allowing access for a treatment option for patients unable to receive standard-of-care treatment. CMS believes both technologies appear to significantly improve clinical outcomes, have a durable response, and allow for a manageable safety profile. **CMS finalizes that both KYMRIAH and YESCARTA meet all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019**. CMS expects that KYMRIAH will be administered for the treatment of adult patients (18 years and older) diagnosed with r/r DLBCL not eligible for ASCT, and YESCARTA will be administered for the treatment of adult patients diagnosed with r/r large B-cell lymphoma after tow or more lines or systemic therapy, including DLBCL not other specified, primary mediastinal large B-cell, high grade B- cell lymphoma, an DLBCL arising from follicular lymphoma. Cases involving these technologies will be identified by ICD-10-PCS procedure codes XW033C3 and XW043C3. Both applicants estimate that the average cost for an administered dose is $373,000. The maximum new technology add-on payment amount for a case involving KYMRIAH or YESCARTA is $186,500 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $71.989 million (based on 373 patients).

CMS notes that on May 16, 2018, it opened a national coverage determination on CAR T-cell therapy for Medicare beneficiaries; the expected national coverage analysis completion date is May 17, 2019. In addition, given the relative newness of CAR T-cell therapy, CMS believes it is premature to adopt changes to its existing payment mechanisms, including structural changes in new technology add-on payments.

b. VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection)

Jazz Pharmaceuticals, Inc. submitted an application for VYXEOS™, a nano-scale liposomal formulation containing a fixed combination of cytarabine and daunorubicin used to treat adult patients with acute myeloid leukemia (AML).[6] The applicant stated that using a proprietary system known as CombiPlex, cytarabine and daunorubicin are co-encapsulated inside the VYXEOS™ liposome at a 5:1 cytarabine:daunorubicin molar ratio. According to the applicant, encapsulation of the drugs addresses several shortcomings of conventional combination drug regiments, specifically the conventional cytarabine and daunorubicin treatment (referred to as the "7+ 3" regimen which includes treatment with cytarabine for 7 days and daunorubicin for the first 3 days of the regimen). The applicant stated encapsulation maintains the synergistic ratios and reduces degradation. VYXEOS™ was approved by the FDA on August 3, 2017 for the treatment of adults with newly diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

Newness. For the first criterion, the applicant asserted that VYXEOS™ does not use the same mechanism of action to achieve a therapeutic outcome as any other drug for AML. According to the applicant, no other AML treatment is designed or is able to deliver a fixed, optimized and synergistic drug: drug ratio of 5:1 cytarabine to daunorubicin, selectively target and accumulate at the site of malignancy, and minimize unwanted drug exposure. The applicant stated that although VYXEOS™ contains no novel active agents, its innovative drug delivery mechanism is a superior way to deliver the two active compounds. As discussed in the proposed rule, CMS was concerned that VYXEOS™ may use a similar mechanism of action compared to current treatment since VYXEOS™ and current treatment of AML involves the same drugs. For the second and third criteria, CMS noted that VYXEOS™ would be assigned to the same MS-DRGs that identify cases with patients treated with AML and that VYXEOS™ involves the treatment of the same patient population as other AML treatment therapies.

The following unique ICD-10-PCS codes were created to describe the administration of VYXEOS™: XW033B3 (Introduction of cytarabine and caunorubicin liposome antineoplastic into peripheral vein, percutaneous approach, new technology group 3) and XW043B3 (Introduction of cytarabine and caunorubicin liposome antineoplastic into central vein, percutaneous approach, new technology group 3).

In response to the proposed rule, the applicant stated that preclinical and clinical evidence confirms the differentiated mechanism of VYXEOS™ from other available treatment option. In addition, the applicant stated VYXEOS™ is not substantially similar to other available drugs and is highly differentiated from the conventional "7+3" free drug dosing treatment regimen; several commented supported these statements. After consideration of comments, CMS believes that VYXEOS™ has a unique mechanism of action and meets the newness criterion.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes that VYXEOS™ meets the cost criterion.

[6] Celator Pharmaceuticals submitted an application for new technology add-on payments for VYXEOS™ for FY 2018. However, the application was withdrawn because FDA approval was after the July 1, 2017 deadline.

Substantial Clinical Improvement. The applicant stated that clinical data results show that 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 improvement in overall survival for high risk patients. CMS summarized the clinical data results, including published information. CMS discussed several concerns, including the finding that improved outcomes may not be statistically significant and the overall improvement in survival from 5.95 months to 9.56 months may not represent a substantial clinical improvement. In addition, CMS was concerned there is a similar rate of adverse events with the use of VYXEOS™ as compared to conventional "7+3" free drug regimen.

In response to the February 2018 New Technology Town Hall meeting, CMS received a written comment from the applicant informing CMS that VYXEOS™ was added to the Category 1 Clinical Practice Guidelines in Oncology recommendations by the National Comprehensive Cancer Network (NCCN).

As discussed in the final rule, the applicant provided additional information to address the concerns presented in the proposed rule. The applicant summarized the efficacy outcomes of the pivotal Phase III Study 301 and noted that significant improvement in overall survival was achieved. In addition, several commenters supported the use of VYXEOS™ as a viable treatment option in the treatment of older adults with high-risk AML. After reviewing this additional information, CMS concludes that VYXEOS™ meets the substantial clinical improvement criterion.

CMS finalizes that VYXEOS™ meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. CMS expects that VYXEOS™ will be administered for use in the treatment of adults who have been newly diagnosed with therapy-related AML or AML with myelodyplasia-related changed. Cases involving VYXEOS™ will be identified by ICD-10-PCS procedure codes XW033B3 and XW043B3. Based on information provided by the applicant, CMS computed that a maximum average of 9.4 vials is used in the inpatient setting and the maximum average cost of VYXEOS™ is $72,850. Therefore, the maximum new technology add-on payment amount for a case involving VYXEOS™ is $36,425 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $34.968 million (based on 960 patients).

c. VABOMERE™ (meropenem-vaborbactam)

Melinta Therapeutics, Inc. submitted an application for VABOMERE™ which is used for the treatment of adult patients who have been diagnosed with complicated urinary tract infections (cUTIs), including pyelonephritis caused by specific bacteria that are resistant to other antibiotic therapies. VABOMERE™ is a beta-lactamase combination antibiotic that combines the carbapenem class antibiotic meropenem (a broad spectrum beta-lactam antibiotic) with vaborbactam (a beta-lactamase inhibitor). Bacteria producing carbapenemase (a beta-lactamase enzyme) have become resistant to beta-lactam antibiotics, such as meropenem. Combining meropenem with vaborbactam protects meropenem from bacterial enzymes and allows the meropenem to kill the bacteria. VABOMERE™ received FDA approval on August 29, 2017.

Newness. For the first criterion, the applicant stated that VABOMERE™'s mechanism of action for the treatment of bacterial infections is not the same or similar mechanism of action of current antimicrobials. The addition of vaborbactam, an inhibitor of beta-lactamases, represents a new mechanism of action and expands the efficacy of meropenem. With respect to the second criterion, potential cases representing patients who may be eligible for treatment with VABOMERE™ would be assigned to the same MS-DRGs as cases with patients diagnosed with a cUTI. For the third criterion, the applicant asserted that VABOMERE™ would treat a different patient population than existing treatment options.

CMS was concerned that VABOMERE™ may be substantially similar to existing beta-lactam/beta-lactamase inhibitor combination therapies and is used to treat a population of adult patients with cUTIs that have other available treatment options. In addition, potential cases would be assigned to the same MS-DRGs as existing beta-lactam/beta-lactamase inhibitor combination therapies currently available.

In response to the proposed rule, the applicant discussed the innovative nature and unique aspects of VABOMERE™, including the fact that VABOMERE™'s mechanism of action is distinct from that of meropenem and that VABOMERE™, unlike meropenem alone, is on-label indicated for the use in the treatment of a cUTI diagnosis. Several commenters believed that VABOMERE™ might be substantially similar to other existing therapies. Other commenters stated that given the recognized shortage of new antibiotics, the unique benefits of VABOMERE™ should not be ignored because of substantial similarities to other medicines.

In response, CMS agrees that VABOMERE™ has a unique mechanism of action that is not similar to other existing technologies because it is a new class of beta-lactamase inhibitor that protects meropenem from degradation by certain enzymes such as carbapenamases. CMS believes that VABOMERE™ is not substantially similar to existing technologies and meets the newness criterion.

Cost. The applicant used the Premier Research Database from 2nd quarter 2015 to 4th quarter 2016 to identify the MS-DRGs with potential patients who may be eligible for treatment with VABOMERE™. CMS noted that because the applicant did not use actual charges form the Premier Research Database, it was not able to determine if the applicant meets the cost criterion. The applicant addressed CMS' concerns and submitted a revised cost analysis using claims from the FY 2016 MedPAR to demonstrate that VABOMERE™ meets the cost criterion. The applicant identified 34 ICD-10-CM diagnosis codes specific to the VABOMERE™ patient population and distributed the diagnosis codes into three different subsets. The applicant conducted a cost analysis for 100 percent of the identified cases, the top 20 MS-DRGs to which potential cases would map, and the top 10 MS-DRGS to which potential cases would map for each subset. As demonstrated in three tables in the final rule, each subset demonstrated the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. CMS appreciated the revised cost analysis and believes that VABOMERE™ meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that clinical data results demonstrate that VABOMERE™ represents a substantial clinical improvement for treatment of antibiotic resistant

infections and offers a treatment option for a patient population unresponsive to currently available treatments. CMS summarized the clinical data results, including published information. CMS discussed several concerns, including the finding that improved outcomes in some trials may not be statistically significant, the small number of patients, and the lack of a comparison to other antibiotic treatments of cUTIs know to be effective against uropathogens. CMS is also concerned that favorable study results are based primarily on the European population and is not applicable to the US, especially given the variable geographic distribution of antibiotic resistance.

In response to the February 2018 New Technology Town Hall meeting, CMS received a written comment from the applicant providing comparison of VABOMERE™ to other antibiotic treatments for a cUTI know to be effective against uropathogens. CMS discussed this data and was still concerned that the data provided does not compare other antibiotic treatments of cUTIs used to treat gram-negative uropathogens.

In response to the concerns presented in the proposed rule, the applicant reiterated the results of the TANGO I and TANGO II trials and noted the results show VABOMERE™ had a statistically significant higher response rate that piperacillin/tazobactam in clinical cure and microbial eradication. As a result of the improved outcomes, the independent data monitoring review board recommended early termination of the randomization in the TANGO II trial to allow patients to cross over to the VABOMERE™ arm. The applicant noted that the statutory and regulatory standards for new technology add-on payments do not preclude the relevance of non-inferiority data and that CMS has previously approved an application for new technology add-on payments based on non-inferior data. The applicant also discussed the challenges associated with clinical studies that involve seriously ill patients and a rare diagnosis.
After reviewing this additional information, CMS concludes that VABOMERE™ meets the substantial clinical improvement criterion.

CMS finalizes that VABOMERE™ meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. CMS notes that the applicant did not request approval for a unique ICD-10-PCS procedure code for VABOMERE™; as a result, hospitals will be unable to uniquely identify the use of the drug on an inpatient claim. CMS acknowledges that VABOMERE™ is the first approved new technology approved for the new technology add-on payment (aside from as oral drug) with no uniquely assigned inpatient procedure code. CMS used the NDC to identify the oral drug Dificid™ for purpose of the new technology add-on payment and will use the same policy for VABOMERE™. FY 2019 cases involving VABOMERE™ that are eligible for the FY 2019 new technology add-on payment will be identified by the NDC of 65293-009-01 (VABOMERE™ Meropenem-Vaborbactam Vial) used in data element LIN03 of the 837i Health Care Claim Institutional form. CMS notes the applicant may request approval for a unique ICD-10-PCS procedure code for FR 2020.
Based on information provided by the applicant, CMS computed the maximum average cost of VABOMERE™ is $11,088. Therefore, the maximum new technology add-on payment amount for a case involving VABOMERE™ is $5,544 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $14.681 million (based on 2,648 patients).

d. remedē® System

Respicardia, Inc submitted an application for the remedē® System used as a transvenous phrenic nerve stimulator in the treatment of adult patients with moderate to severe central sleep apnea (CSA). The technology consists of an implantable pulse generator, a stimulation lead, and a sensing lead. Both leads, in combination with the pulse generator, function to sense respiration, and when appropriate, generate an electrical signal to the phrenic nerve to restore regular breathing patterns. The remedē® System was approved by the FDA on October 6, 2017 for use in the treatment of adult patients diagnosed with moderate to sever CSA. The applicant also noted that the device is also designed to treat CSA in patients with heart failure. Two ICD-10-PCS procedure codes were approved for the placement of the leads (05H33MZ and 05H03MZ) and the implantation of the pulse generator is reported using ICD-10-PCS procedure code 0JH60DZ.

Newness. For the first criterion, the applicant asserted that the remedē® System is a neurostimulation device resulting in negative airway pressure, whereas current treatment devices such as continuous positive airway pressure (CPAP) and adaptive servo-ventilation (ASV) utilize positive airway pressure. For the second criterion, the applicant stated that the technology is assigned to 3 MS-DRGs (for peripheral cranial nerve and other nervous system procedures) that are not used for CPAP and ASV. For the third criterion, the applicant discussed that for patients with CSA and heart failure, the currently available treatment options, CPAP and ASV, worsen mortality and morbidity outcomes and that ASV is contraindicated in the treatment of CSA in patients with heart failure. CMS was concerned that the FDA approved indication was for use in the treatment of adult patients diagnosed with moderate to severe CSA although the applicant's clinical analysis and data results primarily related to patients diagnosed with CSA and heart failure (HF).

As discussed in the final rule, the applicant provided additional analysis and explanations supporting why the remedē® System is not substantially similar to other currently available treatment options. Several other commenters also asserted that neurostimulation of the phrenic nerve is a different mechanism of action. The applicant also provided additional information regarding patients diagnosed with CSA, without a diagnosis of heart failure. After reviewing this addition information, CMS believes that the remedē® System is a different mechanism of action and that cases representing patients receiving this treatment would be assigned to a different MS-DRG than available treatment options. CMS concludes this technology meets the newness criterion.

CMS notes that although the remedē® System received FDA approval on October 6, 2017 the applicant stated the first implant was completed on February 1, 2018 and the applicant believes the newness should begin on February 1, 2018. Since the applicant did not provide additional information to explain the delay to the first implant procedure, CMS continues to believe the newness period begins on October 6, 2017. It may consider any future information that may be provided in future rulemaking.

Cost. The applicant used the Standard Analytical File (SAF) Limited Data Set (MedPAR) for FY 2015 and included all claims for MS-DRGs 040, 041, and 042. All claims were included

because there is no specific ICD-10 procedure and diagnosis code to identify this technology. CMS was concerned that all the cases in MS-DRGs 040, 041, and 042 were used since they are unsure if all these cases represent patients eligible for remedē® System.

In response to CMS' concerns, the application submitted a revised analysis. As discussed in the final rule, the final inflated average case-weighted standardized charge is more than the Table 10 average case-weighted threshold amount. The applicant maintained that it meets the cost criterion. CMS appreciated the applicant's submission of revised cost calculations and agrees that the remedē® System meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that patients with CSA have no other available treatment options and that published studies on both CAC and ASV have not met primary endpoints for treating patients with CSA. The applicant presented results from two studies evaluating the effects of positive airway pressure ventilation treatment. The applicant also provided six published articles of retrospective studies. CMS noted that in three of the studies the majority of patients had been diagnosed with CSA and a HF comorbidity, while the remaining three studies only studied patients diagnosed with CSA and a HF comorbidity. CMS summarized these studies and discussed concerns that include the small patient population, the exclusion of patients with American Heart Association objective assessment Class D (severe limitations) from the pivotal study, and the lack of baseline statistical comparison between treated and control groups controlling for HF status. CMS was also concerned that the remedē® System was not directly compared to the CPAP or ASV treatment options, which are the current treatment options for patients with CSA without HF. CMS was also interested in remedē® System's long-term impact on morbidity and mortality, the longevity of the system, and the possibility of electrical stimulation of unintended targets and devices combined with the possibility of interference from outside devices.

As discussed in the final rule, the applicant provided additional information to address the concerns presented in the proposed rule. Commenters also discussed the reasons why the remedē® System is a substantial clinical improvement. CMS appreciates the thoroughness of the additional information and analyses provided by the applicant and commenters, including the additional data which demonstrated the effectiveness of the remedē® System for the treatment of moderate and sever CSA in all treated patients, regardless of a heart failure comorbidity. The applicant also provided evidence to allay CMS' concerns about longevity of the device, batteries, and leads. CMS agrees that the remedē® System represents a substantial clinical improvement over existing technologies.

CMS finalizes that the remedē® System meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. Cases involving the use of the remedē® System will be identified by ICD-10-PCS procedure codes 0JH60DZ and 05H33MZ in combination with procedure codes 05H03MZ and 05H043MZ. According to the application, the cost of the remedē® System is $34,500 per patient. Therefore, the maximum new technology add-on payment amount for a case involving the remedē® System is $17,250 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $1.380 million (based on 80 patients).

e. Titan Spine nanoLock® (Titan Spine nanoLock® Interbody Device)

Titan Spine submitted an application for Titan Spine nanoLOCK™, a nanotechnology-based interbody medical device with a dual acid-etched titanium interbody system used to treat patients with degenerative disc disease (DDD).[7] The applicant states the combination of surface topographies enables initial implant fixation and produces the nano-scale features that interface with the integrin on the outside of the cellular membrane. According to the applicant, these features enhance bone growth, fusion and stability, which reduce pain, improve a patient's recovery time and produces lower rates of device complications.

Titan Spine nanoLOCK™ received FDA approval on October 27, 2014 for the use of 5 lumbar interbody devices and one cervical interbody device. The FDA approved the nanoLOCK™ TCS-Sterile Packaging Cervical Stand Alone Interbody Fusion Device on December 14, 2015. According to the applicant, the technology was available on the US market on October 1, 2016. Although there are eleven ICD-10-PCS Section "X" New Technology codes, the applicant is concerned the codes do not specify devices with FDA clearance and submitted a request for code revisions at the March 2018 ICD-10 Coordination and Maintenance Meeting.

Newness. For the first criterion, the applicant discussed the Titan Spine nanoLOCK™ technology and how it has a different mechanism of action than other spinal fusion devices. In addition, according to the applicant the nanoLOCK™ is the first and only device in the spinal fusion domain, to apply for and successfully obtain a clearance for nanotechnology from the FDA. With regard to the second and third criteria, the applicant stated the technology would map to the same MS-DRGs as other interbody devices used for patients diagnosed with DDD and the device is used in the treatment of patients with similar types of diseases receiving treatment involving both lumbar and cervical interbody devices. CMS acknowledged there is a uniqueness to the nanotechnology used by the applicant but it is concerned that the Titan Spine nanoLOCK™ interbody devices may be substantially similar to existing technologies.

A commenter stated that similar products to the nanoLOCK™ interbody devices exist. Several commenters, however, referenced studies demonstrating that the nanoscale features exhibit a biological effect that has not been seen in other interbody fusion devices. CMS believes that the Titan Spine nanoLOCK™ uses a unique mechanism of action and meets the newness criterion.
Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes that the Titan Spine nanoLOCK™ meets the cost criterion.

Substantial clinical improvement criterion. The applicant submitted the results of two clinical evaluations: the first evaluation was a case series and the second was a case control study. According to the applicant in the case series both the lumbar and cervical groups showed a trend of improvement in clinical outcomes over time but it was difficult to assess the results due to the relatively limited number of subjects. The applicant reported it has missing values for over 80 percent of the subjects after the 4th post-operative month. CMS noted that based on the results of the case series it is unable to determine whether the findings represent a substantial clinical improvement. CMS also was concerned about the case control study and stated it was unable to

[7] Titan Spine previously submitted an application for new technology add-on payments for Titan Spine nanoLOCK™ in FY 2017.

determine whether the findings regarding length of stay and cumulative post-surgical opioid use for patient receiving nanoLOCK™ devices versus conventional intervertebral body fusion devices is a substantial clinical improvement.

In response to the February 2018 New Technology Town Hall meeting CMS received two written comments. One commenter was concerned that there was not sufficient data from real-world evidence and published studies demonstrating the substantial clinical improvement of the nanoLOCK™ technologies. The commenter also noted that there are other titanium surface devices currently available in the US. The second commenter supported the approval of the new technology add-on payment for the nanoLOCK™ technologies.

In response to the proposed rule, the applicant submitted a Milligram Morphine Equivalent (MME) analysis to demonstrate support for the "substantial clinical value" in the reduction of MME with the implant of a Titan Spine nanoLOCK™ device. CMS summarizes this analysis in the final rule. CMS notes it is unable to determine the substantial clinical value based on this analysis because of the vase amount of missing data and inconsistencies in the data provided. CMS also notes that the applicant did not provide further data to address its concerns about the selection of controls and whether there were adjustments in the statistical analyses controlling for confounding factors. CMS also appreciates the comments in support for this technology but notes that comments based on personal surgical experience were qualitative and did not provide objective data to support the substantial clinical improvement criterion.

CMS believes that the Titan Spine nanoLOCK™ may potentially be a viable alternative to existing technologies but the data does not demonstrate a substantial clinical improvement over existing technologies.

CMS finalizes that the Titan Spine nanoLOCK™ does not meet the criteria for new technology add-on payments.

f. ZEMDRI™ Plazomicin

Achaogen, Inc. submitted an application for Plazomicin, a next-generation aminoglycoside antibiotic found in vitro to have enhanced activity against many multi-drug resistant (MDR) gram-negative bacteria. CMS notes that since publication of the proposed rule, the applicant has announced the trade name for Plazomicin is ZEMDRI™. The applicant received approval from the FDA for ZEMDRI™ for use in the treatment of adults with complicated urinary tract infection (cUTI), including pyelonephritis. The applicant did not receive FDA approval for use in the treatment of bloodstream infections (BSIs). The applicant stated there is a strong need for antibiotics that can treat infections caused by MDR Enterobacteriaceae, specifically carbapenem resistant Enterobacteriaceae (CRE)

The applicant's request for a unique ICD-10-PCS procedure code was granted to identify the use of ZEMDRI™: XW033G4 (Introduction of Plazomicin anti-infective into peripheral vein, percutaneous approach, new technology group 4) and XW043G4 (Introduction of Plazomicin anti-infective into central vein, percutaneous approach, new technology group 4).

Newness. For the first criterion, the applicant stated that Plazomicin has a unique chemical structure designed to improve activity again aminoglycoside-resistant bacteria. According to the applicant, Plazomicin contains unique structural modifications that prevent antibiotic inactivation by bacterial enzymes (aminoglycoside modifying enzymes (AMEs) and beta-lactamase enzymes). For the second and third criteria, CMS believed the potential cases representing patients who may be eligible for treatment with Plazomicin would be assigned to the same MS-DGs as cases representing patients who receive treatments for UTI or BSI and that Plazomicin may not be treating a new patient population since there are other antibiotics that may effectively treat these infections. CMS was concerned that the general mechanism of Plazomicin's action against bacteria is similar to other aminoglycoside antibiotics in that they are bactericidal through inhibition of bacterial protein synthesis.

In response to the proposed rule, the applicant stated that ZEMDRI™'s mechanism of action is not substantially similar to existing aminoglycosides because modifications in the chemical structure allow ZEMDRI™ to withstand resistance and reach the target site of action for antibacterial efficacy. Because of the increasing emergence of antibiotic resistance, the applicant believed that consideration of the mechanism of action for antibiotics should include how the antibiotic defends itself against bacteria inactivation, in addition to how it kills the bacteria. The applicant concluded that although ZEMDRI™ mechanism of bacterial killing is similar to other aminoglycosides, its ability to withstand antibiotic resistance is substantially different. A commenter stated that the unique benefits of this medicine should not be ignored due to the substantial similarities to other medicines.

With respect to the second criterion, the applicant agreed with CMS that the use of ZEMDRI™ would not change the MS-DRG for patients receiving treatment for UTIs. With respect to the third criterion, the applicant agreed that ZEMDRI™ is indicated for resistant and nonresistant strains of bacteria, but the FDA label also includes the following statement limiting the indication to a new patient population: "as only limited clinical safety and efficacy data are available, reserve ZEMDRI™ for use in patients who have limited or no alternative treatment options". Several comments believed that ZEMDRI™ treats a new patient population with very limited treatment options.

After consideration of the public comments and the FDA label, CMS believes that the mechanism of action for ZEMDRI™ is new and is not substantially similar to any existing technologies. CMS considers the newness period to commence on the date of FDA approval, June 25, 2018.

Cost. The applicant searched the FY 2016 MedPAR data for claims reporting 16 ICD-10-CM diagnosis codes for UTI and 45 ICD-10-CM diagnosis codes for septicemia and identified over 2 million cases assigned to 702 MS-DRGs. The applicant performed analysis on this population (100 percent of all cases) and performed a similar analysis based on 75 percent of identified claims, which spanned 43 MS-DRGs. Because the inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount before the addition of the technology, the applicant concludes Plazomicin meets the cost criterion.

The applicant also supplied additional cost analysis for potential cases with cUTI and for potential cases with BSI/bacteremia. For each diagnosis, the applicant performed cost analysis for 100 and 75 percent of identified cases using the FY 2016 MedPAR data and the FY 2018 GROUPER Version 36. The analysis for 100 percent of the cases for both cUTI and BSI/bacteria calculated an inflated average case-weighted standardized charge per case that exceeded the average case-weighted threshold amount. In the 75 percent of all cases sensitivity analysis scenario, for both UTI and BSI/bacteria the final inflated case-weighted standardized charge per case did not exceed the average case-weighted threshold amount. CMS noted that it is possible that Plazomicin may also exceed the average case-weighted threshold amount in the 75 percent cases sensitivity analysis because the price for Plazomicin had not been included.

In the final rule, CMS notes that the FDA approval for ZEMDRI™ was only for the treatment of adults with cUTIs and not for the other proposed indication of BSI. Therefore, CMS is only considering the cost analysis, which considered potential cases representing patients diagnosed with CUTI who may be eligible for treatment with ZEMDRI™. In response to CMS' concerns, The applicant supplied additional information that included the price for ZEMDRI™ and limited analysis to CUTI treatment. This analysis was consistent with the analysis presented in the proposed rule. In both scenarios, the final inflated case-weighted standardized charge per case exceeded the average case-weighted threshold amount and the applicant concludes that ZEMDRI™ continues to meet the cost criterion. CMS agrees that ZEMDRI™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that Plazomicin is a next generation aminoglycoside that offers a treatment option for a patient population who have limited or no alternative treatment options. The applicant provided information from two Phase III studies, CARE and EPIC. The CARE trial compared Plazomicin to colistin, a last-line antibiotic that is standard of care for patients with BSI caused by CRE. The EPIC trial compared Plazomicin to meropenem for patients who have been diagnosis with cUTIs/acute polynephritis. The applicant concluded that these studies demonstrate that Plazomicin represents a substantial clinical improvement over standard therapy.

Although CMS understands the difficulty in enrolling a large number of patients diagnosed with BST and CRE, it was concerned that the results of the CARE study indicating reduced mortality and a treatment advantage for Plazomicin compared to standard of care are not statistically significant due to the small sample size (29 patients). CMS was concerned that the results from the EPIC clinical trial are predominately based on patients enrolled in trials in Eastern Europe and it is not clear how generalizable there results would be to patients in the US. Although the applicant noted that geography is unlikely to affect the results of the study, CMS was concerned because bacterial resistance can vary regionally and it is unknown how quickly resistance to Plazomicin might develop. CMS also noted that Plazomicin is not indicated exclusively for resistant bacteria and it was concerned that the applicant did not provide information demonstrating substantial clinical improvement in treating nonresistant strains.

As discussed in the final rule, the applicant provided additional information to address the concerns presented in the proposed rule. CMS agrees with the applicant that the FDA label addresses some of its concerns because it restricts the use of ZEMDRI™ to patients with a cUTI,

including pyelonephritis, with limited or no alternative treatment options. CMS also appreciates the additional information the applicant submitted explaining why ZEMDRI™ has a low potential for development of resistance. CMS also discusses other commenters' input on why ZEMDRI™ offers a substantial clinical improvement over current therapies for patients with a cUTI. CMS believes that ZEMDRI™ offers a substantial clinical improvement because it is a new antibiotic that offers a treatment option for a patient unresponsive to currently available treatments.

CMS finalizes that ZEMDRI™ meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. Cases involving the use of ZEMDRI™ will be identified by ICD-10-PCS procedure codes XW033G4 and XW043G4. Based on information provided by the applicant, CMS calculates the total cost of ZEMDRI™ per patient is $5,445. Therefore, the maximum new technology add-on payment amount for a case involving ZEMDRI™ is $2,622.50 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $6.806 million (based on 2,500 patients).

g. Giapreza™

The La Jolla Pharmaceutical Company submitted an application for Giapreza™, a synthetic human angiotensin II, administered intravenous (IV) infusion to raise blood pressure in adult patients diagnosed with septic or other distributive shock. Standard therapy for shock currently uses fluid and vasopressors (catecholamines and vasopressins) to raise the mean arterial pressure (MAP). According to the applicant, 35 percent of patients with shock fail to respond to treatment with catecholamines and receive second-line treatment, which is typically vasopressin. Eighty percent of patients on vasopressin fail to respond and have no other alternative treatment option. Giapreza™ received FDA approval on December 21, 2017 for use in the treating adults diagnosed with sepsis or other distributive shock as an IV infusion to increase blood pressure. The applicant submitted a request for approval for a unique ICD-10-PCS code for the administration of Giapreza™.

Newness. For the first criterion, the applicant stated that Giapreza™ is the first synthetic formulation of human angiotensin II, a naturally occurring hormone in the body that increases blood pressure through vasoconstriction, increased aldosterone release, and renal control of fluid and electrolyte balance. The applicant asserted that Giapreza™ is a novel treatment with a unique mechanism of action through the renin-angiotensin-aldosterone system (RAAS). According to the applicant, current treatments with catecholamines (e.g. Norepinephrine and dopamine) work through the sympathetic nervous system and vasopressins (e.g. vasopressin-sodium chloride IV solutions) work through the arginine-vasopressin system to regulate blood pressure.

CMS was concerned that Giapreza™'s general mechanism of action, increasing blood pressure by inducing vasoconstriction through binding to certain G-protein receptors to stimulate smooth muscle contraction, may be similar to norepinephrine, although it does leverage a different body system. Although the applicant stated that Giapreza™ is a new treatment option for critically-ill patients with shock who have limited treatment options, the FDA approval for Giapreza™ does not reserve the treatment as a last-line drug or adjunctive therapy for a subset of patients diagnosed with shock who have failed to respond to SOC. CMS was also concerned that

Giapreza™ was used to treat the same or similar type of disease and a similar patient population receiving SOC therapy for the treatment of shock.

In response to the proposed rule, the applicant indicated that Giapreza™ is not substantially similar to other treatment options because it is the sole member of a new class of vasopressor peptides, and the only one that acts to leverage the renin-angiotensin-aldosterone (RAAS) system. The applicant provided literature and specific citations supporting Giapreza™ unique mechanism of action. The applicant also indicated that Giapreza™ could be administered with norepinephrine because the drug affects vasoconstriction not by augmenting norepinephrine but by an entirely novel mechanism. Other commenters supported the newness criterion, indicating that Giapreza™ is the first and only FDA-approved synthetic human angiotensin II treatment option that activates RAAS to increase mean arterial pressure (MAP).

Regarding the second criterion, the applicant indicated there are inherent difficulties in capturing specific patient types for a condition such as shock and that the current structure of the MS-DRG payment system does not have enough elements to capture patients likely to respond to Giapreza™. To address the third criterion, the applicant contended that although the FDA approval for Giapreza™ is not reserved exclusively for patients with shock who failed to respond to standard-of-care treatment options, Giapreza™ still treats a new patient population that is a significant subset of the larger patient population approved for Giapreza™ treatment. Other commenters discussed how Giapreza™ fills an unmet need for new treatment option.

After review of the additional literature provided by the applicant and consideration of comments, CMS believes that Giapreza™ has a unique mechanism of action, is not substantially similar to existing treatment options, and meets the newness criterion.

Cost. The applicant conducted an analysis of patients with refractory shock who failed to respond to standard of care vasopressors and an analysis for all patients diagnosed with septic or other distributive shock. CMS discussed the broader analysis because it believes it reflects the patient population the FDA approved for treatment with Giapreza™. The applicant used two separate analyses to identify the MS-DRGs for patients diagnosed with shock and performed three sensitivity analyses for each of the two selections: 100 percent, 80 percent, and 25 percent of the MS-DRGs. The applicant concluded the technology meets the cost criterion.

The applicant provided an updated cost analysis to broaden the patient cases, according to the expanded FDA-approved indications. As demonstrated in a summary table in the final rule, the final inflated average standardized charge per case exceeded the Table 10 average case-weighted threshold amounts by an average of $40,001. With this additional analysis, CMS agrees that Giapreza™ meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that the use of Giapreza™ offers clinicians a significant new tool to manage and treat severe hypotension in all adult patients diagnosed with septic or other distributive shock unresponsive to existing vasopressor therapies. The applicant reported data form a randomized, double-blinded placebo controlled trial (ATHOS-3) that examined the ability of Giapreza™ to increase MAP. The applicant maintained that patients with Giapreza™ were three times more likely to achieve acceptable blood pressure

than patients receiving placebo. In addition, the applicant asserted that Giapreza™ demonstrated potential improvement in organ function and reduced the need to increase overall doses of catecholamine vasopressors. The applicant also stated that although the study was not powered to detect mortality effects, there was a nonsignificant trend toward longer survival in the Giapreza™ group.

CMS acknowledged that this is a heterogeneous and difficult patient population to treat and that studies assessing mortality as a primary endpoint are difficult but it was concerned that there is not sufficient evidence connecting surrogate endpoints such as achieving target MAP to overall patient prognosis. In response to concerns about surrogate endpoints, the applicant supplied additional information from the current Surviving Sepsis guidelines, which recommend an initial target MAP of 65 mmHg. CMS was also concerned that the results from the clinical trial may be too narrow to accurate represent the entire patient population and the trial results may not adequately demonstrate that Giapreza™ is a substantial clinical improvement over existing therapies for all patients meeting the FDA approval indications.

In response to the proposed rule, the applicant submitted comments addressing the concerns raised by CMS, reiterated the clinical data findings of the benefits of Giapreza™, and provided additional information about the cardiovascular SOFA score. In response to CMS' concerns about the lack of statistical significance for a decrease in mortality rate, the applicant noted the clinical trial was not powered to definitely prove a decrease in mortality rate. In addition, the applicant contends that as described in the September 7, 2001 final rule (66 FR 46902), a "reduced mortality rate" is only one of a multitude of different standards CMS might use to determine substantial clinical improvement. The applicant also discussed why the benefits that Giapreza™ delivers pertaining to the substantial clinical improvement criterion cannot be assumed to be restricted solely to patients with refractory shock. Other comments supported the clinical results and provided additional explanations why Giapreza™ meets the substantial clinical improvement criterion.

CMS acknowledges that the information submitted by the applicant and other commenters addresses its concerns and agrees that Giapreza™ represents a substantial clinical improvement over existing technologies because it quickly and effectively raises MAP while allowing reduction in other vasopressors. CMS also notes that the FDA-approved label, which cautions that prophylactic treatment for blood clots should be used, addresses the potential safety concern of thrombosis for patients treated with Giapreza™.

CMS finalizes that Giapreza™ meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. Cases involving the use of Giapreza™ will be identified by ICD-10-PCS procedure codes XW033H4 and XW043H4. Based on information provided by the applicant, CMS calculates the total cost of Giapreza™ per patient as $3,000. Therefore, the maximum new technology add-on payment amount for a case involving Giapreza™ is $1,500 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $8.595 million (based on 5,730 patients).

h. Cerebral Protection System (Sentinel® Cerebral Protection System)

Claret Medical, Inc. submitted an application for the Cerebral Protection System (Sentinel® Cerebral Protection System) used as an embolic protection (EP) device to capture and remove thrombus and debris while performing transcatheter aortic valve replacement (TAVR) procedures. The device is percutaneously delivered via the right radial artery and is removed upon completion of the TAVR procedure. The DeNovo request for the Sentinel® Cerebral Protection System was granted on June 1, 2017 and the FDA concluded that this device should be classified into Class II (moderate risk). Section "X" code X2A5312 identifies cases involving TAVR procedures using this device.

Newness. For the first criterion, the applicant stated that there are no other similar products for commercial use in the US for cerebral protection during TAVR procedures. The device is inserted at the beginning of the TAVR procedure and using a minimally invasive catheter, two small filters are placed in the brachiocephalic and left common carotid arteries. The filters collect debris, preventing it from becoming emboli and potentially causing cerebral ischemic lesions. The filters, along with the collected debris, are removed at the completion of the TAVR procedure. For the second criterion, potential cases representing patients eligible for treatment with this device would map to the same MS-DRG as cases involving the TAVR procedure. For the third criterion, the applicant stated there are currently no approved alternative treatment options for cerebral protection during TAVR procedures. In the proposed rule, CMS noted that it appears that the Sentinel® Cerebral Protection System is not substantially similar to other existing technologies.
Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes that the Sentinel® Cerebral Protection System meets the cost criterion.

Substantial Clinical Improvement. According to the applicant, the data provided from 4 key studies showed that the Sentinel® Cerebral Protection System effectively captures brain bound embolic debris and significantly improves clinical outcomes beyond the current standard of care (TAVR procedures with no embolic protection). The applicant acknowledged that the studies have limitations because they are either small, nonrandomized and/or had significant loss to follow-up. According to the applicant, a meta-analysis of EP device studies, the majority of which included use of the Sentinel® Cerebral Protection System device, found the use of cerebral EP devices was associated with a nonsignificant reduction in stroke and death.

CMS discussed its concern that the use of cerebral protection devices may not be associated with a significant reduction in stroke and death. It was also concerned that the studies did not show a substantial decrease in neurologic complications for patients undergoing TAVR procedures.
In response to the February 2018 New Technology Town Hall meeting, a commenter noted that there are similar devices available in Europe and other countries but the Sentinel® Cerebral Protection System is the first and only cerebral EP device available in the US. The commenter also stated the device represents a substantial clinical improvement over current therapies.

In response to the proposed rule, the applicant provided additional information about the Sentinel® trial to address CMS' concerns. The applicant also updated the meta-analysis and notes that the conclusion in the updated analysis states that the totality of the data suggests that

the use of EP during TAVR appears to be associated with a significant reduction in death or stroke. The applicant also cited a recently published meta-analysis from another group that reached the same conclusions.[8] In addition, the applicant referenced a study from the University of Ulm in Germany[9], and information from a number of TAVR centers that routinely use the Cerebral Protection System (Sentinel® Cerebral Protection System) in TAVR procedures and demonstrates substantial clinical improvement with the use of the device.

CMS acknowledges that the information submitted by the applicant and other commenters addressed its concerns and agrees that the Sentinel® Cerebral Protection System represents a substantial clinical improvement by reducing mortality and stroke within 7 days of TAVR procedures as compared to patients undergoing a TAVR procedure without a cerebral protection device.

CMS finalizes that the Sentinel® Cerebral Protection System meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. Cases involving the use of the device will be identified by ICD-10-PCS procedure code X2A5312. The applicant estimates the total cost of the Sentinel® Cerebral Protection System per patient as $2,400. Therefore, the maximum new technology add-on payment amount for a case involving the Sentinel® Cerebral Protection System is $1,400 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $9.100 million (based on 6,500 patients). (CMS uses in the preamble the maximum new technology payment as $1,400 although this is not 50% of the cost of the device reported in the preamble suggesting either an error in transcribing the cost or the add-on payment.)

i. The AQUABEAM System (Aquablation)

PROCEPT BioRobotics Corporation submitted an application for the AQUABEAM System a device used in the treatment of patients with lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH). The AQUABEAM System consists of three main components: a console with two high-pressure pumps, a conformal surgical planning unit with transrectal ultrasound imaging, and a single-use robotic hand-piece. According to the applicant, the combination of surgical mapping and robotically controlled resection of the prostate is designed to offer predictable and reproducible outcomes, independent of prostate size, prostate shape or surgeon experience. The FDA granted the applicant's De Novo request on December 21, 2017 for use of the system in the resection and removal of prostate tissue in patients suffering from lower urinary tract symptoms due to BPH. The device was made available immediately. CMS approved the use of ICD-10-PCS procedure code XV508A4 (Destruction of prostate using robotic waterjet ablation, via natural or artificial opening endoscopic, new technology group 4), effective October 1, 2018.

In response to the proposed rule, the applicant stated that the newness period should begin on April 19, 2018 instead of the data of FDA approval (December 21, 2017) because local no-

[8] Wang N and Phan K, "Cerebral Protection Devices in Transcatheter Aortic Valve Replacement: A Clinical Meta-Analysis of Randomized Controlled Trials", *J Thorac Dis*, 2018;10(3):1927-1935.
[9] Seeger, J., et al., "Cerebral Embolic Protection During Transfemoral Aortic Valve Replacement Significantly Reduces Death and Stroke Compared with Unprotected Procedures," *JACC Cardiovasc Interv*, 2017.

coverage determination in the Medicare population delayed the first case. CMS again reiterates it does not consider how frequently the medical service or technology has been used in the Medicare population in determination of newness. **CMS invites further information from the applicant for consideration in future rulemaking regarding the beginning of the newness period**.

Newness. For the first criterion, the applicant stated AQUABEAM System's use of Aquablation therapy makes it the only technology to utilize a high-velocity room temperature waterjet for tissue resection. Most other BPH surgical procedures utilize thermal energy to resect prostate tissue or require the implantation of clips to pull back prostatic tissue blocking the urethra. In addition, according to the applicant, the operating surgeon does all other surgical modalities, while the AQUABEAM System allows planning by the surgeon and the robot autonomously executes tissue resection. For the second and third criteria, the applicant stated that potential cases will map to the same MS-DRGs as existing BPH treatment options and the AQUABEAM System will treat the same population as other available BPH treatment options.

CMS was concerned that although this device utilizes water to remove tissue, its mechanism of action may not be different from other forms of treatment for patients diagnosed with BPH. It also noted that the use of water to perform tissue removal exists in other areas of surgical treatment. In addition, CMS was concerned that the AQUABEAM System ablates tissue to reduce compression of the urethra is similar to the results from standard operative procedures to widen the urethra. CMS was also uncertain that the use of a robotic hand and computer programming are new mechanisms of action.
The applicant responded to CMS' concerns regarding the mechanism of action of the AQUABEAM System and other commenters supported that the AQUABEAM System is a novel treatment for BPH. After consideration of this information, CMS agrees that the AQUABEAM System has a unique mechanism of actin because it is the first to use waterjet ablation therapy that enables targeted, controlled, heat-free and immediate removal of prostate tissue used for purpose of treating lower urinary tract symptoms caused by a diagnosis of BPH.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes that the AQUABEAM System meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that the AQUABEAM System provides superior safety outcomes compared to the TURP procedure, while providing noninferior efficacy in treating the symptoms that effect the lower urinary tract associated with a diagnosis of BPH. In addition, the therapy demonstrated superior efficacy and safety for larger prostates (prostates sized 50 to 80 ml) as compared to TURP. The applicant provided the results of one Phase I and one Phase II trial published articles, the WATER Study Clinical Study Report (a prospective, multi-center, randomized, blinded study), and a meta-analysis of current treatments. CMS discussed several concerns with the interpretation of the results of the meta-analysis, which tested the effects of three separate treatment options. CMS acknowledged that comparison of multiple clinical studies is difficult, but it is concerned that the analysis did not take into account the varying study designs, sample techniques, and other study specific issues, such as physician skill and patient health status. CMS provided examples where the applicant stated that comparison of treatment options may not be appropriate since different treatment options may be

used based on the prostate size (e.g. Urolift is used for smaller prostate volumes and AQUABEAM System may be used for all prostate sizes). CMS noted that the heterogeneity of samples and methods across studies may lead to the introduction of bias, which makes it difficult to distinguish between bias and actual outcomes. CMS also discussed concerns about the comparison between the AQUABEAM System and the TURP procedure, including a finding of improved safety. CMS was interested in information that compares the safety profile of the AQUABEAM System therapy to other treatment modalities.

CMS acknowledges that the information submitted by the applicant, including additional details about the improved safety, and other commenters, addresses its concern. CMS agrees that the AQUABEAM System is a substantial clinical improvement for the resection and removal of prostate tissue in males suffering from lower urinary tract symptoms due to benign prostatic hyperplasia.

CMS finalizes that the AQUABEAM System meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. Cases involving the use of the device will be identified by ICD-10-PCS procedure code XV508A4. The applicant estimates the total cost of the AQUABEAM System per patient as $2,500. Therefore, the maximum new technology add-on payment amount for a case involving the AQUABEAM System is $1,250 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $521,250 (based on 417 patients).

j. AndexXA™ (Adexanet Alfa)

Portola Pharmaceuticals, Inc. submitted an application for AndexXa™, an antidote to treat patients receiving treatment with an oral Factor Xa inhibitor who suffer a major bleeding episode and require urgent reversal of direct and indirect Factor Xa anticoagulation.[10] Factor Xa inhibitors are oral anticoagulants used to prevent stroke and systemic embolism in patients with atrial fibrillation (AF). Oral anticoagulants are also used to treat patients diagnosed with deep-vein thrombosis and its complications, pulmonary embolism, and patients who have undergone knee, hip, or abdominal surgery.

AndexXa™ received FDA approval on May 3, 2018 and is indicated for use in the treatment of patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. CMS notes that according to the FDA-approved prescribing information, AndexXa™ has <u>not</u> been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FactorXa inhibitors other than the direct FactorXa inhibitors apixaban and rivaroxaban. In this final rule, CMS discusses AndexXa™ only in the context of the FDA-approved indications.

The applicant received approval for two ICD-10-PCS procedure codes (XW03372 and XW04372), effective October 1, 2016.

[10] Portola Pharmaceuticals, Inc. previously submitted an application for new technology add-on payments for AndexXa™ in FY 2017 and FY 2018.

Newness. For the first criterion, the applicant stated that if approved by the FDA, AndexXa™ would be the first reversal agent that binds to direct Factor Xa inhibitors with high affinity, rapidly reduces free plasma concentration of Factor Xa inhibitors, and neutralizes the inhibitors' anticoagulation effect. It also binds to and sequesters antithrombin III molecules that are complexed with indirect inhibitor molecules, disrupting the capacity of the antithrombin complex to bin to native Factor Xa inhibitors. Other reversal agents, such as Kcentra and Idarucizumab, do not reverse the effects of Factor Xa inhibitors. For the second criterion, the applicant stated MS-DRGs do not contain cases that represent patients who have been treated with any anticoagulant reversal agent for Factor Xa inhibitors. For the third criterion, the applicant believed that AndexXa™ would be the first type of treatment option available to patients who are receiving direct or indirect Factor Xa therapy who experience serious, uncontrolled bleeding events or who require emergency surgery. Given this would be the first FDA reversal agent for Factor Xa inhibitors, in the proposed rule, CMS noted that AndexXa™ is not substantially similar to any existing technologies.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes that AndexXa™ meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that AndexXa™ meets an unmet medical need for a universal antidote to direct and indirect Factor Xa inhibitors. Specifically, according to the applicant, if approved, this would be the only agent shown in prospective clinical trials to rapidly and sustainably reverse the anticoagulation activity of Factor Xa inhibitors, is potentially non-thrombogenic, and could supplant current treatments of bleeding from anti-Factor Xa treatments, which have not been shown to be effective in the treatment of all patients. The applicant provided results from two randomized, double-blind, placebo controlled Phase III studies The primary endpoint in both studies was the percent change in anti-Factor Xa activity. The applicant stated that the results from the two Phase III studies and previous proof-of-concept Phase II dose-finding studies showed that AndexXa™ can rapidly reverse coagulation activity of Factor Xa inhibitors and sustain that reversal. The applicant also provided clinical trial data that showed participants in Phase II and Phase III trials has no thrombotic events.

The applicant submitted interim data to show substantial clinical improvement within its target population as part of the ongoing Phase IIIb/IV open-label ANNEXA-4 study. The study population had a mean age of 77 years old (most patients have cardiovascular disease) and the majority of bleeds were intracranial or gastrointestinal. According to the applicant, the interim data from this study demonstrate safe, reliable and rapid reversal of Factor Xa levels in patients with acute bleeding. CMS was concerned the interim data also indicates 18 percent of patients experienced a thrombotic event and 15 percent died following reversal during the 30-day follow-up period. CMS was concerned that there is insufficient data to determine substantial clinical improvement over existing technologies.

In response to the February 2016 New Technology Town Hall meeting CMS received two comments supporting the approval for AndexXa™ and will take these comments into consideration when deciding whether to approve the new technology add-on payments.
In response to the proposed rule, the applicant reiterated that AndexXa™ meets the substantial clinical improvement criterion and that it is the first and only FDA-approved antidote for the

direct Factor Xa inhibitors apixaban and rivaroxaban. The applicant provided additional information from the clinical studies. Several commenters also supported the clinical results as demonstration of substantial clinical improvement for AndexXa™, especially for patients with intracranial hemorrhages that are anticoagulation related to a Factor Xa inhibitor such as apixaban or rivaroxaban,

CMS agrees that AndexXa™ represents a substantial clinical improvement and provides an alternative treatment option to Medicare beneficiaries, Specifically, AndexXa™ provides a rapid, sustained reversal of the anticoagulation effects of Factor Xa inhibitors and is a treatment option for patients who experience severe or life-threatening bleeds, during the administration of Factor Xa inhibitors. CMS reiterates that AndexXa™ is not approved for the treatment of bleeding related to Factor Xa inhibitors other than apixaban and rivaroxaban.

CMS finalizes that AndexXa™ meets all three criteria for new technology add-on payments and approves the technology for add-on payments in FY 2019. Cases involving the use of AndexXa™ will be identified by ICD-10-PCS procedure codes XW03372 and XW04372. The applicant estimates the total cost of AndexXa™ treatment per patient as $28,125. Therefore, the maximum new technology add-on payment amount for a case involving AndexXa™ is $14,062.50 for FY 2019. CMS estimates the FY 2019 add-on payments as approximately $75.966 million (based on 5,402 patients).

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

Legislative Authority. CMS notes that section 1886(d)(3)(E) of the Act requires an annual update to the wage index based on a survey of wages and wage-related costs of short-term, acute care hospitals which the agency collects on Medicare cost reports (CMS Form 2552-10, Worksheet S-3, Parts II, III, and IV).

Core-Based Statistical Areas (CBSAs) for the FY 2019 Hospital Wage Index. CMS uses the OMB delineations implemented beginning with FY 2015 and updated by OMB Bulletin numbers 13-01, 15-01 and 17-01. OMB Bulletin No. 17-01 (the latest update) was issued on August 15, 2017; OMB announced that one Micropolitan Statistical Area (Twin Falls, Idaho (CBSA 46300)) qualifies as a Metropolitan Statistical Area. CMS incorporates the updates into the final FY 2019 wage index, ratesetting, and tables for the final rule.

Codes for Constituent Counties in CBSAs. CBSAs and constituent counties within CBSAs each have unique identifying codes. In the FY 2018 IPPS/LTCH PPS final rule, CMS adopted the policy to only use Federal Information Processing Standard (FIPS) codes to crosswalk counties to CBSAs, and it continues to do so for FY 2019. Tables 2 and 3 of the final rule as well as the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the county changes.

B. Worksheet S-3 Wage Data

The final wage index values are based on data from FY 2015 submitted cost reports and include categories of costs paid under the IPPS (and outpatient costs) for salaries and hours from short-term, acute care hospitals, home office costs and hours, certain contract labor costs and hours (including direct and certain indirect patient care, pharmacy, lab, and nonteaching physician Part A services), and wage-related costs (including pension costs). CMS excludes the following categories of costs: direct and overhead salaries and hours for services not subject to IPPS payment (e.g., SNF and home health services), GME costs (teaching physicians and residents) and certified registered nurse anesthetists, hospital-based RHCs and FQHCs, and CAHs. CMS notes these data are used to calculate wage indices for other providers of services as well as for prospective payments to IRFs, IPFs, LTCHs, and hospital outpatient services.

C. Verification of Worksheet S-3 Wage Data

CMS calculates the final FY 2019 wage index based on wage data of 3,283 hospitals from Worksheet S-3, Parts II and III of the cost report for cost reporting periods beginning during fiscal year 2015; the data file used to construct the wage index includes FY 2015 data submitted to CMS as of June 20, 2018.

As a result of further review by MACs as well as the April and May appeals processes, CMS received improved data for 28 hospitals which it includes in the final wage index. However, CMS also excluded 2 additional providers for aberrant data (i.e., unusually low average hourly wages) relative to their CBSAs. CMS includes data from facilities that were IPPS hospitals in FY 2015 even if they terminated program participation as hospitals, but it excludes data from CAHs and from IPPS hospitals that converted to CAH status. CMS removes 11 hospitals that converted to CAH status after January 22, 2017 through January 26, 2018.

For multicampus hospitals, CMS applies the same methodology it used for the FY 2018 wage index to allot wages and hours data among the different labor market areas where the campuses are located. Table 2 includes separate wage data for the campuses of 16 multicampus hospitals. Effective for the FY 2019 rulemaking cycle and subsequent rulemaking, CMS changes the way in which it designates a subordinate campus in Table 2: CMS places a "B" to designate the subordinate campus in the third position of the CCN (as opposed to its prior placement in the fourth position).

D. Method for Computing the Unadjusted Wage Index

The FY 2019 national average hourly wage, unadjusted for occupational mix, is $42.997789358. CMS no longer computes a separate unadjusted wage index for Puerto Rico because section 601 of the Consolidated Appropriations Act, 2016 (P. L. 114–113) provided for 100 percent payment based on the national standardized amount for Puerto Rico hospitals.

CMS uses the same methodology to compute the unadjusted wage index for FY 2019 that it applied for the final wage index for FYs 2012 through 2018. CMS continues to use the

employment cost index as its data source for wages, salaries and other price proxies in the IPPS market basket.

Other Wage-Related Costs

FY 2019. In the FY 2018 IPPS/LTCH PPS final rule, CMS clarified that 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) (i.e., the "1-percent test").
- 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).

CMS noted that wage-related costs reported as salaries on line 1 should not be included as other wage-related costs on line 18.

In the FY 2018 IPPS/LTCH PPS final rule clarification, the instructions omitted line 15 for Home Office Part A Administrator on Worksheet S-3, Part II from the denominator; CMS corrects that omission by clarifying that, for purposes of calculating the 1-percent test, each individual category of other wage related cost (i.e., the numerator) should be divided by the sum of Worksheet S-3, Part III, Lines 3 and 4, Column 4 (i.e., the denominator).

FY 2020. CMS had proposed to exclude other wage-related costs in calculating the wage index for FY 2020 and subsequent fiscal years. CMS finalizes that proposal. In the FY 2018 IPPS/LTCH PPS proposed and final rules, CMS noted that only a small minority of hospitals report other wage-related costs that meet the 1-percent test. Internal reviews from the wage index desk review process for FY 2019 indicated that only 8 hospitals (of the more than 3,000 hospitals included in the wage index) had other wage-related costs properly reported and included in the wage index. CMS believes that reporting these costs is not an appropriate part of a relative measure of wage costs in a particular market area and that reporting them may distort the average hourly wage for that area. Additionally, the agency's reviews indicate widely divergent types of costs reported as other wage-related costs which may also compromise the accuracy of the wage index.

Some commenters asked whether malpractice costs would still be included in calculating the wage index if other wage-related costs are eliminated. CMS responds that removing other wage-related costs from the wage index means that all categories of other wage-related costs (even those not reported on Line 18 of Worksheet S-3, Part II) are removed. This includes costs such as malpractice insurance associated with employees and contract labor. CMS says it conducted additional analysis to quantify the number of hospitals reporting malpractice insurance on lines

other than Line 18; it reports that only 41 hospitals reported costs (which may include malpractice insurance) that met the 1-percent test on Line 22. Additionally, fewer than 30 hospitals indicated a description of malpractice on line 25 on Worksheet S-3, Part IV, and only three of those hospitals met the 1-percent test. For these reasons, CMS rejects a commenter's suggestion that it revise the core wage-related cost list to include malpractice costs.

Codification of Certain Policies for Multicampus Hospitals

CMS finalizes its proposals to codify treatment of multicampus hospitals in its regulations relating to SCHs (at §412.92), RRCs (at §412.96), for rural reclassification (at §412.103), and MDHs (at §412.108). The codification applies to hospitals (i) with a main campus and one or more remote locations under a single provider agreement, (ii) where services are furnished and billed under the IPPS, and (iii) that meet provider-based criteria at §413.65 as a main campus and remote location of a hospital. CMS notes that these policies do not apply to CAHs as they are not reimbursed under the IPPS.

As codified, a main campus of a hospital may not get SCH, RRC or MDH status, or rural reclassification, independently or separately from its remote location and vice versa. Thus, both the main campus and its remote location(s) must satisfy the relevant qualifying criteria. Where the regulations require data (e.g., bed count, number of discharges, or case-mix index), combined data from the main campus and remote location(s) will be used. For qualifying criteria related to location, mileage, travel time, and distance requirements (i.e., where data cannot be combined), both the main campus and its remote location(s) must independently satisfy the requirements to be reclassified or obtain special status.

CMS' main rationale for these policies is that remote locations are included in the main campus's cost report and share the same provider number. The agency further states that it is not administratively feasible for CMS and MACs to track every hospital with remote locations within the same CBSA and to assign different statuses or rural reclassifications exclusively to the main campus or the remote location(s).

In response to questions about the effective date of the proposals, CMS states that it is merely codifying current policies (without change) that have been and will continue to be in effect. Thus, the agency does not believe it is necessary to grandfather a multicampus hospital with existing special status or reclassification or for a multicampus hospital to reapply for special status or reclassification. CMS notes that an approved SCH or MDH status determination remains in effect unless there is a change in circumstances under which that status was approved. Current SCHs and MDHs must verify that CMS' codification does not result in a change in circumstance. CMS reminds readers that hospitals must report changes in circumstances to their MACs within 30 days.

Commenters are concerned about the impact of these policies on SCHs if another hospital opens a remote location near an SCH or if an SCH opens a remote location near other hospitals. Current regulations provide some safeguards for hospitals with SCH status. However, CMS acknowledges that its current policies for determining whether a nearby hospital is a "like

hospital"[11] with respect to an SCH, which might impact the status of the SCH, may be an area for future rulemaking. The inpatient days of the remote location and the main hospital are not distinguishable in calculating the 8-percent test. CMS recognizes that a remote location within the range of an SCH (or hospital seeking SCH status) which provides only very limited IPPS services may be considered a "like hospital" because it is a remote location of a larger main hospital. CMS will consider the feedback provided for possible future rulemaking.

E. Occupational Mix Adjustment

Section 1886(d)(3)(E) of the Act requires the collection of data every 3 years on the occupational mix of employees for each Medicare participating short-term, acute care hospital to construct an occupational mix adjustment to the wage index. CMS calculated the proposed occupational mix adjustment using a new occupational mix survey based on calendar year 2016 (Form CMS-10079, OMB No. 0938-0907). The deadline for submission to MACs of completed 2016 surveys was July 3, 2017. Preliminary, unaudited calendar year 2016 survey data were posted on the CMS website on July 12, 2017, and MACs revised or verified data elements in the surveys that resulted in edit failures.

CMS calculates the occupational mix adjustment factor using the same methodology it has used since the FY 2012 wage index and applies the adjustment to 100 percent of the FY 2019 wage index. For multicampus hospitals, salaries and hours are allotted among the different labor market areas where its campuses are located. Table 2 of the final rule contains the FY 2019 occupational mix adjusted wage index and includes separate wage data for the campuses of 16 multicampus hospitals.

Because CMS was able to include some occupational mix surveys that had been aberrant for the proposed rule but were improved and used for the final rule, CMS reports a response rate of 95 percent (using surveys from 3114 hospitals). CMS applies proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data. For FY 2019, the unadjusted national average hourly wage is $42.997789358 and the occupational mix adjusted national average hourly wage is $42.955567020.

F. Occupational Mix Adjusted Wage Index

The final FY 2019 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	$41.66099188
National LPN and Surgical Technician	$24.74107416
National Nurse Aide, Orderly, and Attendant	$16.96864849
National Medical Assistant	$18.13188525
National Nurse Category	$35.04005228

[11] The term "like hospital" is defined at 42 CFR 412.92(c)(3) to be a hospital that furnishes short-term, acute care, and the total inpatient days attributable to the units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital IPPS are more than 8 percent of the similarly calculated total inpatient days of the hospital seeking SCH designation.

CMS observes that, based on its analysis of the occupational mix data, the national percentage of hospital employees in the nurse category is 42.1%. At the CBSA level, the percentage of hospital employees in the nurse category ranged from 26.6% to 82%. Applying the occupational mix adjustment to wage data, the wage index values for FY 2019 increased for a larger percentage of urban areas (57 percent) than rural areas (48.9 percent) and decreased for a larger percentage of rural areas (51.1 percent) than urban areas (43 percent). CMS also compared FY 2019 wage data adjusted by the occupational mix from the 2016 survey and the 2013 survey. Overall, CMS found that the wage indexes of 55 percent of CBSAs increased due to the application of the 2016 occupational mix survey data.

G. Application of the Rural, Imputed, and Frontier Floors

Rural Floor. CMS estimates that the rural floor will increase the FY 2019 wage index for 263 hospitals. CMS calculates a final national rural floor budget neutrality adjustment factor of 0.993142. CMS projects that rural hospitals in the aggregate will experience a 0.2 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in urban areas would experience no change in payments; and urban hospitals in the New England region can expect a 2.5 percent increase in payments, primarily due to the application of the rural floor in Massachusetts. CMS expects that 29 urban providers in Massachusetts will receive a rural floor wage index value which increases payments overall to Massachusetts by $121 million in FY 2019 (a 3.3 percent increase). CMS notes that the significant increase in overall payments to hospitals in Massachusetts compared to past years is due primarily to the increase in the Massachusetts rural floor as a result of the recent reclassification of Brigham and Women's Hospital in the city of Boston as a rural hospital under §412.103. Urban Puerto Rico hospitals will receive 0.1 percent increase in IPPS payments.

Expiration of Imputed Floor Policy. In the FY 2018 IPPS/LTCH PPS final rule, CMS extended for one additional year (through September 30, 2018) its temporary imputed floor program. CMS finalizes its proposal to let the imputed floor program (both the original and alternative methodologies) expire effective October 1, 2018. CMS states that it will no longer include the imputed floor as a factor in the national budget neutrality adjustment. The wage index and impact tables for the final rule do not reflect the imputed floor policy.

Under the imputed floor policy, CMS imputes a "floor" for states with no rural counties (i.e., Delaware, New Jersey and Rhode Island). CMS believes that the policy creates a disadvantage in applying the wage index to hospitals in states with rural hospitals but no urban hospitals receiving the rural floor, and that the application of the rural and imputed floors requires transfer of payments from hospitals in states with rural hospitals (where the rural floor is not applied) to hospitals in states where the rural or imputed floor is applied. By discontinuing the imputed floor program, only those states with both rural areas and hospitals located in those rural areas (including any hospital reclassified as rural under §412.103) benefit from the rural floor as provided for under the statute.

While some commenters strongly endorsed the proposal to let the imputed floor policy expire, they noted that states with few rural hospitals (e.g., Massachusetts) can (and are incentivized to) have certain major urban hospitals reclassify as rural because this raises the rural floor in that

state. They note that while the statewide rural floor is required by statute, CMS does have the discretion to establish the method by which the floor is calculated. For example, CMS could revise the calculation to be based on providers that are physically located in rural areas (as opposed to being reclassified as rural). CMS says it will consider these comments in evaluating ways to address wage index disparities. CMS will also consider a suggestion to publish the effects of the nationwide rural floor on Medicare outpatient services during the hospital outpatient prospective payment system rulemaking cycle.

Beginning with FY 2019, there are 3 hospitals in Delaware, 10 hospitals in New Jersey and 9 hospitals in Rhode Island that will no longer receive an increase in their wage index because of the expiration of the imputed floor policy.

Frontier Floor Wage Index. CMS continues its frontier floor wage index policies for FY 2019. Thus, hospitals in Montana, Nevada, North Dakota, South Dakota, and Wyoming will receive the frontier floor value of 1.0000 for FY 2019. This provision is not budget neutral, and CMS estimates an increase of approximately $62 million (0.1 percent) in IPPS operating payments. Rural and urban hospitals located in the West North Central region would experience an increase in payments of 0.2 percent and 0.6 percent, respectively, because many of the hospitals located in this region are frontier state hospitals.

H. Wage Index Tables

In the FY 2016 IPPS/LTCH PPS final rule, CMS streamlined and consolidated the wage index tables associated with the IPPS proposed and final rules for FY 2016 and subsequent fiscal years. Prior to that, the wage index tables 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 website. However, with the exception of Table 4E, CMS consolidated those 11 tables into 2 tables (Tables 2 and 3).

CMS adds a Table 4 entitled "List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019" which is also available on the CMS website. CMS intends to make this information available annually through a Table 4 in the IPPS rulemaking cycles going forward. CMS directs readers to section VI of the Addendum to the final rule for a discussion of the wage index tables for FY 2019.

I. Revisions to the Wage Index Based on Hospital Reclassifications

CMS summarizes its general policies on reclassifications and redesignations, including policy changes implemented under its April 21, 2016 Interim Final Rule with Comment Period (IFC) which was finalized in the FY 2017 IPPS/LTCH PPS final rule. In the IFC (81 FR 23428 through 23438), CMS revised its regulations to permit more than one reclassification to apply to urban hospitals redesignated as rural under §412.103 that are simultaneously seeking reclassification through the Medicare Geographic Classification Review Board (MGCRB). The changes were effective for reclassifications that are first effective for FY 2018 and succeeding fiscal years. Such hospitals may use distance and average hourly wage criteria designated for rural hospitals at §412.230(b)(1) and (d)(1).

A hospital with an active MGCRB reclassification that is subsequently approved for reclassification under §412.103 does not lose its MGCRB reclassification. Thus, a hospital with an active MGCRB reclassification may simultaneously maintain rural status under §412.103 and receive a reclassified urban wage index during the years of its active MGCRB reclassification. The hospital is still considered rural under section 1886(d) of the Act and for other purposes.

In the case of a hospital that has a §412.103 reclassification and that also accepts a MGCRB reclassification, the CBSA to which the hospital is reclassified under the MGCRB determines the area wage index that the hospital receives and the area to which it is classified for purposes of CMS calculations of the wage index. That is, the hospital does not receive the wage index of the rural area to which it is reclassified under §412.103, and CMS does not include the hospital in calculating the wage index of that rural area. For purposes of calculating the wage index, the hospital is included in the urban wage area to which it is reclassified by the MGCRB.

Reclassifications

At the time the final rule was constructed, 303 hospitals were approved by the MGCRB for wage index reclassifications starting in FY 2019. Because such reclassifications are effective for 3 years, a total of 881 hospitals are in a reclassification status for FY 2019. This includes those hospitals initially approved by the MGCRB for FY 2017 (230 hospitals) and FY 2018 (348 hospitals). Twenty-one of these hospitals reclassified back to their geographic location.

Applications for FY 2020 reclassifications are due by September 4, 2018 which is also the deadline for canceling a previous wage index reclassification withdrawal or termination. Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process are incorporated in the final FY 2019 wage index values.

Previously, §412.256(a)(1) required applications for reclassification to be mailed or delivered to the MGCRB with a copy to CMS (which could not be submitted by fax or other electronic means). For applications for FY 2018 and subsequent years, CMS revised its policy so that applications and supporting documentation must be submitted to the MGCRB by the method that the MGCRB prescribes, with an electronic copy to CMS (i.e., by email to wageindex@cms.hhs.gov). The MGCRB now requires applications, supporting documents, and subsequent correspondence to be filed electronically through the MGCRB module of the Office of Hearings Case and Document Management System (OH CDMS). The MGCRB will issue all notices and decisions by email; these documents will be accessible electronically through the OH CDMS. Registration instructions and the system user manual are available at https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing.html.

Revision of Reclassification Requirements for a Provider that Is the Sole Hospital in the MSA

In the FY 2012 IPPS/LTCH final rule (76 FR 51600-51601), CMS established a policy to permit waiver of the average hourly wage comparison criterion under §412.230(d)(1)(iii) for a hospital in a single hospital MSA if the hospital can document that it is the single hospital in its MSA that

is paid under 42 CFR Part 412, subpart D (see §412.230(d)(5)). To document this, a hospital may be required to contact the appropriate CMS regional office or MAC for a statement certifying its status as the single hospital in its MSA; stakeholders have noted that this process is time-consuming, applied inconsistently nationwide, and presents challenges in cases where hospitals have recently opened or closed.

CMS proposed that a hospital would only have to provide the wage index data from the current year's IPPS final rule to show that it is the only hospital in its labor market area with wage data listed within the 3-year period considered by the MCGRB. CMS finalizes its proposal effective for reclassification applications for FY 2021 (which are due September 1, 2019) and subsequent fiscal years. Thus, a hospital in a single hospital MSA applying for FY 2021 need only provide documentation from Table 2 of the Addendum to the FY 2020 IPPS/LTCH final rule demonstrating it is the only CCN listed within the associated "Geographic CBSA" numbers (listed under column H) with a "3-Year Average Hourly Wage (2018, 2019, 2020)" value (listed under column G) to document that it is the single hospital in its MSA.

Clarification of Group Reclassification Policies for Multicampus Hospitals

Remote locations of hospitals in a distinct geographic area from the main hospital campus may seek wage index reclassification; these remote locations are indicated in Table 2 of the final rule with a "B" in the third digit of the CCN (CMS refers to these remote location hospitals as "B locations"). B location hospitals may seek individual and county group reclassification. CMS did not propose any change to its multicampus hospital reclassification policy, but the agency seeks to address a complication with processing county group reclassification applications for multicampus locations that have not yet been assigned a "B" in Table 2 in the rule for a particular fiscal year (which occurs with newly opened or acquired hospitals).

Because the wage index process uses cost reports that end up to 4 years before an upcoming IPPS fiscal year, the published wage data for a hospital used to construct the wage index would not reflect specific wage data for any new B location in a different labor market area. However, the application requirements for county hospital group reclassifications require that all active hospitals located in the county of the group must be listed notwithstanding the fact that the wage data of a new B location are not included in Table 2. Thus, where a hospital remote location is not included in Table 2 of the relevant IPPS final rule, CMS requests that county hospital group applicants list new remote locations with a "B" in the third digit of the hospital's CCN to facilitate MGCRB review. If the application is approved, CMS will include the hospital's B location in Table 2 of the subsequent IPPS final rule, and will instruct MACs to adjust payment for that remote location. Further, CMS will include the B location designation in subsequent rules, without composite wage data, until the wage data of the new location are included in the cost report used to construct the wage index for IPPS purposes. CMS did not receive any comments specific to this clarification and request.

Provisions Relating to Lugar Hospitals

Under established policies, an eligible hospital that waives its Lugar status to receive the out-migration adjustment is treated as rural for all purposes (including for the rural DSH adjustment)

for each fiscal year for which it receives the out-migration adjustment. CMS permits a Lugar hospital to submit a single notice to automatically waive its deemed urban status for the 3-year period of the out-migration adjustment, though the hospital is permitted before its second or third year of eligibility to notify CMS that it no longer seeks the out-migration adjustment and instead elects to return to its deemed urban status.

A Lugar hospital that qualifies for and accepts the out-migration adjustment (or that no longer wants to accept the out-migration adjustment) must notify CMS within 45 days from the date of public display of the proposed rule. A request to waive Lugar status that is timely received is valid for the full 3-year period for which the out-migration adjustment applies; however, the hospital may reinstate its urban status for any fiscal year during that 3-year period. Requests to both waive and reinstate Lugar status may be sent electronically to wageindex@cms.hhs.gov; hospitals should include their CCN and should indicate either "waive Lugar" or "reinstate Lugar" in the subject line.

In response to a commenter's assertion that CMS made a clerical error in assigning a particular hospital to a CBSA under section 1886(d)(8)(B) of the Act, CMS states that it did not make a mistake. CMS says that, consistent with OMB standards, it examines commuting data to central counties of CBSAs (i) to determine whether a hospital qualifies as a Lugar hospital and (ii) in determining the urban area to which the hospital is assigned. CMS does not view those two steps in isolation.

J. Out-Migration Adjustment

The "out-migration" adjustment is an adjustment to the hospital wage index based on commuting patterns of hospital employees.[12] CMS will continue to use the same policies, procedures and computation that were used for the FY 2012 out-migration adjustment. It estimates increased payments of approximately $42 million in FY 2019 for 220 hospitals receiving the out-migration adjustment. This provision is not budget neutral.

For FY 2019, and until CMS finalizes out-migration adjustments based on the next Census or other available data, the out-migration adjustment continues to be derived from the custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata.

Beginning with the FY 2019 rulemaking cycle, CMS adds a new Table 4 entitled "List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2019" which is also available on the CMS website. Table 4 shows a list of counties that are eligible for the out-migration adjustment for FY 2019 identified by FIPS county code, the FY 2019 out-migration adjustment, and the number of years the adjustment will be in effect.

[12] Hospitals located in counties that qualify for the out-migration 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.

K. Reclassification from Urban to Rural and Change to the Lock-In Date

A qualifying hospital located in an urban area may apply to be reclassified as rural under section 1886(d)(8)(E) of the Act and regulations separate from reclassification through the MGCRB. The hospital must meet criteria under §412.103 as well as application requirements. In the FY 2017 IPPS/LTCH PPS final rule, CMS revised its regulations (in §412.103(b)(6)) to require a hospital seeking to reclassify as rural under §412.103 for the next fiscal year to file its application no later than 70 days before the second Monday in June. The application must be approved by the CMS Regional Office. The effective date of the reclassification is the filing date of the application (i.e., when the CMS Regional Office receives the application).

CMS finalizes its proposal to change the lock-in date requirements to eliminate the specific date for filing the application (i.e., 70 days before the second Monday in June) and instead require that the application be approved by the CMS Regional Office involved no later than 60 days after the date of the public display of the IPPS proposed rule for a fiscal year. CMS observes that the 70-day timeframe was a precautionary measure to ensure the agency would receive approval in time to include reclassified hospitals in the wage index and budget neutrality calculations for the fiscal year involved. While CMS encourages hospitals to apply well in advance, it notes that a Regional Office may approve a request in less than 60 days. Thus, any hospital with an approved rural reclassification under §412.103 by the date that is 60 days after the public display of the IPPS proposed rule for a fiscal year will be included in the wage index and budget neutrality calculations for the payment rates for the next fiscal year regardless of the date the application was filed. CMS reiterates that the change does not modify current regulations which permit hospitals that qualify under §412.103(a) to apply for an urban to rural reclassification at any time.

L. Process for Requests for Wage Index Data Corrections

CMS describes the process by which a hospital may submit requests to its MAC to change or revise wage index data and indicates that April 5, 2018 was a hospital's last opportunity to request CMS intervention for a correction of an error the hospital determines was made after review of the CMS final wage index data public use files. Thus, April 5, 2018 was the deadline by which hospitals could challenge the MAC's handling of wage data on any basis (including a policy, factual, or any other dispute) or data corrections made by CMS of which the hospital was notified after the public use file (PUF) was posted on February 2, 2018.

The preliminary FY 2019 wage data files were made available on May 19, 2017 and the 2016 preliminary occupational mix data files were provided on July 12, 2017. CMS posted a PUF on February 2, 2018 with wage index data as of February 1, 2018; the PUF also contained a tab with the Worksheet S-3 FY 2015 wage data and 2016 occupational mix data (if any) of those hospitals deleted from the February 2, 2018 wage data PUF.

CMS posted the final wage index data PUFs on April 27, 2018 which are available at the following CMS Web site: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY-2019-Wage-Index-Home-Page.html.

CMS notes that these files are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data. If a hospital believed a potential error existed because of these reasons, the hospital had to send its request and supporting documentation to CMS and to the MAC no later than May 30, 2018. Appeals must be sent by mail and email. Verified corrections were incorporated into the final wage index in the FY 2019 IPPS/LTCH PPS final rule.

If errors are identified by hospitals after the May 30, 2018 deadline, CMS may make midyear changes to the wage index under the following limited circumstances: 1) the MAC or CMS erred in tabulating the data; and 2) the requesting hospital could not have known about the error, or could not have had an opportunity to correct the error, by the May 30, 2018 deadline for the FY 2019 wage index. If such a correction changes the wage index value for an area, the revised wage index is effective prospectively from the correction date.

CMS may make wage index value changes retroactive to the beginning of the fiscal year involved only under very limited circumstances, as follows: 1) the MAC or CMS erred in tabulating data; 2) the hospital knew and requested a correction before May 30, 2018 for the FY 2019 wage index; and 3) CMS agreed before October 1 that the error was made and should be corrected. However, this would not apply for a hospital that seeks to revise another hospital's data. Additionally, any correction may not be used to revise a prior fiscal year's wage index data. CMS notes that there is retroactive effect where a judicial decision reverses a CMS denial of a hospital's wage index revision request.

Process for Data Corrections by CMS after the February 2 PUF. Hospitals may request additional review of corrections made by CMS to their wage index data after the display of the February 2, 2018 PUF. Under existing appeal deadlines for determinations made by MACs during the desk review process, hospitals may dispute CMS corrections after the February 2, 2018 PUF posting that do not arise from a hospital's request for a wage data revision. A hospital may dispute CMS adjustments under existing deadlines as follows:[13]

- For CMS adjustments made between the February 2, 2018 PUF and March 22, 2018 (i.e., 14 calendar days before the April appeals deadline), hospitals must dispute the correction by April 5, 2018.
- For CMS adjustments made between March 23, 2018 (i.e., 13 calendar days before the April appeals deadline) and May 16, 2018 (i.e., 14 days before the May appeals deadline), hospitals must dispute the correction by May 30. 2018.
- For CMS adjustments with respect to which hospitals were notified on or after May 17, 2018 (i.e., 13 calendar days before the May appeals deadline or later), hospitals may appeal to the PRRB.

Hospitals must request the correction by the first applicable deadline. A hospital that fails to meet the procedural deadlines does not have a later opportunity to submit wage index data corrections or to dispute CMS' decision on requested changes.

[13] See FY 2019 Hospital Wage Index Development Timetable at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY-2019-Hospital-Wage-Index-Development-Time-Table.pdf.

M. Labor-Related Share

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national standardized amount that is attributable to wages and wage-related costs by a factor (a "wage index") that reflects the relative differences in labor costs among geographic areas. Section 1886(d)(3)(E) of the Act directs the Secretary to employ 62 percent as the labor-related share if that would result in higher payments to the hospital than using the national labor-related share. In the FY 2018 IPPS rule, CMS established a national labor-related share of 68.3 percent based on FY 2014-based IPPS market basket.

For FY 2019, CMS is making no changes to the labor-related share. If a hospital has a wage index that is greater than or equal to 1.0, its labor-related share will be 68.3 percent. If a hospital has a wage index that is less than 1.0, its labor-related share will be 62 percent as the lower labor share will result in higher IPPS payments.

IV. Other Decisions and Changes to the IPPS for Operating System

A. Post-Acute Care Transfer and Special Payment MS-DRGs

A post-acute transfer is a discharge from a hospital to a rehabilitation hospital or unit, a psychiatric hospital or unit, a skilled nursing facility or home with written plan for home health services from a home health agency and those services begin within 3 days after the date of discharge. If that transfer occurs prior to the geometric mean length of stay and the patient is grouped to an MS-DRG subject to the post-acute transfer policy, CMS makes payment to the transferring hospital using one of two methodologies: 1) payment at 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; or 2) payment of 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. The second methodology is known as the "special payment methodology" and is specifically for the types of cases that exhibit exceptionally high costs very early in the hospital stay.

If the MS-DRG's total number of discharges to post-acute care equals or exceeds the 55th percentile for all MS-DRGs and the proportion of short-stay discharges to post-acute care to total discharges in the MS-DRG exceeds the 55th percentile for all MS-DRGs, CMS will apply the post-acute care transfer policy to that MS-DRG and to any other MS-DRG that shares the same base MS-DRG. CMS does not revise the list of DRGs subject to the post-acute care transfer policy annually unless it is also making a change to a specific MS-DRG.

2. Changes for FY 2019

CMS evaluated MS-DRGs where it is making a change using data from the FY 2017 MedPAR file. If an MS-DRG qualified for the post-acute care transfer policy, CMS also evaluated that MS-DRG under the special payment methodology criteria. For the final rule, CMS' analysis of new or revised MS-DRGs takes into account the statutory provision that expands the post-acute care policy to hospice discharges.

An unnumbered chart in this section provides a list of 27 new or revised MS-DRGs evaluated for the post-acute transfer policy. Seven MS-DRGs listed on the chart are and will continue to be subject to the post-acute transfer policy (023, 698, 699, 700, 870, 871, and 872).

None of these MS-DRGs are currently subject to the special payment methodology. CMS is making the special payment methodology applicable to MS-DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) and MS-DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) that shares the same base MS-DRG.

There were no public comments on these policies.

3. Expansion of Post-Acute Transfer Policy to Hospice Discharges

Section 53109 of the BBA of 2018 amended section 1886(d)(5)(J)(ii) of the Act to make discharges to hospice subject to the post-acute care transfer policy effective October 1, 2018. CMS is making conforming amendments to 42 CFR §412.4(c) to include discharges to hospice care occurring on or after October 1, 2018 as qualified post-acute care discharges.

If a claim has Patient Discharge Status code of 50 (Discharged/Transferred to Hospice - Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) and the MS-DRG is subject to the post-acute care transfer policy, CMS will apply the post-acute discharge payment policy. CMS claims processing software will be revised to identify cases in which hospice benefits were billed on the date of hospital discharge without the appropriate discharge status code. Such claims will be returned as unpayable to the hospital and may be rebilled with a corrected discharge code.

Public comments opposed the expansion of the post-acute transfer policy to hospice indicating that the rationale for the post-acute care policy does not apply and hospitals would inappropriately keep patients in the hospital longer before discharging patients to hospice. CMS indicates that the statute is unambiguous with respect to applying this policy to hospice beginning in FY 2019. CMS is finalizing its policy as proposed making one minor change to add "provided" to the following phrase which describes the discharges to which the post-acute care policy applies: "hospice care *provided* by a hospice program."

B. Inpatient Hospital Updates

The inpatient hospital update for FY 2019 is calculated by determining the rate of increase in the hospital market basket for IPPS hospitals in all areas less an MPF adjustment and a statutory adjustment, subject to reductions for failing the IQR, EHR programs or both. CMS is using the 2014-based IPPS operating and capital market baskets for the FY 2019 update. IHS Global Insight, Inc.'s (IGI) 2nd quarter 2018 forecast (with historical data through the 1st quarter of 2018) is 2.9 percent. Using IGI's 2nd quarter 2018 forecast, CMS is making an MFP adjustment of -0.8 percentage points. Applicable updates are presented in the below table:

FY 2019	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	2.9	2.9	2.9	2.9
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.725	-0.725
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.175	0.0	-2.175
MFP Adjustment	-0.8	-0.8	-0.8	-0.8
Statutory Adjustment	-0.75	-0.75	-0.75	-0.75
Applicable Percentage Increase	**1.35**	**-0.825**	**0.625**	**-1.55**

C. Rural Referral Centers: Annual Updates to Case-Mix Index and Discharge Criteria

CMS is providing updated minimum national and regional case mix index (CMI) values and updated minimum national and regional numbers of discharges to meet the criteria for determining RRC status. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2018, a rural hospital with fewer than 275 beds must, among other requirements:

- Have a CMI value for FY 2017 that is at least—
    - 1.66112 (national—all urban), or
    - The median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) calculated by CMS for the census region in which the hospital is located.
- Have at least 5,000 (3,000 for an osteopathic hospital) for its cost reporting period that began during FY 2016.

The median regional CMIs are listed in the final rule. A hospital seeking to qualify as an RRC should get its hospital-specific CMI value (not transfer-adjusted) from its Medicare Administrative Contractor (MAC).

D. Low-Volume Hospitals

1. Background

Section 1886(d)(12) of the Act provides a payment in addition to a hospital's IPPS payment for each qualifying low-volume hospital beginning in FY 2005. To qualify as a low-volume hospital, the hospital must be more than a distance specified in the statute from another IPPS hospital and have fewer than a statutory specified number of discharges.

Originally, the hospital had to be 25 miles from another IPPS hospital and have fewer than 800 total discharges (Medicare and non-Medicare). These statutory criteria applied from FYs 2005 to 2010. By regulation, CMS established that a low-volume hospital could only qualify for the adjustment by having fewer than 200 total discharges. If a hospital qualified for the low-volume adjustment, it received a 25 percent adjustment to its payment for each Medicare discharge.

Subsequent statutory changes in effect from FYs 2011 to 2017 altered the criteria to 15 miles from another IPPS hospital and fewer than 1,600 Medicare discharges. The statute also requires CMS to establish an adjustment of 25 percent for hospitals with fewer than 200 Medicare discharges and a continuous linear declining adjustment for each Medicare discharge up to 1,600 Medicare discharges.

Section 50204 of the BBA of 2018 extended the criteria in effect from FYs 2011 to 2017 through FY 2018. In addition, section 50204 established that a hospital will qualify for the low-volume hospital adjustment for FYs 2019 through 2022 by being more than 15 miles from another IPPS hospital and having fewer than 3,800 total discharges (Medicare and non-Medicare). The statutory provision requires CMS to revise its continuous linear declining adjustment formula to reflect the new discharge criteria. For FY 2023 and subsequent years, the qualifying statutory criteria will revert to those initially established (25 miles from another IPPS hospital and fewer than 800 total discharges (Medicare and non-Medicare)). Unless CMS makes future changes to the rules, a low-volume hospital must have fewer than 200 total discharges to qualify for the low-volume hospital adjustment beginning FY 2023.

To implement section 50204, CMS published a separate notice to address FY 2018 implementation of the low-volume hospital provision. The notice concerned itself with needed data and processes for hospitals to apply and qualify for the low-volume hospital adjustment during FY 2018. That process is now complete and is not further addressed in the FY 2019 IPPS final rule.

CMS proposed to make conforming changes to the regulation text at 42 CFR §412.101 to reflect the amendments made by section 50204 of the BBA 2018 for FY 2018. 2. FY 2019 – FY 2022

Distance Criterion. For FYs 2019 through 2022, a hospital can qualify for the low-volume adjustment by being more than 15 road miles (as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414)) from another IPPS hospital. For establishing that the hospital meets the mileage criterion, the use of a Web-based mapping tool as part of the documentation 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 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.

Discharge Criterion. To be eligible for the low-volume adjustment for FYs 2019 through FY 2022, the hospital must have less than 3,800 total discharges (Medicare and Medicaid) during each of these fiscal years. The most recently submitted cost report is used to determine if the

hospital meets the discharge criterion in the current year. In response to a comment, CMS clarified that hospitals should use Worksheet S-3, Part I, Column 15, Line 1 to demonstrate that it meets the discharge criterion.

Applying: **A hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 to receive the low-volume adjustment for FY 2018.** For a hospital whose request for low-volume hospital status is received after September 1, the MAC will apply the low-volume adjustment prospectively within 30 days of the date of the MAC's low-volume status determination.

A hospital receiving the low-volume hospital payment adjustment for FY 2018 may continue to receive a low-volume hospital payment adjustment in FY 2019 without reapplying if it continues to meet the mileage and discharge criteria. The hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2019. CMS notes that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital in order to receive the payment adjustment in that fiscal year. Low-volume hospital status is not based on a "one-time" qualification.

Payment Methodology. Section 50204 also provides that, for discharges occurring in FYs 2019 through 2022, the Secretary shall determine the applicable percentage increase using a continuous, linear sliding scale ranging from a 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent adjustment for low-volume hospitals with more than 3,800 discharges (Medicare and non-Medicare) in the fiscal year.

To implement this requirement, CMS will use continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FYs 2019 through 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment for FYs 2010 – FY 2017. Consistent with the statute, CMS will apply an adjustment of 25 percent to each Medicare discharge for qualifying hospitals with 500 or fewer total discharges. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment would be calculated using the following formula:

> Low-Volume Hospital Payment Adjustment = 0.25 – [0.25/3,300] - (number of total discharges - 500) = (95/330) x (number of total discharges/13,200).

The only public comments on the payment formula noted a typo which has been corrected in the final rule.

CMS revised §412.101(b)(2) to reflect application of the low-volume hospital adjustment for FY 2019 to FY 2022.

The table below shows the qualifying criteria and payment methodology for the low-volume adjustment throughout its history:

Fiscal Year	Distance Criteria	Discharge Criteria	Payment Methodology
2005 - 2010	25 miles	200 Total Discharges[14]	25%
2011 - 2018	15 miles	1,600 Medicare Discharges	Medicare Discharges<200=25%; Declining Linear Adj. Up to 1,600
2019 - 2022	15 miles	3,800 Total Discharges	Proposed: Total Discharges<500=25%; Declining Linear Adj. Up to 3,800 discharges applied to each Medicare Discharge
2023 and later	25 miles	200 Total Discharges	25%

E. Indirect Medical Education Payment Adjustment

Pursuant to statute[15], for discharges occurring in FY 2019, CMS will continue to apply the IME adjustment factor of 5.5 percent for every approximately 10-percent increase in a hospital's resident-to-bed ratio.

F. Disproportionate Share and Uncompensated Care

1. Background

Medicare makes DSH and UCP payments to IPPS hospitals that serve more than a threshold percent of low-income patients. Low-income is defined as Medicare eligible patients also receiving supplemental security income (SSI) and Medicaid patients not eligible for Medicare. To determine a hospital's eligibility for DSH and UCP, the proportion of inpatient days for each of these subsets of patients is used.

Prior to 2014, CMS made only DSH payments. Beginning in FY 2014, the ACA required that DSH equal 25 percent of the statutory formula and UCP equal the product of three factors:

- Factor 1: 75 percent of the aggregate DSH payments that would be made under section 1886(d)(5)(F) without application of the ACA;
- Factor 2: The ratio of the percentage of the population insured in the most recent year to the percentage of the population insured in a base year prior to ACA implementation; and
- Factor 3: A hospital's uncompensated care costs for a given time period relative to uncompensated care costs for that same time period for all hospitals that receive Medicare DSH payments.

The statute precludes administrative or judicial review of the Secretary's estimates of the factors used to determine and distribute UCP. UCP payments are only made to hospitals eligible to receive DSH payments that are paid using the national standardized amount (SCHs paid on the basis of

[14] While the Medicare statute established that a hospital qualifies as low-volume by having fewer than 800 discharges, CMS established by regulation that a hospital must have fewer than 200 discharges to qualify for the low-volume adjustment.

[15] See section 1886(d)(5)(B) of the Act which provides for an IME formula multiplier of 1.35 for discharges occurring on or after October 1, 2007.

hospital specific rates, hospitals not paid under the IPPS and hospitals in Maryland paid under a waiver are ineligible to receive DSH and, therefore, UCP payments).

2. FY 2019 Factor 1

CMS estimates this figure based on the most recent data available. It is not later adjusted based on actual data. CMS used the Office of the Actuary's (OACT) March 2018 Medicare DSH estimates, which were based on the March, 2018 update of the HCRIS and the FY 2018 IPPS final rule impact file. Starting with these data sources, OACT applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

OACT's June 2018 Medicare estimates of DSH is $16.339 billion. Seventy-five percent of this amount is $12.254 billion. OACT's estimates for FY 2019 began with a baseline of $13.230 billion in Medicare DSH expenditures for FY 2015. The table below shows the factors applied to update this baseline to the current estimate for FY 2019.

Factors Applied for FY 2016 through FY 2019 to Estimate Medicare DSH Expenditures Using 2015 Baseline

FY	Update	Discharge	Case-Mix	Other[16]	Total	Estimated DSH Payment (in billions)
2016	1.009	0.9864	1.031	1.0443	1.071589	$14.177
2017	1.0015	0.9931	1.004	1.0662	1.064673	$15.094
2018	1.018088	0.9892	1.02	1.0277	1.055689	$15.935
2019	1.0175	1.0014	1.005	1.00035	1.025384	$16.339

The table below shows the factors that are included in the "update" column of the "Increases from 2016" table. All numbers are based on projections from the President's FY 2019 Budget.

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding	Total Update Percentage
2016	2.4	-0.2	-0.5	-0.8	0.9
2017	2.7	-0.75	-0.3	-1.5	0.15
2018	2.7	-0.75	-0.6	0.4588	1.8088
2019	2.9	-0.75	-0.8	0.5	1.85

[16] The "other" column shows the increase in other factors affecting Medicare DSH estimates, including 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 other columns (such as the change in rates for the 2-midnight stay policy). The "other" column also includes a factor for Medicaid expansion due to the ACA. The factor for Medicaid expansion was developed using public information and statements for each state regarding its intent to implement the expansion. Based on this information, it is assumed that 50 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2016 resided in states that had elected to expand Medicaid eligibility and, for 2017 and thereafter, that 55 percent of such individuals would reside in expansion states.

There were a variety of comments expressing concerns about the detail CMS makes available to determine Factor 1. Of particular concern was CMS' assumptions and information regarding how it accounted for Medicaid expansion. One commenter indicated that CMS assumes Medicaid is underreported to determine Factor 2 because of the stigma associated with receiving Medicaid and is concerned whether the same assumption is made for Factor 1. The commenter was also concerned that CMS did not provide any supporting evidence for this assumption. Another commenter indicated that a September 2017 Report from the Congressional Budget Office (CBO) and the President's 2018 Economic Report indicated that coverage levels were lower than estimated by CMS which would affect OACT's estimates of Medicare DSH payments. Commenters suggested reconciling Factors 1 and 2 after the fact with actual data.

CMS responded as it did to similar comments in prior years:

- Its estimates for proposed rule are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget and Midsession Review of the President's Budget. CMS refers readers to these other resources for further information.
- CMS details information made available with the proposed rule to assist commenters in understanding CMS' estimates.
- CMS indicates that the Factor 2 estimate assumed understated Medicaid reporting because it was based on a survey while no such assumption was required for Factor 1 which uses actual Medicaid enrollment data.
- The agency is declining to reconcile estimates as inconsistent with the statute which included a prohibition against administrative and judicial review of estimates used to determine UCP.

3. FY 2019 Factor 2

Factor 2 adjusts Factor 1 based on the percent change in the uninsured since implementation of the ACA. For FYs 2014-2017, the statute required CMS to use CBO's estimate of the uninsured rate in the under 65 population from before enactment of the ACA for FY 2013. For FY 2018 and subsequent years, the statute requires Factor 2 to equal the percent change in the number of individuals who are uninsured from 2013 until the most recent period for which data are available minus 0.2 percentage points for each of fiscal years 2018 and 2019. In 2018, CMS began using uninsured estimates from the National Health Expenditure Accounts (NHEA) in place of CBO data as the source of change in the uninsured population.[17]

For FY 2019, CMS estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2018 and 2019 is 9.1 percent and 9.6 percent respectively. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates Factor 2 for FY 2019 (weighting the portion of calendar years 2018 and 2019 included in FY 2019) as follows:

[17]The NHEA estimate reflects the rate of uninsurance in the U.S. across all age groups and residents (not just legal residents) who usually reside in the 50 states or the District of Columbia. The NHEA data are publicly available on the CMS website at: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/index.html

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2018: 9.1 percent.
- Percent of individuals without insurance for CY 2019: 9.6 percent.
- Percent of individuals without insurance for FY 2019 (0.25 times 0.091) +(0.75 times 0.096): 9.48 percent

Factor 2 = 1-|((0.0948-0.14)/0.14)| = 1- 0.3229 = 0.6771 (67.71 percent)
0.6771 (67.71 percent) - .002 (0.2 percentage points for FY 2019 under section 1886(r)(2)(B)(ii) of the Act) = 0.6751 or 67.51 percent.

CMS calculated Factor 2 for the FY 2019 final rule to be 0.6751, or 67.51 percent, and the uncompensated care amount for FY 2019 to be $12.254 billion X 0.6751 = $8.273 billion, which is about $1.51 billion more than the FY 2018 UCP total of about $6.767 billion; the percentage increase is 22.6 percent. The below tables show the Factor 1 and Factor 2 estimates for FY 2018 and FY 2019:

FY 2019 Change in UCP
($ in Billions)

	FY 2018	FY 2019	$ Change	% Change
Factor 1	$11.665	$12.254	$0.589	5.05%
Factor 2	0.5801	0.6751	-	16.38%
UCP	$6.767	$8.273	$1.506	22.26%

Public commenters were generally supportive of CMS' calculation of Factor 2 and the use of NHEA estimates of the number of uninsured as a transparent source of data source that allows commenters to understand how the calculations were completed. One commenter indicated that the increase in FY 2019 UCP does not compensate for past year's underpayments that resulted from use of outdated CBO data CMS was required to use by statute. CMS responded as it did above and in prior years noting that through the statutory prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system.

4. FY 2019 Factor 3

The statute instructs the Secretary to estimate the amounts of uncompensated care for a period "based on appropriate data." In addition, it permits the Secretary to use alternative data if the Secretary determines that available alternative data are a better proxy for the costs of IPPS hospitals treating the uninsured.

From FY 2014 through FY 2017, CMS used Medicaid inpatient days where the patient is not eligible for Medicare and Medicare inpatient days for SSI eligible patients (collectively known as low income patient days) as a proxy for hospital uncompensated care costs. CMS believed that it was premature to use Worksheet S-10 data for Factor 3 because of variations in the data and its completeness. In addition, hospitals were not on notice that Worksheet S-10 would be used for purposes of computing UCP prior to FY 2014. For FY 2017, CMS also moved from using 1 year of data to using 3 years of data to allocate UCP. According to CMS, using 3 years of data

mitigates undue fluctuations in the amount of UCP to hospitals from year to year and smooths over anomalies between cost reporting periods.

In the FY 2017 IPPS proposed rule, CMS stated that many of its concerns would no longer be relevant as hospitals were on notice as of FY 2014 that Worksheet S-10 could eventually become the data source to calculate UCP. MedPAC has also indicated that Worksheet S-10 data is a better data source for uncompensated care than low income patient days. In addition, CMS has undertaken extensive analysis of the Worksheet S-10 data, benchmarking Worksheet S-10 data against the data on uncompensated care costs reported to the Internal Revenue Service (IRS) on Form 990 by not-for-profit hospitals.[18] Key findings indicate high correlation between uncompensated care costs reported on IRS Form 990 and Worksheet S-10 and the correlation coefficient has increased over time from 0.71 in 2010 to 0.80 in 2012.

Changes Made Since Publication of 2018 IPPS/LTCH PPS Final Rule

On September 29, 2017, CMS issued Transmittal 11, which, among other things, clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care.[19] In addition, this transmittal clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy may be included on Line 20, Column 1 of Worksheet S-10. These clarifications apply to cost reporting periods beginning on or after October 1, 2013. CMS also modified the application of the CCR.[20]

In light of these changes, CMS provided another opportunity for hospitals to submit revisions to their Worksheet S-10 data for FY 2014 and FY 2015. This additional opportunity resulted in changes to FY 2014 and FY 2015 Worksheet S-10s for over one-half of the hospitals that were eligible to receive Medicare DSH payments. CMS believes that this provides further evidence of the appropriateness of continuing to incorporate Worksheet S-10 data into the calculation of Factor 3.

5. Policies Being Finalized for FY 2019

Use of Worksheet S-10 Data

In the FY 2018 IPPS/LTCH PPS final rule, CMS indicated its planned approach to incorporating Worksheet S-10 data into the calculation of Factor 3:

- FY 2018: 2 years of low income patient days (Medicaid inpatient days from FY 2012 and FY 2013 cost reports and FY 2014 and FY 2015 SSI Medicare inpatient days) and one year of uncompensated care data (FY 2014 Worksheet S-10).

[18] This analysis was performed by Dobson DaVanzo & Associates, LLC, under contract to CMS.
[19] Transmittal 11 is available for download on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf.
[20] Specifically, the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. The CCR will be applied to the charges for uninsured patients approved for charity care or an uninsured discount, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs.

- FY 2019: 1 year of low income patient days (Medicaid inpatient days from FY 2013 and FY 2016 SSI Medicare inpatient days) and 2 years of uncompensated care data (FY 2014 and FY 2015 Worksheet S-10).
- FY 2020: 3 years of uncompensated care data (FY 2014, FY 2015 and FY 2016 Worksheet S-10).

While the above is CMS' planned approach for using Worksheet S-10 data, CMS is only finalizing use of Worksheet S-10 as described above for FY 2019. CMS' policies for FY 2020 remain undecided. In addition, CMS finalized the following policies for FY 2019:

Definition of Uncompensated Care

CMS defines "uncompensated care" (Worksheet S-10, line 3) as the sum of charity care (Worksheet S-10, line 23) and non-Medicare bad debt and non-reimbursable Medicare bad debt (line 29).

Technical Issues and Adjustments

- CMS is using Worksheet S-10 data updated in HCRIS through June 30, 2018.
- If the hospital's uncompensated costs exceed 50 percent of its total operating expenses, CMS determined the hospital's uncompensated care costs:
    - In FY 2014, by applying the ratio of the hospital's uncompensated care costs to total operating expenses from FY 2015 to its FY 2014 total operating expenses;
    - In FY 2015 by applying the ratio of the hospital's uncompensated care costs to total operating expenses from FY 2016 to its FY 2015 total operating expenses.

- CMS assigned a statewide average CCR (urban or rural) for all hospitals with a CCR greater than 3 standard deviations above the national corresponding national geometric mean (the CCR "ceiling") for that fiscal year.
- CMS is continuing to use low-income patient days for Puerto Rico hospitals, Indian Health Service and Tribal hospitals and all-inclusive rate Providers. As Puerto Ricans are ineligible for SSI, CMI is using a national average of 14 percent of the hospital's Medicaid days as a proxy for SSI days.
- CMS applied a scaling factor to the Factor 3 values of all DSH eligible hospitals such that the total UCP are consistent with the available amounts for the applicable fiscal year.
- CMS annualized Medicaid days data and uncompensated care cost data reported on the Worksheet S-10 if a hospital's cost report did not equal 12 months.
- If multiple cost reports begin in the same year:
    - CMS determined if annualization is needed by combining the data across the multiple cost reports.
    - It used data from a cost report that is equivalent to 12 months or if no such cost report exists, the cost report that was closest to 12 months annualized.
    - If the hospital had no cost report beginning in a fiscal year, CMS used data from the cost report that spanned both fiscal years.

- New hospitals are ineligible to receive interim DSH or UCP until they have data showing eligibility. At that time, UCP will be based on their own FY 2019 Worksheet S-10 uncompensated costs as a percentage of FY 2015 uncompensated costs for all hospitals nationwide.
- If a hospital does not have both Medicaid days for FY 2013 and SSI days for FY 2016 available for use in the calculation of Factor 3 in Step 1, CMS will remove that fiscal year from the calculation and divide by the number of years with data.
- CMS published Factor 3 for all eligible hospitals as well as list of hospital mergers. Commenters have until 8/31 to submit comments on the accuracy of this information. Comments may be submitted to: Section3133DSH@cms.hhs.gov. Changes in response to these comments will be posted on the website prior to October 1.
- CMS will continue to make interim UCP in FY 2019 on a per-discharge basis based on CMS' calculated uncompensated care payment for the hospital for a fiscal year divided by the average number of discharges, or claims, in the most recently available three fiscal years of the Medicare claims dataset.
- Cost report settlement will only include adjustments for changes in whether the hospital is eligible to receive empirically justified DSH payments.

    - The MAC will recoup payments from hospitals that received interim payments but were determined at cost report settlement not to be eligible for DSH.
    - For a hospital that does not receive interim payments later determined to be eligible for DSH, the MAC will calculate the UCP for the hospital based on the Factor 3 value determined prospectively and published with the final rule.

6. Public Comments and Responses to Use of Worksheet S-10

Lack of Accurate and Consistent Reporting: Most commenters stated that it is premature to use Worksheet S-10 data due to a lack of clear and concise line-level instructions for reporting. Despite CMS' efforts to improve the clarity of the instructions through Transmittal 11 and providing hospitals with the opportunity to revise Worksheet S-10 for FY 2014 and FY 2015, commenters continued to find inconsistent reporting among hospitals and questionable accuracy of the updated data. Commenters provided several examples of why they believe the data remains inaccurate for many hospitals. Some commenters recognized that CMS is contacting select hospitals to verify reported data that continues to appear aberrant. Other noted improvements in the data.

CMS responded that continued use of Worksheet S-10 will improve the accuracy and consistency of the reported data. In addition, CMS intends to continue with its efforts to review the Worksheet S-10 data submitted by hospitals, consider the various issues in the comments to develop further refinements to the instructions and engage in significant provider education. In response to comments asking that hospitals be allowed to further amend their FY 2014 and FY 2015 Worksheet S-10s, CMS indicated that it would not provide that opportunity to affect FY 2019 UCP. However, the rule leaves open the possibility that CMS will allow revisions to those cost reports to affect FY 2020 and FY 2021 UCP.

Insufficient Time to Revise Cost Reports: Commenters provided a litany of concerns about Transmittal 10 (November 17, 2016) and Transmittal 11 (issued on September 29, 2017) and the opportunity to resubmit cost reports. Even though commenters appreciate the attempts to improve clarity of the instructions, commenters felt that revisions to the instructions and opportunities to resubmit cost reports were highly burdensome. Hospitals had insufficient time and resources to make changes consistent with the new instructions that they found to be highly complex and, in some situations, unclear.

CMS responded that it believes hospitals were provided sufficient time to address the changes outlined in Transmittal 11 and submit an amended Worksheet S-10 as evidenced by the many hospitals that were able to resubmit information by the deadlines. The rule further states that Transmittal 11 was designed to be responsive to previous stakeholder concerns and some commenters indicated that it has resulted in in improvements in consistency and data accuracy.

Data Source: A number of commenters indicated that the March update to HCRIS continues to reflect incorrect data for their own hospital despite having resubmitted Worksheet S-10 per Transmittal 11. CMS responded that it is using June 30, 2018 HCRIS update to calculate Factor 3 for the final rule. The rule states that CMS is taking the unprecedented step of releasing such a recent HCRIS update without having fully reviewed the information because of the unique circumstances that affected hospitals' ability to resubmit their Worksheet S-10 for FY 2014 and FY 2015 and the delays in processing by the MACs. Hospitals will have until August 31, 2018 to review and submit comments on the accuracy of the data file published in conjunction with the final rule relative to information they submitted to their MAC.

Administrative Procedure Act and Other Legal Procedural Issues: Some commenters indicated that CMS is required to accept and consider Worksheet S-10 information submitted during the public comment period under the Administrative Procedures Act and also cited Court precedent that CMS is required to use the best available data. Other commenters expressed concerns about seeing their Worksheet S-10 data used to distribute UCP for the first time in the IPPS final rule. Other commenters suggested that CMS allow for administrative or judicial review of its Medicare DSH payment calculations.

CMS is using the June 30, 2018 HCRIS update to perform the Factor 3 calculations for the final rule—the best data available at the time CMS determined final rule UCP. Data must be submitted through the cost report submission process. CMS is not considering any data not included with the June 30 HCRIS update that is included in the public comments to avoid having multiple potentially conflicting sources of information.

CMS emphasizes that there is no requirement under either the Administrative Procedure Act or the Medicare statute that CMS make the actual data that will be used in a final rule available as part of the notice of proposed rulemaking. Rather, it is sufficient to provide stakeholders with the proposed methodology and the data sources that will be used, so that they may have a meaningful opportunity to submit their views on the proposed methodology and the adequacy of the data for its intended purpose.

Delaying Use of Worksheet S-10: Many commenters recommended that CMS delay the use of Worksheet S-10 until hospitals can provide accurate and consistent data and prepare for potential losses due to policy changes. Similar comments suggested not moving forward with the planned transition, freezing the use of the Worksheet S-10 at its FY 2018 weight of 33 percent or some other figure. Various other alternatives were also suggested in the comments including extending the transition period from 3 years to a longer period.

CMS responded that as it can no longer conclude that low income patient days is better than Worksheet S-10 for allocating UCP. For this reason, it declined to delay moving to Worksheet S-10 or adopting any of the alternative ideas suggested by the public commenters.

Auditing: Many commenters urged CMS to implement a desk auditing process to ensure the accuracy and consistency of the Worksheet S-10 data. One commenter requested there be a comprehensive audit, not a desk audit. Several commenters raised concerns about the preclusion on judicial review and that this may allow MACs to make errors that are unappealable. Others expressed concern about inconsistent and arbitrary decisions made by MACs in their reviews of Worksheet S-10 data with respect to discounts under hospital's financial assistance policy. Commenters expressed concern that MACs may lack sufficient guidance, instruction, and training on this issue. Some commenters indicated that audits of Worksheet S-10 for the EHR incentive program were poorly done.

CMS intends 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 and strives to take lessons learned from EHR to improve the audits of Worksheet S-10 for purposes of Medicare UCP. The rule says audits are expected to begin in the Fall of 2018 and CMS will undertake provider education and further refinement of the instructions for the Worksheet S-10 as appropriate.

Stop-Loss: Some commenters asked that CMS implement a stop-loss policy to protect hospitals affected by the transition to Worksheet S-10 data. Another commenter noted that a stop-loss policy would not be warranted, given that a 3-year phase-in is an appropriate way to temporarily reduce the impact of new provisions.

CMS responded that its primary reason for using a 3-year average is to provide assurance that hospitals' UCP will remain reasonably stable and predictable. While the 3-year average effectively functions as a transition, that is not its purpose. Furthermore, as the Worksheet S-10 data is a better data source on uncompensated care than low income patient days, CMS disagrees with commenters who suggest the use of a longer phase-in to determine Factor 3.

Data Trimming: There are a variety of comments concerned that CMS' trims are inadequate. A hospital with uncompensated care costs equal to 50 percent of total costs is subject to a trim while the average is equal to 6 percent. Others that believe a review and audit should be completed before data is not used. Specific concerns were raised about all-inclusive rate hospitals that are not required to complete Worksheet C, Part I, which is used for reporting the CCR on Line 1 of the Worksheet S-10.

CMS agrees that, in an ideal circumstance, trims without audits would not be needed. However, providers have had sufficient time to amend their data and/or contact CMS to explain incorrect data. As a result, CMS is finalizing its trim policies. CMS indicates that because all-inclusive rate providers have charge structures that differ from other IPPS hospitals, it using low-income patient days from FY 2013 for Factor 3.

Graduate Medical Education: Commenters stated that CCRs for teaching hospitals are understated because Line 1 uses data from Worksheet C, Column 3 ("costs," which do not include GME) and Worksheet C, Column 8 ("charges," which does include GME). Commenters recommended using the "costs" definition from Worksheet B, Part I, Column 24, Line 118 to reconcile the discrepancy.

CMS responded that the purpose of UCP is to provide additional payment to hospitals for treating the uninsured, not for the costs incurred in training residents. In addition, because the CCR is also used in other IPPS rate-setting purposes, CMS is reluctant to adjust the CCRs only for uncompensated care costs.

Definition of Uncompensated Care: Commenters reiterated points made in prior years about including Medicaid payment shortfalls in the definition of uncompensated care indicating that not doing so disadvantages hospitals in states that expanded Medicaid. Some commenters noted that Worksheet S-10 provides an incomplete picture of Medicaid shortfalls and should be revised to instruct hospitals to deduct inter-governmental transfers, certified public expenditures, and provider taxes from their Medicaid revenue.

CMS continues to believe there are compelling arguments for excluding Medicaid shortfalls from the definition of uncompensated care including consistency with MedPAC and other key stakeholders. Conceptual issues aside, CMS indicates that it would not be feasible to include Medicaid payment shortfalls in the definition of uncompensated care because Medicaid pays hospitals a single DSH payment that, in part, covers the hospital's costs in providing care to the uninsured and, in part, covers estimates of Medicaid "shortfalls." In addition, in some states, hospitals return a portion of their Medicaid revenues to the State via provider taxes, making the computation of "shortfalls" even more complex.

Miscellaneous Concerns with CMS Instructions: Commenters raised a number of very specific concerns with CMS instructions. CMS indicated that many of these concerns were addressed in Transmittals 10 and 11 while it will consider others in future guidance.

7. Impact Analysis

The regulatory impact analysis presented in Appendix A of the final rule includes the estimated effects of the changes to UCP for FY 2019 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,448 hospitals that are projected to be eligible for DSH in FY 2019.

Changes in FY 2019 UCP compared to FY 2018 are accounted for by increases in Factor 1 and Factor 2 as well as by an increase in the number of hospitals eligible to receive DSH in FY 2019.

Factor 1 increased from $11.665 billion to $12.254 billion while Factor 2 increased from 58.01 percent to 67.51 percent. As a result, the total amount of UCP is estimated at $8.273 billion, a 22.26 percent increase from FY 2018 UCP (about $6.767 billion). The payment increase for any individual hospital will vary as payment impacts solely from Factor 3 are redistributive. A percent change in UCP payments of less than 22.26 percent indicates that hospitals within that category are projected to experience a smaller increase compared to the average for all hospitals, and a percent change of more than 22.26 percent indicates the category of hospitals is receiving a higher increase in UCP than the average for all hospitals. The below shows impacts for selected categories of hospitals:

Hospital Type	All Final Rule Changes
All Hospitals	22.26%
Large Urban	22.30%
Other Urban	20.26%
Rural	36.66%
Beds: 0-99 (Urban)	44.83%
Beds: 250+ (Urban)	19.40%
New England (Urban)	7.75%
Middle Atlantic (Urban)	5.51%
West South Central (Urban)	45.06%
Pacific (Urban)	2.89%
Major Teaching	17.23%
Non-Teaching	28.62%

G. Sole Community Hospitals and Medicare Dependent Hospitals

1. Implementation of BBA 2018 Provisions MDHs

To qualify as an MDH, a hospital must:

- Be located in a rural area or have acquired rural status under the application process specified by section 1886(d)(8)(E) of the Act and 42 CFR §412.103;
- Not have more than 100 beds; and
- Not be a SCH and at least 60 percent of the hospital's inpatient days or discharges (including Medicare Advantage) must be attributable to inpatients who are entitled to Part A using either:
    - The cost reporting period beginning in FY 1987; or
    - Two of the three most recently audited cost reporting periods for which settled cost reports are available.

MDHs are paid the IPPS amount plus 75 percent of the difference between the IPPS amount and their per discharge costs from one of several different base years.

BBA 2018

Extension. The MDH program expired on September 30, 2017 but was retroactively extended by section 50205 of the BBA 2018 from October 1, 2017 through September 30, 2022. As BBA 2018 was enacted after the MDH program expired, some former MDHs may have become SCHs or given up their acquired rural status. These hospitals would need to reapply for MDH status and once qualified, MDH status would be applied prospectively during FY 2018. Otherwise, MDH status would be automatically reinstated on October 1, 2017 if a hospital had MDH status on September 30, 2017.

All-urban states. Hospitals in all-urban states (Delaware, Rhode Island and New Jersey) were previously unable to qualify for MDH status because the states lack rural areas. Section 50205 permits a hospital in an all-urban state to qualify for MDH status if it meets MDH classification criteria described above and meets one of the following criteria for rural reclassification under section 1886(d)(8)(E)(ii)(I) of the Act and 42 CFR §412.103:

- The hospital is located in a rural census tract of an urban county.
- The hospital is located in an area that is designated as rural by any state law or regulation in effect as of January 1, 2018.
- The hospital is designated as rural by any state law or regulation in effect as of January 1, 2018.
- The hospital would qualify as a rural referral center or sole community hospital if the hospital were located in a rural area.

CMS notes that hospitals in all urban states seeking MDH status must follow the applicable procedures for both rural reclassification and MDH classification at 42 CFR §§412.103(b) and 412.108(b), respectively. Determination of MDH status is effective 30 days after the date the MAC provides written notice to the hospital, and payment of MDH rates to MDHs in all-urban states applies to discharges occurring on or after the effective date of the MAC's determination of MDH status for the hospital. A hospital in an all-urban state with MDH status will not be considered as having reclassified as rural; rather it will be treated as having satisfied one of the criteria described above for purposes of MDH classification. Public comments supported CMS' proposed implementation of BBA 2018 MDH provisions.

2. Effective Dates for SCH and MDH Classification Status

The effective date for SCH classification status and payment adjustment is 30 days after the date of written notification of approval. The regulations do not set a deadline for CMS to approve an application for SCH status. The effective date for acquired rural status under section 1886(d)(8)(E) of the Act and 42 CFR §412.103 is the date on which CMS receives the reclassification application. An urban hospital may reclassify as rural under 42 CFR §412.103 to qualify as an SCH or an RRC.

To minimize the lag between the effective date of rural reclassification and SCH status, CMS is revising the effective date for SCH classification status to the date the MAC receives a complete SCH application. This policy would apply for applications received on or after October 1, 2018. To be considered complete, an application must include the request for SCH classification and all supporting documentation needed to show that the hospital meets criteria for SCH status as of

the application date (including having acquired rural status). CMS would also make the effective date change for geographically rural hospitals seeking SCH status. In the final rule, CMS clarified that the effective date for SCH status will apply on the date the MAC, rather than CMS, receives the SCH application. CMS does not receive applications for SCH status.

CMS adopted parallel changes for the effective date of MDH status determinations.

H. Hospital Readmissions Reduction Program:

1. Background

The Hospital Readmissions Reduction Program (HRRP) reduces payments to Medicare PPS hospitals having readmissions exceeding an expected level. The list of conditions to which the HRRP applies in FY 2018 is: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); total hip arthroplasty (THA)/total knee arthroplasty (TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass surgery (CABG).

The HRRP formula includes a payment adjustment floor of 0.9700, meaning that a hospital subject to the HRRP receives an adjustment factor that is between 1.0 (no reduction) and 0.9700 (or a greatest possible reduction of 3 percent) of base operating DRG payments. Hospital-specific excess readmissions ratios are posted on the *Hospital Compare* website; hospitals are given a 30-day review and correction period before these data are made public.

As adopted in the FY 2018 IPPS/LTCH final rule, beginning with FY 2019, CMS will implement changes required under the 21st Century Cures Act (P.L. 114-255), which directs the Secretary to assign hospitals to peer groups based on the proportion of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligibles,[21] and to develop a methodology that allows for separate comparisons for hospitals within these groups. The methodology is described below.

CMS reminds readers that technical specifications for quality measures for the HRRP are provided along with non-substantive updates on the CMS website in the Measure Methodology Reports at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html, and additional resources on HRRP are on the QualityNet.org website under the inpatient hospital tab.

2. HRRP Policies for FY 2019

For FY 2019, CMS retains the same six conditions and the previously adopted methodology for calculating the HRRP reduction, using the new dual-eligible peer groups. The applicable periods from which HRRP data will be collected for FYs 2019, 2020 and 2021 are adopted, and certain

[21] These are individuals who are entitled to Medicare Part A benefits and who meet the definition of full benefit dual eligible individual under section 1935(c)(6) of the Social Security Act, which for a state for a month is an individual who– (i) has coverage for the month for covered part D drugs under a Part D prescription drug plan or an MA-PD plan; and (ii) is determined eligible by the state for full Medicaid benefits for such month under section 1902(a)(10)(A) or 1902(a)(10)(C), by reason of section 1902(f), or under any other category of eligibility for full Medicaid benefits, as determined by the Secretary.

definitions pertaining to the dual-eligible stratification are codified in the regulatory text. The final rule also includes a discussion of CMS' review of program measures in the context of its Meaningful Measures Initiative, which results in changes to other Medicare hospital quality reporting and pay-for-performance programs as described in other sections of this summary. In particular, CMS finalizes its proposal to remove the readmission measures from the Inpatient Quality Reporting (IQR) Program so as not to duplicate measures with the HRRP. (See section VIII.A below.)

Applicable Periods for FYs 2019, 2020 and 2021. CMS finalizes that the proportion of dual eligibles, excess readmissions ratios and the payment adjustment factors (including aggregate payments for excess readmissions and aggregate payments for all discharges) will be based on claims data from the 3-year periods shown in the following table. The FY 2018 applicable period is also shown in the table for reference. The applicable March update to the MedPAR file is used. For example, for FY 2019, CMS will use the March 2015 update of the FY 2014 MedPAR file, the March 2016 update of the FY 2015 MedPAR file, the March 2017 update of the FY 2016 MedPAR file and the March 2018 update to the FY 2017 MedPAR file to identify discharges occurring during the applicable period.

HRRP "Applicable Period"	
Payment Year	**Discharge Dates**
FY 2018	July 1, 2013-June 30, 2016
FY 2019	July 1, 2014-June 30, 2017
FY 2020	July 1, 2015-June 30, 2018
FY 2021	July 1, 2016-June 30, 2019

Commenters expressed concern about the continued use of 3-year periods given the resulting combination of claims using ICD-9 and ICD-10 coding. In addition to the advantage that longer reporting maximizes the number of hospitals in scoring and public reporting, CMS says that its analysis of data from the 2015 through 2018 reporting periods found little impact of the change to ICD-10. Specifically, year-to-year changes between 2015 and 2016, which included ICD-9 claims only, are similar to year-to-year changes for the following years, which included a mix of ICD-9 and ICD-10 claims. In addition, the readmission rates for 2018 reporting are similar to those for earlier years.

Codification of Definitions. CMS codifies certain definitions that were adopted in the FY 2018 IPPS/LTCH final rule. These are the definitions of "applicable period for dual eligibility" (the 3-year data period used as the applicable period for the HRRP program); "dual-eligible" (a beneficiary identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Modernization Act (MMA) files in the month the beneficiary was discharged from the hospital); and "proportion of dual-eligibles" (the number of dual-eligible patients among all Medicare fee-for-service and Medicare Advantage stays during the applicable period).

3. Payment Adjustment Methodology for FY 2019

No changes are made to the previously finalized dual-eligible peer group methodology that begins in FY 2019. As adopted in the 2018 IPPS/LTCH final rule, beneficiaries will be counted

as a full-benefit dual eligible patient if they are identified as having full-benefit dual status in the State MMA file for the month during which they were discharged from the hospital. The number of stays attributed to dual eligibles is divided by the total number of inpatient stays by beneficiaries enrolled in fee-for-service Medicare or Medicare Advantage. The HRRP 3-year applicable period (shown in the table above) will be used in calculating the proportion of dual eligible stays. Hospitals will be grouped by quintiles (five peer groups) based on the proportion of dual-eligible patients. The payment adjustment for a hospital is calculated using the following formula comparing a hospital's excess readmissions ratio to the median excess readmission ratio (ERR)[22] for the hospital's peer group, where "payment" refers to base operating DRG payments, dx refers to an HRRP condition (i.e., AMI, HF, pneumonia, COPD, THA/TKA, or CABG), and NM_M is a budget neutrality factor (neutrality modifier)[23] that is the same across all hospitals and all conditions.

$$P = 1 - \min\{.03, \sum_{dx} \frac{NM_M * Payment(dx) * \max\{(\text{ERR(dx)} - \text{Median peer group ERR(dx)}),0\})}{All\ payments}\}$$

CMS reports many comments were received on HRRP risk adjustment and the previously adopted methodology. Because no proposals were made to modify these policies, it considers the comments outside the scope of the final rule, but some responses are included due to stakeholder interest. A number of these stress the program's statutory requirements. However, CMS also notes that it may consider more flexible methods for peer group formation. All comments will be considered for future policymaking. CMS also commits to continuing to monitor the HRRP for unintended consequences such as the inappropriate shifting of care or increased patient morbidity and mortality.

The final FY 2019 readmissions payment adjustment factors will be posted in the fall of 2018 as Table 15 on the CMS website at the following link, once hospitals have been given an opportunity to review and correct the calculations. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

4. Accounting for Social Risk Factors in the HRRP

CMS continues its discussion of accounting for social risk factors (also sometimes referred to as socioeconomic status (SES) factors or socio-demographic status (SDS) factors) in its quality reporting and value-based purchasing programs. It cites the July 2017 final report of the National Quality Forum (NQF)[24] on its 2-year trial period of risk adjustment for social risk factors, and

[22] An Excess Readmissions Ratio (ERR) is calculated for each HRRP condition as the ratio of predicted-to-expected readmissions. Predicted readmissions are the number of unplanned readmissions predicted for a hospital based on the hospital's performance with its case mix and its estimated effect on readmissions. Expected readmissions are the number of unplanned readmissions expected for an average hospital with similar case mix.

[23] Using the most recently available full year of MedPAR data, CMS will compare total Medicare savings across all hospitals under the current method and under the stratified method and calculate a multiplicative factor to produce the same savings as the previous method when applied to each hospital's payment adjustment.

[24] NQF. *Evaluation of the NQF Trial Period for Risk Adjustment for Social Risk Factors*, July 2017. Available with related materials at http://www.qualityforum.org/SES_Trial_Period.aspx

notes that NQF has launched a follow-up 3-year initiative[25] that will continue to include social risk factors in outcome measures submitted for endorsement and will also explore unresolved issues that surfaced in the initial trial.

As a next step, CMS is considering options to increase the transparency of quality measure disparities shown among patient groups within and across hospitals, such as stratification of Inpatient Quality Reporting Program outcome measures. It plans to continue to work with the Assistant Secretary for Planning and Evaluation, the public, and other stakeholders to identify policy solutions that improve health equity while minimizing unintended consequences.

While comments were not specifically sought, some were received, and CMS will consider these as it continues to review the issue of social risk factors.

5. Impact Analysis

CMS estimates that 2,599 hospitals will be penalized under the HRRP in FY 2019, with penalties totaling $566 million. A table in the regulatory impact analysis section of the final rule shows the distribution of HRRP penalties as a percent of payments by type of hospital. The penalized hospitals represent 85 percent of the 3,062 hospitals that could potentially be penalized. Across all hospitals, penalties are shown to represent 0.67 percent of FY 2017 base operating DRG payments. The proportion of hospitals that are penalized ranges from 69 percent of hospitals with fewer than 50 beds (aggregate penalty of 0.66 percent) to 94 percent of hospitals with 100 or more medical residents (aggregate penalty of 0.52 percent). HRRP adjustments were calculated using discharges from the FY 2019 HRRP applicable period (July 1, 2014 – June 30, 2017).

I. Hospital Value-Based Purchasing Program:

Changes are made to the Hospital Value-Based Purchasing (VBP) Program, including changes to the criteria for removal of measures, removal of 4 measures, and adoption of performance standards for FYs 2021-2024. The proposed removal of the safety domain and 6 patient safety measures is not finalized, however.

1. Background

Under the Hospital VBP Program, CMS calculates a VBP incentive payment percentage for a hospital based on its Total Performance Score (TPS) for a specified performance period. A hospital's VBP incentive payment adjustment factor for a fiscal year combines a uniform 2 percent contribution to the VBP incentive payment funding pool (a reduction to each hospital's base operating DRG payments) and a hospital-specific incentive payment percentage that results from the hospital's TPS. A hospital's adjustment factor may be positive, negative or result in no change in the payment rate that would apply absent the program. (The total amount available for value-based incentive payments for a fiscal year is specified in statute and estimated by the Secretary; it has been 2.0 percent since FY 2017.)

[25] See http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.

For each payment year, CMS specifies through rulemaking a VBP Program measure set. For each measure, a baseline period and a performance period are finalized. A hospital's performance on each measure during the performance period is assessed (resulting in achievement points) and compared to its performance during the baseline period (resulting in improvement points). Measures available for inclusion in the Hospital VBP Program are those that are included in the IQR Program and have been included on the *Hospital Compare* website for at least one year prior to the start of the relevant performance period. CMS calculates a TPS for each hospital by summing the greater of the hospital's achievement or improvement points for each measure to determine a score for each domain, weighting each domain score, and adding together the weighted domain scores. CMS then converts each hospital's TPS into a value-based incentive payment percentage using a linear exchange function, under which the sum of all hospitals' payments will equal the amount of dollars contributed to the VBP funding pool.

Based on the March 2018 update of the FY 2017 MedPAR file, CMS estimates that the total amount available for VBP Program payments in FY 2019 is approximately $1.9 billion (i.e., 2.0 percent of base operating DRG payments).

CMS has posted on the FY 2019 IPPS final rule web page a Table 16A which includes proxy hospital-specific value-based incentive payment adjustment factors for FY 2019. These proxies are based on hospitals' TPSs from the FY 2018 Hospital VBP Program and are updated from the proposed rule to reflect data from the March 2018 update to the FY 2017 MedPAR file.

Under previously finalized policies, Hospital VBP Program scoring for FY 2018 payment was based on 13 measures across four domains. Once adopted, measures are retained until they are removed by rulemaking.

2. Retention and Removal of Measures – General Considerations

CMS modifies the regulatory text to provide that although a measure must be selected for the Hospital VBP Program from the IQR Program measure set and data on the measure must have been included on *Hospital Compare* for at least one year prior to the start of the Hospital VBP Program performance period, such a measure need not continue to remain in the Hospital IQR Program. (In section VIII.A below, changes to the Hospital IQR Program are discussed, including removal of measures that are continued in the Hospital VBP Program.)

Responding to concerns of some commenters, CMS cites the statutory requirement that performance on VBP Program measures be posted on *Hospital Compare* and says that for VBP measures removed from the IQR program, it will continue to report hospital performance in a manner similar to that used for reporting of performance on IQR Program measures. In addition, CMS says that as it considers public reporting options it will take into account commenter concerns about reporting performance data for hospitals not included in the VBP Program.

CMS also adopts for the Hospital VBP Program the list of seven factors used for considering removal of measures from the Hospital IQR Program and adds an eighth factor. These current Hospital IQR Program removal factors consider whether 1) the measure is "topped out;" 2) it

does not align with current clinical guidelines or practice; 3) another more broadly applicable measure is available; 4) performance or improvement on the measure does not result in better patient outcomes; 5) another available measure is more strongly associated with the desired patient outcomes; 6) collection or public reporting of the measure leads to negative unintended consequences other than patient harm; and 7) it is not feasible to implement the measure specifications. CMS notes that none of the factors results in automatic removal; these are considerations that are taken into account on a case-by-case basis.

The newly finalized removal factor is 8) the costs associated with a measure outweigh the benefit of its continued use in the program. Comments received on the addition of this factor were mixed, and in addressing commenter concerns CMS emphasizes that it will evaluate costs and benefits on a case-by-case basis, that the various types of costs listed in the proposed rule were not intended to be a complete list of its considerations, and that input from the range of stakeholders will be taken into account. CMS says it will balance the costs and benefits to a variety of stakeholders, although it also notes that while many entities may benefit from a measure's inclusion in the VBP Program, the primary benefit is to patients and caregivers.

A proposed policy is finalized under which, if it believes a measure in the Hospital VBP Program poses "specific patient safety concerns," CMS may promptly remove the measure from the program without rulemaking and notify hospitals of its removal through routine communication channels to hospitals, vendors, Quality Improvement Organizations, and use of the QualityNet website. Removal will be confirmed in the next IPPS rulemaking. Other measure removals that do not involve specific patient safety concerns will continue to be proposed through the rulemaking process. Responding to comments, CMS says that it intends to use this authority narrowly and expects that a high level of evidence from multiple sources would be required in most circumstances to remove a measure outside of rulemaking for patient safety concerns.

3. Removal of Hospital VBP Program Measures

Elsewhere in the final rule, CMS discusses the Meaningful Measures Initiative[26], which it launched in October 2017 as part of its effort to reduce the regulatory burden on the healthcare industry, lower health care costs, and enhance patient care. Meaningful Measures is a component of the agency's Patients Over Paperwork Initiative and is aimed at identifying the highest priority areas of quality measurement and quality improvement that are most vital to improving patient outcomes.

In this section of the final rule CMS discusses its view of how the Hospital VBP Program, the HRRP and the Hospital Acquired Conditions Reduction Program together are a collective set of hospital value-based purchasing programs. Together, the goals of the programs and the measures used address the Meaningful Measures Initiative priorities of making care safer, strengthening person and family engagement, promoting coordination of care, promoting effective prevention and treatment, and making care affordable. CMS believes that the programs should not add

[26] See https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiavevGenInfo/MMF/General-info-Sub-Page.html.

unnecessary complexity or costs associated with duplicative measures across programs. It has taken a holistic approach in evaluating each of the measures in the context of all three programs.

While CMS proposed that the Hospital VBP Program should focus on measurement priorities that are not covered by the HRRP or the HAC Reduction Program, it has been persuaded by commenters that duplication of patient safety measures in both the HAC Reduction Program and the VBP Program is appropriate. Thus, it sees the VBP Program as including measures related to clinical outcomes, patient and caregiver experience, patient safety, and healthcare costs.

Consistent with that approach, 4 measures are finalized for removal from the Hospital VBP Program. The table below shows the measures that are removed, the effective dates, the removal factor basis, and whether the measure is retained in another Medicare hospital quality reporting or pay-for-performance program. All four measures are retained in the IQR Program and will continue to be reported on *Hospital Compare*.

Six patient safety measures, including five measures reported through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) and the patient safety composite measure were proposed for removal because these measures are also used in the HAC Reduction Program. Removal of these measures, along with the elective delivery measure, would have resulted in removal of the entire safety domain from the VBP Program.

However, in response to commenters CMS elected to retain the patient safety domain and six of the measures from that domain in the VBP Program. (The elective delivery measure is finalized for removal.) It was persuaded by commenters that because these patient safety measures track infections and adverse events involving significant health risks and other costs to Medicare beneficiaries it is appropriate to provide incentives for hospitals to avoid them through more than one program. In addition, CMS cites reports showing success in reducing hospital-acquired infections which it says further supports keeping these measures in the VBP Program as well as the HAC Reduction Program. These programs have different scoring and incentive structures. As discussed in section VIII.A below, CMS is finalizing its proposal to remove these measures from the Hospital IQR Program.

Measure (NQF #)	Removal begins	End of data collection	Removal factor	Retained in another program?
Elective Delivery (0469)	FY 21	12/31/18	8- costs	IQR
AMI 30-day episode payment (2431)	FY 21**	n/a	8- costs	IQR
HF 30-day episode payment (2436)	FY 21**	n/a	8- costs	IQR
PN 30-day episode payment (2579)	FY 22**	n/a	8- costs	IQR
** These measures were previously finalized for the VBP but not yet implemented; the removal date reflects when they would have been added to the program.				

The elective delivery measure is removed because of the costs of duplication with the IQR Program. CMS also notes that more than half the hospitals that receive a score earn the maximum 10 achievement points, and the measure therefore no longer meaningfully differentiates performance among hospitals for purposes of VBP Program scoring.

The three payment episode measures that are removed, all of which were previously finalized for future adoption in the Hospital VBP Program and have not yet been implemented, will also continue as part of the IQR Program. CMS believes that these measures are duplicative of that program, and notes that the overall Medicare Spending per Beneficiary (MSPB) measure is retained as an efficiency measure in the Hospital VBP Program. (Section VIII.A of this summary discusses CMS' removal of the MSPB measure from the IQR Program.)

Under the final rule, the total number of VBP Program measures for FY 2021 is reduced from 15 to 12 measures. Beginning in FY 2022 there will be 13 measures, as the COPD mortality measure is scheduled for addition to the VBP Program in FY 2022.

Summary Table VBP-1: Measures and Domains by Payment Year					
Measure	**2018**	**2019/ 2020**	**2021**	**2022**	**2023**
Clinical Care – *Renamed 'Clinical Outcomes' beginning 2020*					
Acute Myocardial Infarction (AMI) 30-day mortality rate	X	X	X	X	X
Heart Failure (HF) 30-day mortality rate	X	X	X	X	X
Pneumonia (PN) 30-day mortality rate	X	X	X	X	X
Complication rate for elective primary total hip arthroplasty/total knee arthroplasty		X	X	X	X
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate			X	X	X
CABG 30-day mortality rate				X	X
Safety					
AHRQ PSI–90 patient safety composite	X	Removed			
Patient Safety and Adverse Events composite					X
Central Line Associated Blood Stream Infection (CLABSI)	X	X	X	X	X
Catheter Associated Urinary Tract Infection (CAUTI)	X	X	X	X	X
Surgical Site Infection: Colon Abdominal hysterectomy	X	X	X	X	X
Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia	X	X	X	X	X
Clostridium Difficile infection (CDI)	X	X	X	X	X
Perinatal Care: elective delivery < 39 weeks gestation	X	X	Removed		
Patient and Caregiver Centered Experience of Care/Care Coordination ***(Person and Community Engagement)***					
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)					

Summary Table VBP-1: Measures and Domains by Payment Year					
Measure	**2018**	**2019/ 2020**	**2021**	**2022**	**2023**
• Communication with Nurses • Communication with Doctors • Responsiveness of Hospital Staff • Pain Management (before 2018)* • Communication About Medicines • Cleanliness and Quietness of Hospital Environment • Discharge Information • Overall Rating of Hospital • 3-Item Care Transition measure	X	X	X	X	X
Efficiency and Cost Reduction					
Medicare Spending per Beneficiary	X	X	X	X	X
AMI payment per 30-day episode			Removed		
HF payment per 30-day episode			Removed		
Pneumonia (PN) payment per 30-day episode				Removed	
*The pain management component of HCAHPS was removed beginning with the FY 2018 payment determination.					

2. Accounting for Social Risk Factors in the Hospital VBP Program

In this section, CMS provides a discussion of accounting for social risk factors that is similar to the one provided with respect to the HRRP, which is summarized in section IV.H.4 above. Comments received in response are described and will be considered by CMS as it continues work on this issue.

3. Changes to VBP Program Domains and Weighting

CMS finalizes its proposal to change the name of the Clinical Care Domain to "Clinical Outcomes" beginning with FY 2020.

Proposals to remove the patient safety domain and reweight the remaining three domains are not adopted. Because it had proposed to remove all the measures from the safety domain, CMS had also proposed to remove the safety domain from the VBP Program beginning with FY 2021 payment and to reweight the Clinical Outcomes domain at 50 percent and continue to weight the Person and Community Engagement (HCAHPS) and Efficiency/Cost Reduction (MSPB) domains at 25 percent each.

Therefore, the final rule maintains four domains for the VBP Program, and in calculating the TPS domain scores will continue to be weighted equally at 25 percent each.

4. Requirements for Minimum Measures and Cases

CMS reviews the previously finalized policies for minimum cases required to receive a measure score and minimum measures for a domain score; no changes to these requirements are made.

The requirements include a minimum 100 completed surveys for a Personal and Community Engagement domain (HCAHPS) score, a minimum of 25 cases for each of the measures in the (newly named) Clinical Outcomes domain, and 25 cases for the MSPB measure. A hospital must have at least two measure scores in the Clinical Outcomes domain in order to have a score for that domain. In light of the final rule decision to retain the Safety domain, CMS clarifies that a hospital must have scores on at least two measures to have a score for this domain. For the NHSN measures, a minimum of 1 predicted infection is required for a score; for the patient safety composite measure hospitals must report at least three eligible cases for at least one underlying indicator.

5. Performance and Baseline Periods

CMS previously adopted performance and baseline periods for most VBP Program measures based on length; the specific time periods are therefore automatically updated each year. No changes are made to those policies. The final rule includes tables that display the baseline and performance periods for each fiscal year beginning with 2020 through 2024.

6. Performance Standards

The final rule includes a series of tables that display previously adopted and newly finalized numeric performance standards for certain VBP Program measures for FYs 2021-2024.

7. Impact Analysis for FY 2019

The impact analysis section of the final rule includes a table and discussion of the estimated impact of the VBP Program for FY 2019 by type of hospital. The table is updated from the proposed rule, but these are still proxy calculations that rely on the FY 2018 hospital performance scores to estimate the effects of the 2019 VBP Program. CMS has posted on its website Table 16A, which shows the updated proxy VBP adjustments and an updated exchange function slope. In the fall of 2018, after hospitals have been given an opportunity to review and correct their actual TPSs for FY 2019, CMS will post in Table 16B on the FY 2019 IPPS final rule page of the CMS website the actual FY 2019 value-based incentive payment adjustment factors and exchange function slope.

J. Hospital-Acquired Condition Reduction Program

CMS finalizes a new method for weighting measures when scoring hospital performance for the HAC Reduction Program. While the current six HAC Reduction Program measures are retained for FY 2019, elsewhere in this rule these measures are removed from the IQR Program effective with the FY 2022 payment determination (2020 reporting). Therefore, CMS also finalizes its proposal to adopt for the HAC Reduction Program data collection, data validation, and public reporting policies similar or identical to those that currently apply to these measures under the IQR Program.

1. Background

Under the HAC Reduction Program, which was implemented beginning in FY 2015, a 1-percent reduction in IPPS payments is made to hospitals that are identified as being in the worst performing quartile with respect to a set of HAC measures. Currently, six measures are grouped into two domains, as shown in the Summary Table below, which also shows historical program measures.

Originally, hospitals were assigned to deciles for each measure and points awarded to each decile, but beginning in FY 2017 CMS changed the HAC Reduction Program scoring methodology to a "Winsorized Z-Score Method." The Total HAC score is calculated by averaging the z-scores on measures in Domain 2, multiplying this average by the weight for Domain 2 (currently 85 percent) and adding it to the Domain 1 score which is the z-score for the composite patient safety measure, multiplied by the Domain 1 weight (currently 15 percent). The Total HAC Score will be used to define the top quartile of hospitals subject to the penalty.

An extraordinary circumstances exception policy was adopted for the HAC Reduction Program beginning in FY 2016.

2. HAC Reduction Program Measures

As noted with respect to the VBP Program above, CMS discusses its view of how the HRRP, the Hospital VBP Program, and the Hospital Acquired Conditions Reduction Program together are a collective set of hospital value-based purchasing programs. It believes that the programs should not add unnecessary complexity or costs associated with duplicating measures across programs. Specifically, CMS believes that the HAC Reduction Program is focused on making care safer and reducing harm through measures of "never events" and conditions that are often, if not always, preventable.

As noted in section IV.I.3 above, CMS had proposed to remove these measures from the both the Hospital VBP and IQR programs but in this final rule retains the measures in the VBP Program and removes them from the IQR Program. Responding to some commenters' concerns, CMS notes that hospitals that fail to report quality measure data for HAC Reduction Program purposes will be assessed the worst possible score for those measures, which it believes is sufficient incentive to ensure that all eligible hospitals submit all required data to the HAC Reduction Program.

Summary Table: HAC Reduction Program Measures, Performance Periods, and Domain Weights						
	FY 2015	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**
Domain 1						
PSI-90 composite (see note)	X	X	X			
Patient Safety and Adverse Events Composite/modified PSI 90 (see note)				X	X	X
Applicable Time Period/Performance Period	7/1/11-6/30/13	7/1/12-6/30/14	7/1/13-6/30/15	7/1/14-9/30/15	10/1/15-6/30/17	7/1/16-6/30/18
Domain 1 weight	35%	25%	15%	15%	*	*

Summary Table: HAC Reduction Program Measures, Performance Periods, and Domain Weights						
	FY 2015	**FY 2016**	**FY 2017**	**FY 2018**	**FY 2019**	**FY 2020**
Domain 2: CDC NHSN Measures						
Central Line-associated Blood Stream Infection (CLABSI)	X	X	X	X	X	X
Catheter-associated Urinary Tract Infection (CAUTI)	X	X	X	X	X	X
Surgical Site Infection (SSI): ◦ SSI Following Colon Surgery ◦ SSI Following Abdominal Hysterectomy		X	X	X	X	X
Methicillin-resistant staphylococcus aureus (MRSA)			X	X	X	X
Clostridium difficile (CDI)			X	X	X	X
Applicable Time Period (Performance Period)	1/1/12-12/31/13	1/1/13-12/31/14	1/1/14-12/31/15	1/1/15-12/31/16	1/1/16-12/31/17	1/1/17-12/31/18
Domain 2 weight	65%	75%	85%	85%	*	*
* CMS eliminates the domains and provides for equal weighting of HAC Reduction Program measures. See text discussion.						
Note: PSI-90 is a composite of eight measures: PSI-3 (pressure ulcer rate), PSI-6 (iatrogenic pneumothorax rate), PSI-7 (central venous catheter related blood stream infections rate), PSI-8 (postoperative hip fracture rate), PSI-12 (postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT rate), PSI-13 (postoperative sepsis rate), PSI-14 (wound dehiscence rate), and PSI-15 (accidental puncture or laceration rate). The Patient Safety and Adverse Events composite "modified PSI-90" removed PS-07; added PSI-9 (postoperative hemorrhage or hematoma rate), PSI-10 (physiologic and metabolic derangement rate), and PSI-11 (postoperative respiratory failure rate); re-specified the PSI-12 and PSI-15 rates; and changed the weighting of component indicators.						

CMS refers readers to the QualityNet.org website for technical specifications and other information on the PSI-90 Domain 1 measure (for which stewardship is transitioning to CMS) and to the NHSN Web site at: http://www.cdc.gov/nhsn/acute-care-hospital/index.html for information on the CDC NHSN healthcare-associated infection measures.

3. Accounting for Social Risk Factors in the HAC Reduction Program

In this section, CMS provides a discussion of this topic similar to the one provided with respect to the HRRP, which is summarized in section IV.H.4 above. CMS appreciates stakeholder feedback in its ongoing review of social risk factors.

4. HAC Reduction Program Data Collection

CMS finalizes its proposed adoption of IQR Program data collection processes for the HAC Reduction Program, with a delay. The program will begin receiving NHSN measure data beginning with January 1, 2020 infection events (January 1, 2019 had been proposed). This timing corresponds with HAC Reduction Program annual performance periods and the finalized removal of these measures from the IQR Program beginning with 2020 calendar year reporting. Quarterly reporting requirements, deadlines, and data submission through the NHSN will not change from the IQR Program policies. The IQR Program exceptions policy under which hospitals with too few procedures or lacking locations that do not meet the NHSN criteria may apply for a measure exception is continued. Hospitals will receive the same quarterly updates on

NHSN measures via the QualityNet secure portal. No changes are made to the process for submission, review and correction of claims data or data used for the chart-abstracted NHSN measures. The review and correction procedures for HAC Reduction program scores for 2019 would be unchanged, but it would be renamed as the "Scoring Calculations Review and Correction Period" to more clearly convey the intent and limitation of this process and distinguish it from the earlier process during which hospitals can review and correct underlying data.

Responding to comments, CMS says it does not expect hospitals to notice any changes to the submission of the NHSN data as a result of the change, and indicates that public reporting of the data will continue on a quarterly basis, and the data will be displayed on *Hospital Compare* in the same way.

5. HAC Reduction Program Data Validation

CMS proposes a HAC Reduction Program data validation process that it says reflects to the greatest extent possible the processes in place for the IQR Program. (Currently the HAC Reduction Program has no separate data validation process for the program's measures; this occurs through the IQR Program data validation process.) Under the final rule, the five chart-abstracted NHSN measures will be subject to validation under the HAC Reduction Program beginning with Q3 2020 discharges for FY 2023 payment. This reflects timing of adoption of the data collection requirements for the NHSN measures to the HAC Reduction Program, which is delayed one year from the proposed rule.

All subsection (d) hospitals will be eligible for random selection for the data validation sample because they are all subject to the HAC Reduction Program. Under the IQR Program only hospitals actively participating in that program are eligible for selection; CMS says that for FY 2018, 44 of the hospitals subject to the HAC Reduction Program chose not to participate in the IQR Program.

The same sample sizes will be used for this new data validation program as apply to the IQR Program: 400 randomly selected hospitals and 200 hospitals selected using targeting criteria. Similar targeting criteria will be used for the latter group. Hospitals eligible for targeted selection are those that failed validation in the previous year; submit data to NHSN after the data submission deadline had passed; have not been randomly selected in the past 3 years; passed validation in the previous year but had a two-tailed confidence interval that included 75 percent; or failed to report to NHSN at least half of actual infection events detected as determined through the previous year's validation.

A similar standard will be used to determine whether a hospital passes validation. The IQR Program scores hospitals on the NHSN measures based on an agreement rate between the hospital-reported infections compared to events identified as infections by trained CMS abstractors using a standard protocol. However, under the IQR Program the NHSN measures are combined with clinical process of care measures in determining whether the hospital passes or fails validation. For the HAC Reduction Program, CMS finalizes that beginning in FY 2023, the NHSN measures will be scored the same way, by computing a confidence interval for the NHSN measures, and with a hospital passing validation when the upper bound of the confidence interval is 75 percent or higher.

An educational review component will be included in the HAC Reduction Program data validation process. A hospital selected for validation will have 30 days after receiving quarterly validation results to seek educational review. During this 30-day period, hospitals may review, seek clarification, and potentially identify a CMS validation error. In addition, if an educational review requested for any of the first three quarters finds a CMS validation error, the corrected quarterly score will be used to compute the final confidence interval. A difference from the IQR Program process is that if a 4th quarter educational review identifies an error, CMS will use the corrected quarterly score in computing the final confidence interval.

Another difference from the IQR Program data validation is in how the penalty for failing validation will be applied. In the IQR Program, hospitals selected for validation are assigned to either submit validation templates for CLABSI and CAUTI or for MRSA and CDI. Up to four candidate cases are selected from each of the assigned templates, and two candidate colon and abdominal hysterectomy cases are selected from claims data. A hospital that fails to meet any part of the validation process receives a full payment reduction.

For the HAC Reduction Program, CMS finalizes that a hospital failing validation will be assigned the maximum Winsorized z-score only for the set of measures that CMS validated rather than an "all or nothing" assignment of maximum scores for the entire domain. CMS believes this approach is fairer to hospitals and will lessen the likelihood of a hospital receiving a HAC Reduction Program penalty due to data validation failure. The policy is also consistent with the current HAC Reduction Program policy of assigning the maximum Winsorized z-score for an NHSN measure when a hospital fails to submit data for the measure.

The HAC Reduction Program data validation period includes the four middle quarters of the program's 2-calendar year performance period for NHSN measures. (The IQR Program reporting period for these measures is one calendar year.) This validation period aligns with the current NHSN measure validation quarters. HAC Reduction Program validation will begin with the July 2020 (Q3) infection event data. A table in the final rule sets out key dates for the initial HAC Reduction Program validation.

Finally, CMS also adopts the Data Accuracy and Completeness Acknowledgement (DACA) requirements for the HAC Reduction Program. Between April 1 and May 15th each year hospitals must acknowledge through the QualityNet Secure Portal the accuracy and completeness of the data they submitted in the prior calendar year. The HAC Reduction Program DACA requirement will begin in 2021 for 2020 data.

6. Public Reporting

CMS references its statutory obligation and commits to continuing to make hospital-specific HAC Reduction Program measure data publicly available on *Hospital Compare*, including hospital scores on each measure, hospital domain scores, and the hospital's total HAC score. Once the quarterly NHSN measures are removed from the IQR Program, the quarterly data on these measures will continue to be made available on *Hospital Compare* in the same form and manner as they are displayed there now as part of the IQR Program.

7. Changes to HAC Reduction Program Scoring

CMS adopts its proposal to change the weighting of measures in calculating the Total HAC Score beginning with 2020 using the "equal measure weighting" approach. Currently Domain 1 (the PSI 90 patient safety composite measure only) receives a weight of 15 percent and Domain 2 (5 NHSN measures) receive a weight of 85 percent. CMS notes that for hospitals with scores on all six measures, each measure receives roughly the same weight (17 percent for the Domain 2 measures and 15 percent for PSI 90), but measure weightings become disproportionate when a hospital only has a score on one or two Domain 2 measures.

The new approach eliminates the domains and weights each of the six measures equally in calculating the Total HAC Score. Under this "equal measure weights" approach, each measure will receive a weight of 16.7 percent if the hospital has a score on each of the six measures, increasing to 50 percent each if only two measures were scored and 100 percent if only one measure is scored. CMS believes this approach addresses concerns about the disproportionate weight assigned to Domain 2 measures when a hospital only has scores for one or two such measures. In the proposed rule, CMS also sought comments on an alternative "variable domain weights" approach under which the two domains would be retained but the weight applied to each domain would depend on the number of Domain 2 measure scores the hospital has. CMS says that it prefers the equal measure weights approach because "it reduces the percentage of low-volume hospitals in the worst-performing quartile in the simplest manner to hospitals, while not greatly increasing the potential costs on other hospital groups," and because in the future if it changes the number of program measures the scoring methodology would not need to be changed.

The final rule includes a table, updated from the proposed rule, showing the impact of the change in weighting on the percentage of hospitals in the worst performing quartile (i.e., hospitals penalized) under the two alternative methodologies. The equal measure weights approach results are shown below. For many categories the numbers are similar to those in the proposed rule but notably for teaching hospitals the increase in the percentage of penalized hospitals is substantially higher: 3.6 percent versus 2.4 percent in the proposed rule table.

Estimated Impact of Scoring Approach on Percentage of Hospitals in Worst-Performing Quartile by Hospital Group (from final rule table)

Hospital Group	Equal Measure Weights
Teaching hospitals: 100 or more residents (N=248)	2.4%
Safety-net hospitals* (N=644)	0.6%
Urban hospitals: 400 or more beds (N=360)	2.2%
Hospitals with 100 or fewer beds (N=1,169)	-1.8%
Hospitals with a measure score for:	
Zero Domain 2 measures (N=188)	0.0%
One Domain 2 measure (N=269)	-4.2%
Two Domain 2 measures (N=225)	-0.8%
Three Domain 2 measures (N=198)	-2.5%
Four Domain 2 measures (N=253)	-0.4%
Five Domain 2 measures (N=2,022)	1.0%
*Hospitals in the top quintile for DSH percent.	

CMS says many commenters supported the change to the equal measure weights approach, but others were opposed or expressed concern that assisting low-volume hospitals would come at the expense of teaching hospitals and others. CMS says that like other policies this change will benefit some hospitals more than others, but that it is more equitable for most hospitals.

Other comments are addressed, including the suggestion that the minimum number of expected infections required for a hospital to receive a score on the NHSN infection measures be reduced below 1.0 expected infection so that more hospitals are scored on these measures. CMS says that it has analyzed this approach and its preliminary findings tended to exacerbate the scoring issues associated with low-volume and small hospitals instead. CMS says it will continue to work with CDC and seeks to optimize the participation of low-volume facilities while maintaining measure reliability and validity.

8. Performance Period for FY 2021

CMS finalizes that the HAC Reduction Program "applicable period", or performance period, for FY 2021 will be the 24-month period from July 1, 2017 through June 30, 2019 for the PSI-90 measure and January 1, 2018 through December 31, 2019 for the NHSN measures. These dates are consistent with previously adopted periods under the program.

9. Request for Comments on Possible Future Measures

CMS discusses suggestions it received from commenters regarding possible additional HAC Reduction Program measures. CMS had specifically sought comments on the potential for the program's future adoption of eCQMs. Comments will be considered in future policymaking. CMS notes that the statute requires the HAC Reduction Program measures to address hospital-acquired conditions, so some suggestions would not be appropriate for this program.

10. Impact Analysis

The impact analysis section of the final rule includes an updated table that shows the estimated distribution of hospitals in the worst performing quartile of Total HAC scores for FY 2019 by hospital characteristic. (The display copy of this table appears to have typographical errors.) This analysis is updated from the proposed rule (and notably does not reflect the equal measure weighting approach, which in this rule is finalized to begin in FY 2020). While by definition, 25 percent of hospitals overall would be in the worst quartile and subject to the penalty (804 hospitals total), this proportion varies from about 12 percent for rural hospitals with 100 or more beds to 45 percent of teaching hospitals with 100 or more medical residents. High-DSH hospitals are also more likely than others to be in the worst performing quartile. No estimate of the dollar amount of HAC Reduction Program penalties is provided.

K. Payments for Indirect and Direct Graduate Medical Education Costs

1. Background

Teaching hospitals receive payments from Medicare to compensate them for their indirect medical education (IME) and direct graduate medical education (DGME) costs. These payments are based on the number of full-time equivalent (FTE) residents trained by the hospital. The

Balanced Budget Act of 1997 established a cap on the number of allopathic and osteopathic residents that a hospital may include in its FTE resident count for IME and DGME payment purposes. Hospitals have generally been limited to the number of FTE residents that they counted in their most recent cost reporting period ending on or before December 31, 1996.

However, there are provisions in the law and regulations that allow hospitals that did not train residents in 1996 to establish new graduate medical education residency training programs and have their caps established at a point in time after they have started training residents. These provisions are designed to allow the training program to be at full capacity before the caps are established.

In addition, there are provisions that allow multiple teaching hospitals that jointly participate in resident training to aggregate their individual resident caps. These provisions allow multiple teaching hospitals jointly involved in training residents to have the flexibility to schedule training and have their FTE caps increase and decrease as long as the total number of FTE residents trained in the aggregate does not exceed the combined caps for each teaching hospital participating in an affiliated group.

2. Changes to Medicare GME Affiliated Groups for New Urban Teaching Hospitals

CMS' rules place restrictions on new teaching hospitals participating in affiliated groups. From FY 1997 – FY 2005, new teaching hospitals were prohibited from participating in affiliated groups. This restriction was adopted out of concern that hospitals with existing medical residency training programs could, with the cooperation of new teaching hospitals, circumvent the statutory FTE resident caps by establishing new medical residency programs in the new teaching hospitals solely for the purpose of affiliating with the new teaching hospitals to receive an upward adjustment to their FTE caps. This would effectively allow existing teaching hospitals to achieve an increase in their FTE resident caps beyond the number allowed by their statutory caps (70 FR 47452). Beginning in FY 2006, CMS modified its regulations to allow new teaching hospitals to participate in affiliated groups as long as the arrangement only resulted in an increase in the FTE cap of the new teaching hospital and not existing teaching hospitals in the group.

The final rule indicates that CMS has received questions about whether an affiliated group consisting solely of new urban teaching hospitals is permissible. CMS responded that the regulations (prior to this one) did not allow for a Medicare GME affiliation agreement consisting solely of new urban teaching hospitals as new teaching hospitals can only affiliate to increase their cap.

However, as the concern about gaming would not apply to new teaching hospitals, CMS proposed to revise the regulations to specify that new urban teaching hospitals (e.g. hospitals that first began training residents on or after January 1, 1995) may form a Medicare GME affiliated group and therefore be eligible to receive both decreases and increases to their FTE caps only if the decrease results from being part of the Medicare GME affiliated group. CMS is finalizing this proposal without change.

In the final rule, CMS is also allowing new and existing teaching hospitals to enter into affiliation agreements. The existing teaching hospital's FTE cap may increase or decrease if the increase is occurring for resident slots from a new teaching hospital whose cap has been established for 5 years or more. In applying the 5-year waiting period, a new urban teaching hospital can lend FTE cap slots to an existing teaching hospital under a Medicare GME affiliation agreement, effective with the residency training year that is at least 5 years after the start of the hospital's cost reporting period that coincides with or follows the start of the sixth program year of the first new program.

Because Medicare GME affiliation agreements can only be entered into at the start of the July 1 academic year, CMS is making the change effective beginning with affiliation agreements entered into for the July 1, 2019 through June 30, 2020 residency training year. The change applies to both Medicare GME affiliation agreements and emergency Medicare GME affiliation agreements (special rules that allow hospitals not otherwise eligible to form an affiliated group to aggregate their caps when there is a public health emergency).

3. Comments/Responses

New Medical Residency Program: CMS was asked to clarify whether the term "new teaching hospital" means any hospital that has qualified for an adjustment for a new medical training program going back to 1995 or a hospital that is still in its cap building period. CMS responded that a "new teaching hospital" includes both a hospital that already completed its cap-building period and received its own permanent FTE caps (based on training residents in a new program(s) that received initial accreditation or began on or after January 1, 1995), or a hospital that at some point in the future will train residents for the first time in a new program and complete its cap building period and receive its own permanent FTE caps. At least one of the hospitals in an affiliated group must have an established cap as the caps do not apply to teaching hospitals in their cap building period.

CMS further indicates that hospitals without residents are able to participate in affiliated groups with teaching hospitals for training residents in existing programs. In this scenario, there are no new resident cap slots available and the cap for the existing teaching hospital can only decrease. Not mentioned is that such a policy could have permanent implications for the hospital that previously did not train residents such as the creation of an FTE cap based on residents in the existing program and establishment of a per resident amount at a time when the hospital has very low per resident training costs as it is only serving as a training site for a residency program based at another hospital. A hospital should enter into such an arrangement fully understanding that it may permanently disadvantage itself from being able to train residents in a future period.

Allowing New and Existing Teaching Hospitals to Affiliate After a Waiting Period: One commenter stated there are many teaching hospitals that started training programs after the 1996 caps were established. These hospitals have since become associated with larger teaching hospitals and medical schools. The commenter suggested that 10 years after the new teaching hospital first began training residents, CMS allow the hospital to lend cap slots to existing teaching hospitals that are part of related organizations. The 10-year period is consistent with the length of time a hospital must remain reclassified as rural in order to retain any increases to its

IME cap associated with being rural. Another commenter made a similar suggestion with the added feature of limiting the number of resident slots that a new hospital could lend to an existing hospital under an affiliation agreement.

CMS responded that it may be administratively difficult to ensure the term "related organizations" is applied consistently. It also felt there would be complexities with limiting the number of slots that could be subject to a reduction in an existing teaching hospital's resident cap as part of an affiliated group. However, CMS did agree with the idea of allowing a new teaching hospital to enter into an affiliation agreement with an existing teaching hospital that would allow the existing teaching hospital's FTE cap to increase if the increase is occurring for resident slots from a new teaching hospital whose cap has been established for 5 years or more.

4. Notice of Closure of a Teaching Hospital and Opportunity to Apply for Available Slots

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes.

Notice of Closure of Memorial Hospital of Rhode Island, Located in Pawtucket, RI, and the Application Process

CMS is notifying the public of the closure of Memorial Hospital of Rhode Island. The rule describes this closure as "Round 13" and includes the following information about Memorial Hospital of Rhode Island:

Round 11 Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
410001	Memorial Hospital of Rhode Island	Pawtucket, RI	39300	January 1, 2018	73.66	72.62

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the ACA is 90 days following notification to the public of a hospital closure (77 FR 53436). **Hospitals that wish to apply for and receive slots from the above hospital must submit applications (Section 5506 Application Form posted on Direct Graduate Medical Education (DGME) directly to the CMS Central Office no later than October 31, 2018. The mailing address for the CMS Central Office is included on the application form. Applications must be received, not postmarked, by the CMS Central Office by the October 31, 2018 deadline date.** The application is available at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.html

Hospitals should also access this same website for a list of the policies and procedures for applying for slots, and the redistribution of the slots.

The hospital must send a hard copy of the section 5506 slot application to the mailing address in the application. The hospital is strongly encouraged to notify the CMS Central Office of the mailed application by sending an email to: ACA5506application@cms.hhs.gov. In the email, the hospital should state:

> On behalf of [insert hospital name and Medicare CCN#], I, [insert your name], am sending this email to notify CMS that I have mailed to CMS a hard copy of a section 5506 application under Round 13 due to the closure of Memorial Hospital of Rhode Island. If you have any questions, please contact me at [insert phone number] or [insert your email address]."

An applying hospital should not attach an electronic copy of the application to the email. The email will only serve to notify the CMS Central Office to expect a hard copy application that is being mailed to the CMS Central Office.

CMS has not established a deadline by when it will issue determinations. However, CMS reviews all applications received by the deadline and will notify applicants as soon as possible.

L. Rural Community Hospital Demonstration Program

1. Background

Section 410A(a) of the Medicare Modernization Act 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 paid rural community hospitals in rural areas of 10 States with low population densities (as identified by the Secretary) reasonable cost for covered inpatient hospital services furnished to Medicare beneficiaries. The original demonstration was required to begin on January 1, 2005 and last five years. The ACA extended the program for an additional five years and the 21st Century Cures Act extended the program for five more years.

The ACA opened participation to hospitals in 20 states, and the 21st Century Cures Act expanded eligibility to hospitals in all states with priority being given to hospitals in the 20 states with lowest population densities. In selecting hospitals for participation in the demonstration, the Secretary may consider whether the hospital is located in an area where a hospital closed in the previous five years and the population density of the state where the hospital is located. On April 17, 2017, CMS issued a solicitation for applications to select additional rural community hospitals to participate in the demonstration during the 5-year 21st Century Cures Act extension period; 13 hospitals were selected to participate in the demonstration (referred to as "newly participating hospitals). One newly participating hospital withdrew from the demonstration bringing the total participation of previously participating and newly participating hospitals to 29 during FY 2018. Newly participating hospitals begin their 5-year participation period effective with the start of the first cost reporting period beginning on or after October 1, 2017.

2. Budget Neutrality Calculation

a. Background

For hospitals participating in the budget neutral, rural community hospital demonstration program, CMS uses a 3-step methodology to calculate the budget neutrality offset amount that is applied across aggregate IPPS payments. CMS calculates the budget neutrality offset amount by subtracting the sum of the estimated aggregate amount of payments to all hospitals participating in the demonstration program for covered inpatient hospital services, including the costs of swing bed services (if any), that would otherwise be made in the absence of the demonstration (calculated under Step 2 of the methodology) from the aggregate reasonable cost amount payments made to all such hospitals for those services estimated to be made under the demonstration (calculated under Step 1 of the methodology).

1. CMS identifies a general reasonable cost amount using hospital data for all participating hospitals from "as submitted" cost reports for the hospitals' cost reporting periods for the most recently available fiscal year.
2. CMS updates the estimated reasonable cost amounts for all hospitals under the demonstration by the *IPPS market basket percentage increases* for the fiscal year involved and the preceding two fiscal years, and multiplies that figure by a 3-percent annual volume adjustment for each fiscal year (Step 1).
3. CMS updates the estimated payments that would otherwise be made to those hospitals absent the demonstration by the *applicable percentage increases* for the fiscal year involved and the preceding two fiscal years and multiplies that figure by a 3-percent annual volume adjustment for each fiscal year (Step 2).

In the proposed rule, CMS said it was evaluating whether the 3-percent annual volume adjustment (which was intended to reflect the possibility that hospitals' inpatient caseload may increase) was appropriate in light of empirical trends specific to participating hospitals. CMS found an overall decline of Medicare inpatient discharges for the 17 previously participating hospitals of about 14 percent and for the 12 newly participating hospitals, CMS found an increase of about 1.7 percent. Considering the overall trend, the agency determines that the additional 3-percent adjustment is no longer justified. It eliminates the adjustment from the estimates of Steps 1 and 2 above.

Under the methodology, CMS also adds to the budget neutrality adjustment amount calculated above an amount equal to the difference between the actual and estimated costs of the demonstration for a fiscal year. The sum of these two amounts comprises the budget neutrality offset amount to the IPPS for the fiscal year for which a particular rulemaking cycle applies.

For FY 2016, CMS made modifications to the methodology to take into account that the demonstration program had begun to phase out by October 1, 2015. Specifically, in calculating the estimated reasonable cost amount and the estimated amount that would otherwise be paid without the demonstration for FY 2016, CMS excluded the financial experience of the hospitals that ended participation before October 1, 2015. In addition, for the 8 hospitals that would end their participation on a rolling basis before September 30, 2016, CMS prorated the FY 2016

estimated reasonable cost amounts and the estimated amounts that would otherwise be paid to the hospitals without the demonstration project based on the ratio of (i) the number of months the hospital participated in the project in FY 2016 to (ii) the FY 2016 12-month period. The methodology was unchanged for the 7 hospitals with end dates on or after September 30, 2016.

For FY 2017, because the demonstration had substantially phased out by October 1, 2016, CMS did not make any adjustment to the standardized amounts for the rural community hospital demonstration program. Of the 14 remaining hospitals participating, only 4 would participate past September 30, 2016 and only for the last quarter of calendar year 2016. Instead, CMS calculated the costs of the demonstration and the resulting budget neutrality factor for FY 2017 once the finalized cost reports for cost reporting periods beginning in FY 2016 became available. CMS had planned to reconcile the budget neutrality offset amounts for FYs 2011 through 2016 with the actual costs of the demonstration for those years at one time when all of the finalized cost reports for cost reporting periods beginning in those fiscal years became available. CMS anticipated doing the reconciliation in FY 2020.

b. FY 2018

The FY 2018 budget neutrality methodology is similar to the methodology CMS used before FY 2017. Generally, CMS estimates costs of the demonstration through "as submitted" cost reports and the appropriate update factors which would be incorporated into a budget neutrality offset amount applied to the national IPPS rates for the upcoming fiscal year. Additionally, CMS includes in the offset amount, the amount by which the actual costs of the demonstration exceeded the estimated costs for a given year (determined using finalized cost reports). However, CMS reflects demonstration costs for years before FY 2018 for previously participating hospitals that continued to participate.

Using finalized cost reports, CMS determines actual demonstration costs for cost reporting periods beginning on the day immediately following the last day of the hospitals' performance periods in the ACA extension period through the last day of the cost reporting periods ending in FY 2018. CMS said it would incorporate those costs in the budget neutrality offset amount in a future IPPS final rule, and determine actual demonstration costs for all hospitals participating during the Cures Act extension period in the same fiscal year.

For FY 2018, CMS bases costs on as submitted cost reports and applies a hospital-specific prorating factor and appropriate updates. The hospital-specific prorating factor for FY 2018 (for hospitals with a cost reporting period start date after October 1, 2017) is the ratio of the number of months between the end of the cost reporting period ending in FY 2018 and the end of the fiscal year, to 12. For newly participating hospitals, CMS will follow the same budget neutrality methodology described earlier. As noted earlier, CMS does not apply the 3-percent volume adjustment to these estimates.

For the final rule, the estimated cost of the demonstration for FY 2018 is $31,070,880 which CMS includes in the budget neutrality offset adjustment for FY 2019. This amount takes into account the one hospital that withdrew from the demonstration and the agency's decision to no longer apply the 3-percent volume adjustment.

c. FY 2019

For FY 2019, the budget neutrality methodology will be similar to the FY 2018 budget neutrality methodology. CMS estimates the costs of the demonstration using the FY 2018 methodology with differences. CMS uses the same "as submitted" cost reports to estimate FY 2019 preliminary cost and payments amounts, but it updates those FY 2019 amounts by the final FY 2019 market basket percentage increase and applicable percentage increase. CMS omits the 3-percent volume adjustment. CMS does not use hospital-specific prorating factors for FY 2019 since it expects all participating hospitals to participate in the demo for the entire 12-month period of FY 2019. As a result, the estimated demonstration costs for FY 2019 are $70,929,313 (which also takes into account the one hospital that withdrew from the demonstration) which CMS includes in the budget neutrality offset adjustment.

To meet the budget neutrality requirement for the second 5-year extension period, CMS will determine the actual costs of the demonstration from finalized cost reports of previously and newly participating hospitals when they become available and include the difference between actual and estimated costs as an adjustment to the upcoming year's final rule.

CMS includes the difference between actual and estimated costs for the demonstration for FYs 2011, 2012 and 2013 in the budget neutrality offset adjustment to the national IPPS rates for FY 2019.

3. Reconciling Actual and Estimated Demonstration Costs for Previous Years (2011, 2012, and 2013)

As noted above, before enactment of the 21st Century Cures Act additional 5-year extension, CMS had planned to reconcile the budget neutrality offset amounts for FYs 2011 through 2016 with the actual costs of the demonstration for those years at one time when all of the relevant finalized cost reports became available. CMS had anticipated doing so in FY 2020. Because of the 21st Century Cures Act extension, CMS reverts to its general procedure to reconcile estimated and actual demonstration costs. Thus, as finalized cost reports become available, CMS will determine the difference between actual and estimated costs of the demonstration for the fiscal year involved.

CMS adjusts the budget neutrality offset amount by the combined differences between actual and estimated costs of the demonstration as indicated on finalized cost reports for FYs 2011, 2012 and 2013. For FYs 2011, 2012 and 2013, actual costs of the demonstration were less than estimated costs by $29,971,829, $8,500,373, and $5,398,382, respectively.

4. Total Final Budget Neutrality Offset Amount for FY 2019

The total budget neutrality offset amount for FY 2019 is $58,129,609, calculated as the sum of Steps 1 and 2 less the sum of Steps 3, 4 and 5 as follows:

Step 1. $31,070,880 (which is the difference between the sum of estimated reasonable cost amounts paid under the demonstration for FY 2018 to participating hospitals and the sum of

the estimated amount of payments that would otherwise be made to such hospitals absent the demonstration).
Step 2. $70,929,313 (which is the difference between the sum of estimated reasonable cost amounts paid under the demonstration for FY 2019 to participating hospitals and the sum of the estimated amount of payments that would otherwise be made to such hospitals absent the demonstration).
Step 3. $29,971,829 (which is the difference between actual and estimated costs of the demonstration for FY 2011).
Step 4. $8,500,373 (which is the difference between actual and estimated costs of the demonstration for FY 2012).
Step 5. $5,398,382 (which is the difference between actual and estimated costs of the demonstration for FY 2013).

CMS notes that it will incorporate the actual costs of the demonstration for previously participating hospitals for FYs 2015, 2016 and 2017 into a single amount which will be included in the budget neutrality offset amount for a future fiscal year, which CMS expects might be FY 2020 or FY 2021.

M. Hospital Inpatient Admission Orders Documentation Requirements

1. Background

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50938 through 50942), CMS codified through regulations at 42 CFR §412.3 the longstanding policy that a beneficiary becomes a hospital inpatient if formally admitted pursuant to the order of a physician (or other qualified practitioner as provided in the regulations) in accordance with the hospital conditions of participation (CoPs). CMS required that a written inpatient admission order be present in the medical record as a specific condition of Medicare Part A payment. In the extremely rare circumstance the order to admit is missing or defective, yet the intent, decision, and recommendation of the ordering physician or other qualified practitioner to admit the beneficiary as an inpatient can clearly be derived from the medical record, medical review contractors are provided with discretion to determine that this information constructively satisfies the requirement that a written hospital inpatient admission order be present in the medical record.

2. Revisions Regarding Admission Order Documentation Requirements

CMS expresses concern that some otherwise medically necessary inpatient admissions are being denied payment due to technical discrepancies with the documentation of inpatient admission orders. Common technical discrepancies consist of missing practitioner admission signatures, missing co-signatures or authentication signatures, and signatures occurring after discharge. CMS has concluded that if the hospital is operating in accordance with the hospital CoPs, medical reviews should primarily focus on whether the inpatient admission was medically reasonable and necessary rather than occasional inadvertent signature documentation issues unrelated to the medical necessity of the inpatient stay. It was not CMS' intent that order documentation requirements themselves should lead to the denial of payment for an otherwise medically reasonable necessary inpatient stay, even if such denials occur infrequently.

CMS is eliminating the requirement that a physician order must be present in the medical record and be supported by the physician admission and progress notes, in order for the hospital to be paid for hospital inpatient services under Medicare Part A. Hospitals and physicians are already required to document relevant orders in the medical record to substantiate medical necessity requirements. If other available documentation, such as the physician certification statement (when required), progress notes, or the medical record as a whole, supports that all the coverage criteria (including medical necessity) are met, and the hospital is operating in accordance with the CoPs, CMS believes it is no longer necessary to also require specific documentation of inpatient admission orders as a condition of Medicare Part A payment. CMS' revised policy does not change the requirement that an individual is considered an inpatient if formally admitted as an inpatient under an order for inpatient admission.

3. Comments/Responses

General Comments: While there were comments in support of the proposal, many commenters raised specific concerns about the change including:

- Whether CMS would not be able to distinguish between orders that were simply defective and orders that were intentionally not signed;
- Concerns about whether in the absence of an inpatient order, patients would be knowledgeable about their appeals rights and financial liability;
- Whether coverage of SNF services would be at risk due to issues such as lack of clarity in the medical record or a MAC's misinterpretation of physician intent;
- Whether admission orders are now optional;
- Whether a patient can be admitted after receiving 2 midnights of observation care after the patient is discharged from the hospital;
- Whether there is any change to the requirements for who can admit patients;
- How inpatient only procedures are affected by the absence of an order;
- Whether CMS will provide a list of permissible technical discrepancies with inpatient admission orders; and
- Concerns that the policy presents a problem for the capture of specific data elements necessary for compliance with electronic clinical quality measures.

CMS's general response to these concerns was that its policy does not change the requirement that, for purposes of Part A payment, an individual becomes an inpatient when formally admitted as an inpatient under an order for inpatient admission. The physician order remains a significant requirement because it reflects a determination by the ordering physician or other qualified practitioner that hospital inpatient services are medically necessary and initiates the process for inpatient admission. The medical record as a whole should reflect whether there was a decision by a physician or other qualified practitioner to admit the beneficiary as an inpatient or not. The absence of a valid admission order by itself is insufficient to deny Part A payment. For all of the above issues, CMS indicates that its policy is unchanged as the only change is that an inpatient order is not being required as a specific condition of payment.

Medical Review: Some commenters stated that because of perceived uncertainty and lack of clarity in comparing previous policy to the new policy that CMS should incorporate precise instructions into post-discharge medical review instructions for audits performed by Medicare contractors. The commenters expressed concern that inpatient admissions will still be denied based solely on timeliness or completion of the attending physician's order and that other Medicare regulations will be referenced as the source of denial.

CMS responded that it will continue to stay engaged with medical review contractors so that there is awareness and understanding of CMS' revised policy on this issue. CMS may revise manuals and/or issue additional sub-regulatory guidance as needed.

Effective Date: There were comments asking whether CMS is clarifying or changing the policy. A clarification would have retroactive effect while a change in policy is effective prospectively. CMS responded that its policy requiring the inpatient admission order as a specific condition of payment is effective prospectively for dates of admission occurring on or after October 1, 2018. Previous manual guidance applies to dates of admission before October 1, 2018. This guidance indicates that it is within the discretion of the medical reviewer to determine that the requirement for the order is constructively met if the intent to admit the patient is clear and it otherwise would have been reasonable and necessary to treat the patient on an inpatient basis.

Other Payment Systems: Commenters requested that CMS make analogous changes to inpatient rehabilitation and psychiatric facility admissions. CMS will take this comment into consideration in future rulemaking.

V. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2019. For FY 2018, CMS established a national capital Federal rate of $453.95. For FY 2019, CMS is establishing a national capital Federal rate of $459.72.

Update Factor:

For FY 2019, CMS is increasing the national capital Federal rate by 1.4 percent based on the capital input price index (CIPI) of 1.4 percent after considering other factors shown in Table 1 below. Real across DRG case mix change and projected case-mix change net to a 0.0 adjustment for case mix. There is no adjustment for FY 2017 reclassification and recalibration or forecast error correction.

Table 1

FY 2019 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE	
CIPI	1.4
Intensity	0.0
Case-Mix Adjustment Factors:	
Real Across DRG Change	0.5
Projected Case-Mix Change	0.5
Net Case-Mix Adjustment (Projected - Real)	0.0
Subtotal	1.4

FY 2019 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE	
Effect of FY 2017 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Proposed Update	1.4

Other Adjustments:

The FY 2019 budget neutrality adjustment factor which is applied to the national capital Federal rate for changes in the MS-DRG classifications and relative weights and changes in the geographic adjustment factors (GAFs) is 0.9975; this adjustment in FY 2018 was 0.9987.

The FY 2019 outlier adjustment factor is 0.9494, compared to 0.9483 in FY 2018. The outlier reduction factor is not built permanently into the capital rate each year; that is, it is not applied cumulatively in determining the national capital Federal rate. The FY 2019 outlier adjustment of 0.9494 yields a net change in the outlier adjustment to the national capital Federal rate for FY 2019 compared to FY 2018 of 1.0051 (0.9494/0.9483), which is a 0.12 percent change. Thus, the outlier adjustment increases the FY 2019 national capital Federal rate by 0.12 percent.

Final Calculation:

The final rule includes the following table to show how each of the factors and adjustments affects the computation of the FY 2019 national capital Federal rate in comparison to the FY 2018 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2018 Capital Federal Rate and FY 2019 Capital Federal Rate

	FY 2018	FY 2019	Change	Percent Change
Update Factor*	1.0130	1.0140	1.0140	1.40
GAF/DRG Adjustment Factor*	0.9987	0.9975	0.9975	-0.25
Outlier Adjustment Factor**	0.9483	0.9494	1.0012	0.12
Capital Federal Rate	$453.95	$459.72	1.0127	1.27

* The update factor and the GAF/DRG budget neutrality adjustment factor are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2018 to FY 2019 resulting from the application of the 0.9975 GAF/DRG budget neutrality adjustment factor for FY 2018 is a net change of 0.9975 (or -0.25 percent).
** The outlier adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2019 outlier adjustment factor is 0.9494/0.9483, or 1.0012 (or 0.12 percent).

Considering the update factor and the budget neutrality adjustments, CMS establishes a national capital Federal rate for FY 2019 equal to $459.72, representing a 1.27 percent increase over the FY 2018 rate of $453.95.

Exception Payments. The rule continues exception payments if a hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control.

New Hospitals. Medicare defines a "new hospital" as a hospital that has operated for less than 2 years. CMS notes that a new hospital is paid 85 percent of its Medicare allowable capital-related reasonable costs through the first 2 years of operation unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate.

VI. Changes for Hospitals Excluded from the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals

Based on IGI's 2018 second quarter forecast, CMS is setting a 2.8 percent rate-of-increase for FY 2019 to the target amount for cancer hospitals, children's hospitals, and religious nonmedical health care institutions, as well as for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. The FY 2019 rate-of-increase percentage would be applied to the FY 2018 target amounts to calculate the FY 2019 target amounts for these hospitals.

B. Changes to Regulations Governing Satellite Facilities

Hospitals within Hospitals

42 CFR §422.22(e) defines a "hospital-within-a-hospital (HwH)" as "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." To ensure that an HwH is separate and distinct from the hospital that it is within, CMS has established "separateness and control requirements." Effective October 1, 2017, CMS only requires HwHs to meet the separateness and control requirements when an IPPS excluded hospital (such an LTCH, children's or cancer hospital) is within an IPPS hospital. The separateness and control requirements do not have to be met when an IPPS excluded hospital is within another IPPS excluded hospital.

Satellites within IPPS-exempt Hospitals and Units

42 CFR §422.22(h) defines a "satellite" as "a part of a hospital that provides inpatient services in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital." The satellite could also be within an IPPS-excluded unit (e.g. a satellite of an IPPS-excluded rehabilitation or psychiatric unit) of an IPPS-excluded hospital (e.g. a LTCH, children's or cancer hospital). Effective October 1, 2018, CMS is applying the same separateness and control rules to satellites within IPPS hospitals and units as it does for HwHs.

Public commenters were generally supportive of CMS' proposal. Some commenters requested that CMS go beyond its proposal and also exempt satellites from rules which form the basis of their exclusion from the IPPS. CMS declined to exempt satellites from these additional rules and noted that doing so would make them subject to less restrictive rules than HwHs and would be inconsistent with CMS's goals to align the two categories of facilities. CMS is finalizing its proposals without modification.

HwHs and Satellites Remain Subject to CoPs

CMS cautions that payment rules, such as the HwH and satellite facility rules, do not waive or supersede the requirement that all hospitals must comply with the CoPs. All hospitals, regardless of payment status, must always demonstrate separate and independent compliance with the hospital CoPs, even when an entire hospital or a part of a hospital is located in a building also used by another hospital, or in one or more entire buildings located on the same campus as buildings used by another hospital.

Grandfathered IPPS-Excluded Satellites

The final rule further indicates that the new policy would not affect IPPS-excluded satellite facilities that are co-located with IPPS hospitals that are currently grandfathered under 42 CFR §412.22 (h)(2)(iii)(A)(2). Those satellite facilities would continue to maintain their IPPS-excluded status without complying with the separateness and control requirements so long as all applicable requirements at 42 CFR §412.22(h) are met.

C. Changes to Regulations Governing Excluded Units of Hospitals

Under existing regulations at 42 CFR §412.25, an excluded psychiatric or rehabilitation unit cannot be part of an institution that is excluded in its entirety from the IPPS. This policy was adopted because it would have been redundant to allow an IPPS-excluded hospital to have an IPPS-excluded unit because both the hospital and the unit would have been paid under the same payment system methodology (reasonable costs subject to a per discharge limit or target amount). In addition, CMS was concerned about the possibility of IPPS-excluded hospitals artificially inflating their target amounts by operating IPPS-excluded units (58 FR 46318).

Given the introduction of prospective payment systems for both inpatient rehabilitation facilities and units (collectively IRFs) and psychiatric hospitals and units (collectively IPFs), CMS no longer believes it is redundant for an IPPS-excluded hospital to have an IPPS-excluded unit, nor is it possible for IPPS-excluded hospitals to use units to artificially inflate their target amounts, because Medicare payment for discharges from the units would not be based on reasonable cost.

CMS is revising 42 CFR §412.25(a)(1)(ii) to specify that effective with cost reporting periods beginning on or after October 1, 2019, an IPPS-excluded hospital will be permitted to have an excluded psychiatric and/or rehabilitation unit. In addition, CMS is revising 42 CFR §412.25(d) to specify that an IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital (for example, an IRF may not have an IRF unit). CMS believes that this change would be consistent with the current preclusion in 42 CFR §412.25(d) that prevents one hospital from having more than one of the same type of IPPS-excluded unit.

The rule indicates that an IPPS-excluded hospital operating an IPPS-excluded unit must continue to be in compliance with other Medicare regulations and CoPs applicable to the hospital or unit. Noncompliance with any of the hospital CoPs at 42 CFR §482.1 through §482.58 at any part of a certified hospital represents noncompliance for the entire Medicare-certified hospital. For

example, the CoPs that govern IPFs would apply to an IPF that operates an excluded rehabilitation unit, and those CoPs require that certain psychiatric treatment protocols apply to every IPF patient (including those in the rehabilitation unit).

CMS is making these regulatory changes effective for cost reporting periods beginning on or after October 1, 2019, to allow sufficient time for both CMS and IPPS-excluded hospitals to make the necessary administrative and operational changes to fully implement the changes. Public comments supported this proposal but asked that it be implemented for cost reporting periods beginning on or after October 1, 2018 and not cost reporting periods beginning on or after October 1, 2019. CMS declined to adopt this suggestion "given the administrative and operational changes that must be made in order to fully implement this policy."

Some commenters opposed this proposal indicating that it is unfair for an LTCH to have a rehabilitation unit but not allow a rehabilitation hospital to have an LTCH unit. Others were concerned about the impact on patient care indicating the policy would be inconsistent with the CoPs which do not allow hospitals to jointly meet health and safety regulations. CMS rejected these comments noting there is no provision in law that allows for an LTCH unit and the rule specifically notes that a unit of an excluded hospital would have to meet the CoPs independently based on the its type of unit.

D. Report on Exception Payments

Section 4419(b) of the Balanced Budget of 1997 requires the Secretary to publish annually in the *Federal Register* a report describing the total amount of adjustment payments made to excluded hospitals and hospital units during the previous fiscal year. CMS furnished a table in the final rule showing it made exception payments totaling $8.8 million to 5 IPPS exempt hospital in FY 2017.

E. Critical Access Hospitals (CAHs)

The FCHIP Demonstration is designed to develop and test new models of care for 10 participating CAHs in Montana, Nevada, and North Dakota beginning August 1, 2016. The law requires the demonstration to be budget neutral. CMS would recoup any additional expenditures attributable to the FCHIP through a reduction in payments to CAHs nationwide. 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 2019.

VII. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

A. Background

Section 1206 of Pathway for SGR Reform Act established a dual-rate payment structure for LTCHs beginning in FY 2016. "LTCH PPS standard federal payment rate case" refers to cases where the criteria for site neutral payment rate exclusion are met and "site neutral payment rate case" refers to any LTCH PPS case when the criteria are not met. Site neutral cases will be paid an IPPS comparable amount. The criteria for exclusion from the site neutral payment are:

1. Case cannot have a principal diagnosis relating to a psychiatric diagnosis or rehabilitation (the DRG criterion); and
2. Either:
   (a) Case must be immediately preceded by discharge from an acute care hospital that included at least 3 days in an intensive care unit (the ICU criterion); or
   (b) Case must be immediately preceded by discharge from an acute care hospital and the LTCH discharge must be assigned to an MS-LTC-DRG based on the beneficiary's receipt of at least 96 hours of ventilator services in the LTCH (the ventilator criterion).

For FY 2016 and FY 2017, site neutral cases were paid based on a blended payment rate comprised of 50 percent of the IPPS comparable amount and 50 percent of the LTCH PPS standard Federal payment rate. Section 51005 of the BBA 2018 extended the transitional blended payment rate for site neutral payment rate cases for discharges occurring in cost reporting periods beginning in FYs 2018 and 2019.

CMS is updating the LTCH PPS as follows:

Summary of Changes to LTCH PPS Rates for FY 2019*	
Standard Federal Rate, FY 2018	$41,415.11
Rule Update factors	
Update as required by Section 1886(m)(3)(C) of the Act	+1.35%
Penalty for hospitals not reporting quality data	-2.0%
Net update, LTCHs reporting quality data	+1.35% (1.0135)
Net update, LTCHs not reporting quality data	-0.65% (0.9935)
Rule Adjustments	
Wage index budget neutrality adjustment	0.999713
Budget neutrality adjustment to eliminate the 25 percent threshold policy	0.990884
Standard Federal Rate, FY 2019	
LTCHs reporting quality data ($41,415.11∗1.0135∗0.999713*0.990884)	$41,579.65
LTCHs not reporting quality data ($41,415.11*0.9935*0.999713*0.990884)	$40,759.12
Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$27,124
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$25,769
Impact of Policy Changes on LTCH Payments in FY 2019	
Total estimated impact	0.9% ($39 million)
LTCH standard federal payment rate cases (64% of LTCH cases)	1.0% ($35 million)
Site neutral payment rate cases (36% of LTCH cases)**	0.4% ($4 million)
*More detail is available in Table IV, "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for Standard Payment Rate Cases for FY 2019." Table IV does not include the impact of site neutral payment rate cases. ** LTCH site neutral payment rate cases are paid a rate that is based on the lower of the IPPS comparable per diem amount or 100 percent of the estimated cost of the case.	

B. LTCH PPS MS-DRGs and Relative Weights

1. Background

The annual recalibration of the MS-LTC-DRG relative weights for FY 2019 is determined using data only from claims qualifying for LTCH PPS standard federal rate payment and claims that would have qualified if that rate had been in effect. FY 2019 relative weights are from the March 2018 update of the FY 2017 MedPAR file exclusive of LTCH cases meeting the site neutral payment criteria. The data are trimmed to exclude all-inclusive rate providers, Medicare Advantage claims, and demonstration project participants, yielding the "applicable LTCH data." The applicable LTCH data are used with Version 36 of the GROUPER to calculate the FY 2019 MS-LTC-DRG relative weights.

2. Patient Classification into MS-LTC-DRGs and Development of Relative Weights

CMS is continuing to use the MS-DRG system as the basis for the MS-LTC-DRGs. It is also continuing to use its current methodology and established policies related to the hospital-specific relative-value methodology, volume-related and monotonicity adjustments, and the steps for calculating the relative weights with a budget neutrality factor.

C. Application of the Site Neutral Payment Rates

Section 51005 of the BBA 2018 extended the transitional blended payment rate for site neutral payment rate cases for 2 years for discharges occurring in cost reporting periods beginning in FYs 2018 and 2019. In addition, section 51005(b) of the BBA 2018 specifies that the IPPS comparable amount used in the transitional blended payment shall be reduced by 4.6 percent for FYs 2018 through 2026.

CMS is implementing this provision by reducing the IPPS comparable amount used in the transitional site neutral payment by 4.6 percent effective for discharges occurring on October 1, 2017 through September 30, 2026 (e.g. on the basis of a federal fiscal year). If a hospital's cost reporting period begins on January 1, 2018, the 2-year extension in the transitional payment amount will be effective for discharges occurring on or after January 1, 2018 through December 31, 2019. However, the reduction in the IPPS comparable amount used in determining the transitional site neutral payment will be effective beginning 3 months earlier—for discharges occurring on or after October 1, 2017 and on or before September 30, 2026.

Public comments opposed applying the 4.6 percent adjustment to the IPPS comparable amount on the basis of a federal fiscal year rather than a cost reporting period that matches the 2-year extension of the blended site neutral payment amount. Commenters stated that applying the 4.6 percent payment reduction based on the federal fiscal year is inconsistent with CMS' previous implementation of other statutes and related LTCH provisions found in the same section of the statute. Some commenters asked CMS examine the legislative intent of the provision and delay its implementation until FY 2020.

CMS responded that the statutory language is clear that the 4.6 percent payment reduction is for discharges in federal fiscal years 2018 through 2026 without reference to cost reporting periods. The transitional blended payment provision under section 51005(a) specifically states that the payments are to be made based on discharges in the individual hospital's cost reporting period beginning in a particular fiscal year. As the statutory language is clear, CMS believes it is determinative of the statutory intent and it does not have authority to delay implementation of the reduction to the IPPS comparable amount until FY 2020.

While CMS agrees that the application of the 4.6 percent payment reduction on a federal fiscal year basis is not the same as surrounding areas of the statute, CMS states that the clear distinction in the statutory language supports its implementation of the statute. CMS responds to specific examples where commenters suggested CMS is applying the policy in this context differently than others, specifically with respect to Medicare DSH and uncompensated care payments and various moratoria on the establishment of LTCHs.

D. LTCH PPS Payment Rates and Other Changes

1. Overview LTCH PPS Payment Rate Adjustments

LTCH discharges meeting the site neutral payment rate exclusion criteria are paid based upon the LTCH PPS standard federal payment rate. Site neutral payment rate cases are paid based on the lower of the IPPS comparable per diem amount rate or 100 percent of the estimated cost of the cases.

2. Annual Update for LTCHs

The update is equal to the 2013-based LTCH market basket of 2.9 percent less 0.8 percentage points for multifactor productivity and -0.75 percentage points required by statute. For LTCHs failing to submit data to the LTCH Quality Reporting Program (QRP), the annual update would be reduced by 2.0 percentage points. The LTCH update for FY 2019 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	2.9%	2.9%
Multifactor Productivity	-0.8	-0.8
Statutory Factor	-0.75	-0.75
Quality Data Adjustment	0.0	-2.0
Total	1.35%	-0.65%

3. Area Wage Levels and Wage Index

CMS is computing the wage index in a manner that is consistent with prior years and adopting a wage level budget neutrality adjustment of 0.999713.

4. Budget neutrality adjustment to eliminate the 25 percent threshold policy

CMS is adopting a budget neutrality adjustment of 0.990884 for FY 2019 for elimination of the 25 percent policy. (More details on this adjustment in section VII. E.)

5. Cost-of-Living (COLA) Adjustment

To account for higher living costs, a COLA is provided to LTCHs in Alaska and Hawaii. The COLA is determined by comparing Consumer Price Index growth in Anchorage, Alaska and Honolulu, Hawaii to that of the average U.S. city. The COLA is capped at 25 percent and updated every 4 years. Below are the FY 2019 COLAs:

Cost-of-Living Adjustment Factors for Alaska and Hawaii	FY 2019
Alaska	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.25
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.25
City of Juneau and 80-kilometer (50-mile) radius by road	1.25
All other areas of Alaska	1.25
Hawaii	
City and County of Honolulu	1.25
County of Hawaii	1.21
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

6. High-Cost Outlier (HCO) Case Payments

Section 1886(m)(7)(A) of the Act requires CMS to reduce the LTCH standard federal payment rate by 8 percent for outliers. Section 1886(m)(7)(B) requires CMS to set the outlier threshold such that estimated outlier payments equal 7.975 percent of the estimated aggregate payments for standard federal payment rate cases. Consistent with the statute, CMS established an HCO threshold of $27,124. The HCO payment continues to equal 80 percent of the difference between HCO threshold and the estimated costs of the case.

The FY 2019 fixed-loss amount of $27,124 is lower than the $30,639 threshold that CMS proposed. Public comments expressed concern about the impact on the proposed rule threshold from a hospital with a very high CCR (1.029) drawing 2.65 percent of all outlier payments despite accounting for only 0.116 percent of all LTCH PPS standard federal payments. CMS responded that, although it believes that it was validly using that provider's information to set the proposed rule fixed loss amount, the threshold for the final rule declined from using later CCR data (March 2017 update to the FY 2017 provider-specific file) that resulted in the provider's CCR being 0.323 instead of 1.029.

CMS estimates that the current FY 2018 HCO threshold of $27,381 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases of approximately 7.4 percent of estimated total LTCH PPS payments in FY 2018, which is below the 7.975 percent target by approximately 0.6 percentage points.

For site neutral cases, CMS is establishing a fixed-loss amount of $25,769. CMS is again applying a 5.1 percent reduction to the site neutral payment rate to account for the estimated additional HCO payment for site neutral cases in FY 2019. Some commenters continue to object to this adjustment saying that it results in savings, not budget neutrality on site neutral cases because the budget

neutrality adjustment for outliers to the IPPS standardized amount already accounts for the additional HCO payments that will made to site neutral cases. CMS disagrees and refers commenters to its response on this issue in earlier rules (82 FR 38545 through 38546, 81 FR 57308 through 57309, and 80 FR 49621 through 49622).

7. LTCH PPS Updates Related to IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS is continuing its policy that calculation of the "IPPS comparable amount" (42 CFR §412.529) and the "IPPS equivalent amount" (§412.534 and §412.536) include an applicable operating Medicare DSH and uncompensated care payment amount. For FY 2019, the DSH/uncompensated care amount equals 75.63 percent of the operating Medicare DSH payment amount, based on the statutory Medicare DSH payment formula prior to the amendments made by the ACA adjusted to account for reduced payments for uncompensated care resulting from expansion of the insured population under the ACA.

E. Elimination of the "25-Percent Threshold Policy" Adjustment

The "25 percent threshold policy" is a per discharge payment adjustment in the LTCH PPS that is applied to payments for Medicare 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 metropolitan statistical area 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 paid at an IPPS comparable amount (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). CMS later expanded the 25 percent threshold policy beginning in 2008 to include all LTCHs and LTCH satellite facilities (72 FR 26919 through 26944). Several laws delayed implementation of the 25 percent threshold policy. CMS delayed application of the 25 percent policy by regulation for FY 2018.

Since the introduction of the site neutral payment rate in FY 2016, many public commenters have asserted that the new site neutral payment rate would alleviate the policy concerns underlying the establishment of the 25 percent threshold policy. CMS has considered these requests and took note of the significant changes to LTCH admission practices and the LTCH PPS payment structure since the advent of the 25 percent threshold policy's adoption, such as the introduction of the site neutral payment rate beginning in FY 2016. One effect of these changes is the creation of a financial incentive for LTCHs to limit admissions according to the criteria for payment at the LTCH PPS standard Federal payment rate. While these changes do not specifically address the regulatory requirement that an LTCH may not act as an IPPS step-down unit, CMS believes that the creation of these financial incentives likely results in LTCH providers closely considering the appropriateness of admitting a potential transfer to an LTCH

setting, regardless of the referral source, thereby lessening the concerns that led to the introduction of the 25 percent threshold policy.

As a result of its review, CMS is eliminating the 25 percent threshold policy. Independent of elimination of the 25 percent policy, CMS believes that aggregate LTCH PPS payments are sufficient. CMS cites MedPAC reports from 2011 through 2018 as its basis for this statement. Therefore, it does not believe that it would be appropriate to change the aggregate amount of LTCH PPS payments on a permanent basis from eliminating the 25 percent threshold policy. The 25 percent threshold policy would have reduced LTCH PPS payments for certain discharges. Therefore, eliminating the 25 percent threshold policy would be expected to result in an increase in aggregate LTCH PPS payments.

As a result, CMS is making adjustments to make elimination of the 25 percent policy budget neutral. CMS cites section 123 of the Balanced Budget Refinement Act, as amended by section 307(b) of the Medicare Benefits Improvement and Protection Act as its authority to make this adjustment.

Commenters supported eliminating the 25 percent threshold policy but opposed the corresponding budget neutrality adjustment stating: 1) CMS has not recovered payments for violations of the 25 percent threshold policy and, therefore, it would be incorrect to state that eliminating the 25 percent threshold policy would increase Medicare spending; 2) LTCHs would adjust to a fully implemented 25 percent threshold policy, thereby minimizing the penalty amount; (3) implementation of the site neutral payment rate has led to yearly decreases in LTCH payments from FY 2016 to FY 2019 due to a reduction in the overall volume of LTCH cases and this decrease in LTCH payments eliminates the need for any further budget neutrality adjustments; and 4) the statutory delay in FY 2017 (and prior years) and the regulatory delay in FY 2018 in full implementation of the 25 percent threshold policy were never paired with a budget neutrality adjustment and, therefore, an adjustment as a result of the elimination of the policy is unwarranted.

CMS responded that if the 25 percent threshold policy were to go into full effect, it would reduce the LTCH PPS payments for certain discharges; therefore, elimination of the 25 percent threshold policy would necessarily result in an increase in aggregate LTCH PPS payments. A budget neutrality adjustment is necessary to ensure that the elimination of the 25 percent threshold policy does not increase aggregate LTCH PPS payments in FY 2019 and future years. Past decisions not to apply a budget neutrality adjustment does not preclude the need for future adjustments as those past extensions did have a cost to Medicare. CMS acknowledged potential behavioral changes that could minimize the penalty amount; it also provided examples of behavioral changes that could potentially result in LTCHs treating more site-neutral cases above the 25 percent threshold increasing the cost of eliminating the policy. The budget neutrality adjustment will be based on 2017 LTCH claims data with no assumptions about behavioral change.

Other commenters state that the budget neutrality adjustment overstates the cost of eliminating the 25 percent threshold policy by failing to reflect the phase-out of the transitional blended rates to site neutral rate cases. CMS agrees that its proposed budget neutrality adjustment did not take

into account that site neutral payment rate cases will no longer be paid based on a transitional blended payment basis in FY 2020 and subsequent years, and, therefore, applying a single one-time permanent budget neutrality adjustment would overly reduce payments for FY 2020 and beyond. To address this, CMS modifies its methodology for calculating the budget neutrality adjustment.

Using the March 2018 update of the FY 2017 MedPAR files, CMS estimates that eliminating the 25 percent threshold policy will increase aggregate LTCH PPS payments by approximately $35 million (compared to $36 million in the proposed rule) in FY 2019; $33 million in FY 2020 (during the rolling end of the transitional blended payment rate for site neutral payment rate cases); and $28 million in FY 2021 and subsequent years. CMS is applying budget neutrality adjustment factors of:

- For FY 2019, a temporary, one-time factor of 0.990884 (-0.91 percent);
- For FY 2020, a temporary, one-time factor of 0.990741 (-.093 percent); and
- For FY 2021 and subsequent years, a permanent, one-time factor of 0.991249 (-0.88 percent).

The final rule details the methodology for determining these adjustments including how to account for ending of the blended payments on the basis of cost reporting periods.

F. Impact of Payment Rate and Policy Changes to LTCH PPS Payments

1. CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the payment rate and policy changes, for all LTCHs from FY 2018 to FY 2019, will be an increase 0.9 percent or $39 million in aggregate payments (from $4.502 billion to $4.540 billion). This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard federal payment rate cases of approximately 1.0 percent ($35 million) and a projected increase in payments to site neutral payment rate cases of 0.4 percent (approximately $4 million).

CMS modeling assumes that approximately 64 percent of LTCH cases would be paid the LTCH PPS standard federal payment rate and 36 percent of LTCH cases would be paid the site neutral payment rate. The increase in LTCH PPS standard federal payment rate cases results from the 1.35 percent update and the -0.9 percent one-time temporary budget neutrality adjustment for the elimination of the 25 percent threshold policy and an estimated 0.6 percent increase in HCO payments resulting from FY 2018 HCO payments being less than the target and FY 2019 payments being set such that HCO payments equal the target.

Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for Standard Payment Rate Cases for FY 2019" in the final rule shows the detailed impact by location, participation date, ownership type, region, and bed size for only LTCH PPS standard federal payment rate cases and does not include the detailed impact in payments for site neutral payment rate cases.

The overall impact of LTCH PPS standard federal payment rate cases is estimated to result in an increase in aggregate LTCH payments in FY 2019 relative to FY 2018 of approximately $35 million or 1.0 percent. CMS reports that regional differences in impacts are largely due to updates to the wage index.

Summary of Impact of Changes to LTCH PPS for Standard Federal Payment Rate Cases for FY 2019*		
LTCH Classification	**Number of LTCHs**	**Estimated percent change in payments per discharge**
All LTCH providers	409	1.0%
By Location:		
Rural	21	0.9%
Urban	388	1.0%
By Ownership Type:		
Voluntary	77	1.6%
Proprietary	319	0.9%
Government	13	1.5%
By Region		
New England	12	0.3%
Middle Atlantic	24	1.2%
South Atlantic	66	1.0%
East North Central	68	0.7%
East South Central	36	1.1%
West North Central	28	1.0%
West South Central	120	0.9%
Mountain	26	0.4%
Pacific	29	1.9%
*More detail is available in Table IV, "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for Standard Federal Payment Rate Cases, For FY 2019," (see page 2,537 of display copy).		

2. Tables

The complete set of tables providing detail on the LTCH PPS for FY 2019 is at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/LTCHPPS-Regulations-and-Notices-Items/LTCH-PPS-CMS-1694-F.html?DLPage=1&DLEntries=10&DLSort=3&DLSortDir=descending

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the final rule, substantial changes are made to the quality reporting programs that apply to acute inpatient hospital stays, PPS-exempt cancer hospitals, and long-term care hospitals. In addition, extensive changes are made to the meaningful use regulatory requirements associated with the Health Information Technology for Economic and Clinical Health (HITECH) Act.

A. Hospital Inpatient Quality Reporting (IQR) Program

CMS finalizes its proposal to remove 39 measures from the Hospital IQR Program for the FYs 2020 through 2023 payment determinations; 19 of these measures will continue to be used in either the HRRP, the Hospital VBP Program or the HAC Reduction Program and hospital-specific performance on these 19 measures will still be reported on *Hospital Compare*. In discussing its decision to remove these measures, CMS reviews its commitment to the Meaningful Measure Initiative, which includes streamlining how providers report and access data while maintaining or improving consumer understanding of the data publicly reported on *Hospital Compare*. The relationship among the three hospital pay-for-performance programs is also discussed (see item IV.I.3 above).

As part of its holistic review across all hospital quality and pay-for-performance programs, CMS sees the purposes of the Hospital IQR Program as focusing on measure topics not covered in the other programs' measures. As noted in the discussion of the Hospital VBP Program (section IV.I.2 above), CMS finalizes its proposal that although Hospital VBP Program measures must be selected from among Hospital IQR Program measures, once a measure is added to the VBP Program it would not need to continue as a Hospital IQR Program measure. CMS believes that reducing measure duplication among the programs will advance its goal of streamlining regulations to reduce unnecessary costs, increase efficiencies and improve beneficiary experience.

Under the final rule, the IQR Program measure set for FY 2020 includes a total of 31 mandatory measures – 27 that are specified, and 4 eCQMs selected by the hospital from a list of 15 available eCQMs. By 2022, these numbers are reduced to a total of 19 measures – 15 that are specified and 4 eCQMs chosen from a list of 8 available eCQMs. A summary table at the end of this section shows the previously adopted and newly finalized measure sets beginning with FY 2018 through 2023. No new measures were proposed for addition to the Hospital IQR Program. Technical specifications for Hospital IQR Program measures are available from the CMS QualityNet website at www.qualitynet.org, and for eCQMs at http://ecqi.healthit.gov/.

2. Retention and Removal of Measures – General Considerations

CMS reviews the previously adopted seven factors that it considers for removal of a measure from the Hospital IQR Program and adopts an eighth new factor. This policy is identical to the one discussed with respect to the Hospital VBP Program in item IV.I.2 above. The seven current Hospital IQR Program factors consider whether 1) the measure is "topped out;" 2) it does not align with current clinical guidelines or practice; 3) another more broadly applicable measure is available; 4) performance or improvement on the measure does not result in better patient outcomes; 5) another available measure is more strongly associated with the desired patient outcomes; 6) collection or public reporting of the measure leads to negative unintended consequences other than patient harm; 7) it is not feasible to implement the measure

specifications. CMS notes that none of the factors results in automatic removal; these are considerations that are taken into account on a case by case basis.

The new removal factor is 8) the costs associated with a measure outweigh the benefit of its continued use in the program. CMS reviews the different types of costs associated with measures. It also notes that beneficiaries may find it confusing to see public reporting on the same measure in different programs. CMS says its goal is to move the program forward in the least burdensome manner possible while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize quality improvement.

No changes are made to the policy for retaining measures adopted for the Hospital IQR Program until they are proposed for removal, suspension or replacement.

The majority of commenters supported the addition of factor 8. In responding to others, CMS emphasizes that in applying this factor on a case-by-case basis it will employ a transparent process and will consider views on costs and benefits from a variety of stakeholders. CMS believes that while many stakeholders benefit from inclusion of measures, the key benefit is to patients and caregivers.

3. Removal of 39 Hospital IQR Program Measures

CMS finalizes its proposal to remove a total of 39 measures from the Hospital IQR Program, although the timing for removal of some measures has changed from the proposed rule. The final rule provides for removal of 19 measures beginning with the FY 2020 payment determination, 5 beginning with FY 2021 (instead of 10 as proposed); 14 with FY 2022 (instead of 9 as proposed) and 1 beginning with FY 2023. The following table summarizes the measures that are removed, the effective date, the removal factor cited and whether the measure will continue in one or more of the three pay-for-performance programs.

Measure	**Removal Effective (payment year)**	**Removal factor**	**Retained in another program?**
Survey on patient safety culture	FY 20	4- no outcome improvement	
Safe surgery checklist	FY 20	8- costs	
PSI 90 patient safety composite	FY 20	8- costs	VBP, HAC
NHSN CDI NQF #1717	FY 22	8- costs	VBP, HAC
NHSN CAUTI NQF #0138	FY 22	8- costs	VBP, HAC
NHSN CLABSI NQF# 0139	FY 22	8- costs	VBP, HAC
NHSN MRSA NQF #0176	FY 22	8- costs	VBP, HAC
Colon/abdominal hysterectomy SSI NQF #0753	FY 22	8- costs	VBP, HAC
AMI readmissions NQF #0505	FY 20	8- costs	HRRP
CABG readmissions NQF #2515	FY 20	8- costs	HRRP
COPD readmissions NQF # 1891	FY 20	8- costs	HRRP
HF readmissions NQF #0330	FY 20	8- costs	HRRP
PN readmissions NQF #0506	FY 20	8- costs	HRRP
THA/TKA readmissions NQF #1551	FY 20	8- costs	HRRP
Stroke readmissions	FY 20	8- costs	(1)
AMI mortality NQF #0230	FY 20	8- costs	VBP

Measure	Removal Effective (payment year)	Removal factor	Retained in another program?
HF mortality NQF #0229	FY 20	8- costs	VBP
COPD mortality NQF #1893	FY 21	8- costs	VBP
PN mortality NQF # 0468	FY 21	8- costs	VBP
CABG mortality NQF #2515	FY 22	8- costs	VBP
THA/TKA complications NQF #1550	FY 23	8- costs	VBP
Medicare spending per beneficiary (MSPB) NQF #2158	FY 20	8- costs	VBP
Cellulitis payment episode	FY 20	8- costs	(2)
GI hemorrhage payment episode	FY 20	8- costs	(2)
Kidney/UTI payment episode	FY 20	8- costs	(2)
Aortic Aneurysm payment episode	FY 20	8- costs	(2)
Chole/ CDE payment episode	FY 20	8- costs	(2)
Spinal fusion payment episode	FY 20	8- costs	(2)
Influenza immunization NQF #1659	FY 21	1-topped out; 8-costs	
Median ED arrival to departure time admitted patients (ED-1) NQF #0495	FY 21	8- costs	(3)
Admit decision time to ED departure (ED-2) NQF #0497	FY 22	8- costs	(4)
Potentially preventable VTE (VTE-6)	FY 21	8- costs	(5)
eCQM primary PCI received within 90 minutes (AMI-8)	FY 22	8- costs	
eCQM home management plan of care (CAC-3)	FY 22	8- costs	
eCQM version of ED-1 NQF #0495	FY 22	8- costs	
eCQM hearing screening (EHDI-1a) NQF #1354	FY 22	8- costs	
eCQM elective delivery (PC-01) NQF#0469	FY 22	8- costs	(6)
eCQM stroke education (STK-08)	FY 22	8- costs	
eCQM assessed for rehabilitation (STK-10) NQF #0441	FY 22	8- costs	

(1) CMS notes that the Hospital-Wide All-Condition Preventable Readmission measure includes stroke cases.
(2) CMS notes that these measures overlap with the MSPB measure which would be retained in the VBP Program.
(3) A similar measure is included in the Outpatient Quality Reporting Program for discharged ED patients.
(4) The eCQM version of this measure is retained in the Hospital IQR Program.
(5) Two related eCQMs addressing venous thromboembolism (VTE) are retained (VTE-1 and VTE-2).
(6) The chart-abstracted version of this measure is retained in the Hospital IQR Program.

CMS discusses the rationale for removal of each measure and responds to many comments. In most cases the measures are removed from the Hospital IQR Program because they duplicate measures in one of the three pay-for-performance programs. CMS believes that removing from the IQR Program measures that are adopted for the other programs will better enable it to focus the IQR Program on new quality measures.

A number of comments were concerned with public reporting of performance on the measures being removed, with commenters believing that the public would have less information if measures are retained for other programs but removed from the IQR Program. CMS points to statutory requirements for public reporting of HAC Reduction Program and VBP Program measures and commits to continuing to publicly report data in the same manner as has been done for the IQR Program.

Some commenters were concerned that the "de-duplication" policy of removing measures included in multiple programs from the IQR Program would mean that the VBP Program measures would no longer be drawn from IQR Program measures that have been reported on *Hospital Compare* for at least one year. CMS reminds readers that this policy will continue because it is a statutory requirement of the VBP Program.

In addition to those general comments and the information summarized in the table above, discussions of the removal of these measures included the following:

- *Hospital Survey on Patient Safety Culture.* CMS notes that this measure was initially added to the Hospital IQR Program to collect information on hospital use of patient safety culture surveys. It has found that 98 percent of hospitals report using some version of such a survey, and that 70 percent used the AHRQ Surveys on Patient Safety Culture. Data collection on this measure ended with May 15, 2018.
- *Safe Surgery Checklist.* In addition to reducing reporting burden by removing this measure, CMS provides data indicating that this measure is trending toward "topped out" status, as the "yes" response rate for FYs 2017 and 2018 were 96 percent and 97 percent, respectively. Data collection on this measure ended with May 15, 2018.
- *Patient safety measures.* CMS discusses the burden on providers of monitoring three different feedback reports based on different reporting periods for these five NHSN measures and PSI 90. The NHSN measures are removed beginning with the 2020 reporting period/FY 2022 payment determination (one year later than was proposed) and the claims-based PSI 90 measure beginning with the FY 2020 payment determination (as proposed). CMS notes that these measures will be retained in both the VBP Program and the HAC Reduction Program and performance will continue to be reported on *Hospital Compare* despite their removal from the IQR Program. The delay in removal is intended to ensure consistency in collection and reporting for continued use in the VBP Program and until such time as the data collection, reporting and validation is transferred to the HAC Reduction Program. CMS believes that ultimately retaining these measures in two programs will balance concerns of commenters supporting removal with those who want to retain the measures. The final rule also includes a table showing the update penalty associated with failure to report IQR Program measures for 2015 through 2018, which averaged 0.28 percent; CMS believes the financial incentives of the HAC Reduction Program and the VBP Program are sufficient to ensure hospitals continue to report and strive for high performance on these measures.
- *Stroke readmissions.* Unlike the other readmission measures, this measure is not included in the HRRP. CMS removes it based on new removal factor 8 and believes that this measure overlaps with the Hospital IQR Program's measure of Hospital Wide All-Cause Unplanned Readmissions. CMS acknowledges that condition-specific readmission measures may provide hospitals with actionable feedback but says that hospitals would continue to have an incentive to reduce stroke readmissions in order to improve performance on the hospital-wide all-conditions readmissions measure.
- *Mortality measures*. The staggered removal dates for the five mortality measures reflect when the measures have previously been finalized for addition to the VBP Program. The removal dates therefore prevent any gap in public reporting of these measures. For example, the COPD and pneumonia mortality measures are not scheduled for addition to

the VBP Program until the FY 2021 payment year, and similarly the CABG mortality measure will begin as part of the VBP Program measure set with FY 2022 payment.

- *THA/TKA complications*. This measure will be removed from the IQR Program beginning with the FY 2023 payment determination. CMS chose this timeframe because the Comprehensive Care Joint Replacement Model requires use of IQR Program data on this measure through the FY 2022 payment determination.
- *Clinical-episode payment measures.* Six clinical-episode payment measures are removed because the measure data are already captured within the Medicare spending per beneficiary (MSPB) measure, which is retained in the Hospital VBP Program. CMS notes that some hospitals may appreciate the condition-specific information, but it believes that hospitals would prefer to focus improvement efforts on total payment rather than total payment plus payment for condition-specific episodes. These measures were only recently implemented for the IQR Program and data on them have not yet become publicly available on *Hospital Compare.* CMS also believes that the particular payment measures removed are of less use to beneficiaries and providers because they do not have corresponding clinical quality measures.
- *Influenza Immunization.* CMS shares data indicating that performance on this measure has been topped out for the FYs 2016, 2017 and 2018, and that data for the first two quarters of 2017 show similar performance. The cost of reporting this measure is another reason for its removal. CMS notes that the Influenza Vaccination Coverage Among Healthcare Personnel is retained in the IQR Program.
- *ED throughput (ED-1 and ED-2) chart-abstracted measures*. CMS discusses the burden of information collection for these chart-abstracted measures and points out that hospitals will have the opportunity to continue to report on the eCQM version of ED-2, Admit Decision Time to ED Departure Time for Admitted Patients. CMS believes that ED-2 has greater clinical significance for quality improvement and provides more actionable information than ED-1 (Median Time from ED Arrival to ED Departure for Admitted ED Patients). Further, CMS notes that the Outpatient Quality Reporting Program includes a measure of ED throughput, OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients. The ED-1 measure will be removed beginning with FY 2021 payment, but the ED-2 measure is retained for another year because the first results of the ED-2 eCQM validation will be available beginning with the FY 2021 payment determination, and CMS believes it is important to keep the chart-abstracted version of the measure to allow for comparative analysis of the accuracy.
- *Potentially Preventable Venous Thromboembolism (VTE-6)*. Regarding removal of the VTE-6 measure, CMS believes that two eCQMs addressing VTE provide hospitals with more actionable data. They are VTE Prophylaxis (VTE-1) and Intensive Care Unit VTE Prophylaxis (VTE-2).
- *eCQMs*. CMS removes 7 of the 15 eCQMs available to hospitals for reporting under the Hospital IQR Program beginning with the FY 2022 payment determination (2020 reporting year). Hospitals must report on four of the remaining measures. As discussed below in section VIII.D.12, a parallel change is made for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, now to be named the Medicare and Medicaid Promoting Interoperability Programs. Removal begins with FY 2022 payment (CY 2020 reporting) rather than an earlier date because stakeholders have emphasized the time needed for vendors and hospitals to make eCQM changes. CMS says that it is

exploring opportunities to develop relevant eCQMs for CAHs and small or rural hospitals.

- CMS notes that only one hospital elected to report on the measure AMI 8: Primary PCI Received Within 90 Minutes of Hospital Arrival.
- CMS believes that removal of the home management plan of care (CAC-3) and the stroke education and stroke rehabilitation assessment eCQMs (STK-8 and STK-10) are appropriate because these are measures that can be met primarily through documentation without evaluating the clinical quality of the activity, CMS has issued guidance that measure developers should avoid such constructs, and The Joint Commission has removed these measures from its eCQM measure set. Further, CMS believes that the remaining stroke eCQMs are more meaningful to patients and providers.
- Regarding the newborn hearing screening measure, CMS believes that the costs outweigh the benefits because this screening is already a widely practiced standard of care and mandated under many state laws.
- The measure of elective delivery (PC-01) is retained as a chart-abstracted measure and the eCQM removed. CMS believes that this measure is less burdensome to hospitals than other chart-abstracted measures because hospitals report aggregated counts through a QualityNet web-based tool.

4. Possible Future Hospital IQR Program Measures

CMS sought public comment on the possible future inclusion of two new measures in the Hospital IQR Program. One is a measure that assesses hospital-wide mortality and the other is an eCQM addressing hospital harm opioid-related adverse events. In addition, general comments were sought on adoption of eCQMs.

Hospital-Wide Mortality. CMS sought comment on whether to propose one or both of two versions of a hospital-wide mortality measure that it has developed: Claims-Only, Hospital-Wide, All-Cause Risk Standardized Mortality Measure or Hybrid Hospital-Wide, All-Cause Risk Standardized Mortality Measure. The final rule describes these measures in detail including an overview, data sources, outcome, cohort, risk adjustment, and calculation of the risk-standardized mortality rate. The involvement of technical panels and other stakeholder groups is described. CMS plans to submit both measures to the NQF for endorsement as early as FY 2019 after the measures have been fully specified for use with ICD-10. Additional information on the measures, including the core clinical data elements used in the hybrid version and other technical elements, is available on the CMS website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html#Claims%20Only%20Hospital%20Wide.

CMS notes that the measures use the same cohort definition, outcome assessment and claims-based risk variables, but the hybrid version also builds on prior efforts to use a set of core clinical data elements extracted from hospital EHRs to enhance the risk adjustment. The core clinical data elements are similar but not identical to those used for the Hybrid Hospital-Wide Readmission Measure (NQF #2879) which is included in the Hospital IQR Program as a

voluntary measure for reporting between January and June 2018. (CMS is considering proposing it as a mandatory measure as early as the FY 2023 payment determination.)

Both versions of the measure were submitted to the Measure Applications Partnership (MAP) as part of the 2017 Measures Under Consideration (MUC) List, and the MAP conditionally supported both measures pending NQF endorsement. It recommended that the hybrid version have a voluntary reporting period before becoming a mandatory measure.

CMS addresses several concerns raised by the MAP. It agrees that the NQF process should consider the need for clinical and social risk adjustment factors and exclusions to assure that the measure does not disproportionately penalize hospitals treating more complex patients. It says that concerns about potential for unnecessary interventions for patients at the end of life were carefully considered in measure development, and exclusions apply to hospice patients and patients admitted with certain cancer diagnoses with limited changes of survival. While acknowledging that condition-specific mortality measures may be more actionable and informative, CMS says that a single comprehensive marker of hospital quality encourages organization-wide improvement, allows more hospitals to meet volume requirements for inclusion in measurement, and offers more rapid detection of performance changes because only one year of data are needed to calculate performance. CMS also believes that this measure would meet the Meaningful Measures Initiative goal of fewer measures.

CMS responds to numerous comments on this possible future measure. Among the responses, it indicates that the measure separates surgical and nonsurgical admissions to account for differences in mortality risk between these patient populations. Also, development of an eCQM version of a 30-day mortality measure is not feasible because EHRs do not include information about deaths outside the hospital. Details of risk adjustment are discussed and readers are referred for more information to https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html. The potential for unintended consequences and the exclusion for hospice patients is discussed. CMS says that if it proceeds with either of these measures hospitals would receive confidential, service line division and patient-level data to support quality improvement as well as overall measure performance.

Hospital-Harm—Opioid-Related Adverse Events eCQM. This in-hospital outcome measure assesses the proportion of a hospital's patients who had an opioid-related adverse event as measured by administration of naloxone. The measure was included in the 2017 MUC list submitted to the MAP, which recommended it be refined and resubmitted. In particular the MAP suggested adjusting the numerator to account for the impact of chronic opioid users. It also suggested testing in additional facilities, and CMS says it is currently using output from the Measure Authoring Tool in multiple hospitals using multiple EHR systems. CMS plans to submit the measure for NQF endorsement through the Patient Safety Committee in November 2018. The measure specifications are discussed and more information is available under "Hospital Harm" at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/PC-Updates-on-Previous-Comment-Periods.html.

CMS received from commenters a number of suggestions for how the measure might be implemented, changes to measure exclusions which it says it will consider. Regarding comments that use of naloxone is not a good proxy for opioid-related adverse events, CMS acknowledges that naloxone administration alone does not conclusively indicate a harm, but cites clinical literature in which it is used as an indicator of opioid-related adverse respiratory events.

General Adoption of eCQMs. In the proposed rule CMS asked a series of specific questions regarding the implementation of eCQMs in the Hospital IQR Program, the Medicare and Medicaid Promoting Interoperability Programs among others. The questions addressed the costs of eCQMs to hospitals and health IT vendors; barriers to use of eCQMs; best ways to reduce costs and maximize benefits of eCQMs; how to encourage hospitals and health IT vendors to engage in improvements to existing eCQMs and test new eCQMs; willingness of hospitals and health IT vendors to participate in pilots or models of alternative approaches to measurement such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches; and additional public resources that hospitals and health IT vendors would like to have to support testing, implementation, and reporting of eCQMs.

Comments received on the specific questions are summarized in the final rule. CMS says it will consider commenter suggestions as it develops future policies and points out that it has also been holding listening sessions with hospitals and health IT vendors about EHR and eCQM issues. Comments will also be shared with the Office of the National Coordinator for HIT and its other partners.

5. Accounting for Social Risk Factors in the Hospital IQR Program

In this section, CMS reviews the issues around accounting for social risk factors in the Hospital IQR Program and provides information on the next step it is considering to increase the transparency of health disparities shown by quality measures. Specifically, it says it is considering implementing two complementary methods. The first method (the hospital-specific disparity method) would calculate differences in outcome rates among patient groups within a hospital while accounting for their clinical risk factors. It would also allow for a comparison of those differences across hospitals. The second approach would assess outcome rates for subgroups of patients, such as dual eligible patients, across hospitals, allowing for a comparison among hospitals on their performance caring for their patients with social risk factors.

CMS also discusses the complexity of interpreting stratified outcome measures and describes its plans to include stratified data on the Pneumonia Readmission measure (NQF #0506) data for dual-eligible patients in hospitals' confidential feedback reports beginning Fall 2018 using both methodologies identified above. For the future, CMS is considering expanding its efforts to provide stratified data in hospital confidential feedback reports for other measures, including other social risk factors beyond dual-eligible status, and eventually making stratified data publicly available on *Hospital Compare*. CMS is also considering how these methodologies may be adapted to apply to other CMS quality programs in the future.

A CMS contractor convened a Technical Expert Panel (TEP) in the spring of 2018 to solicit feedback from stakeholders on approaches to consider for stratification for the Hospital IQR Program. CMS also anticipates receiving additional input from hospitals once the confidential feedback reports of the stratified results are provided.

In responding to comments it received on this information, CMS reports that many commenters supported the hospital-specific disparity method under consideration. It notes that the second method (group-specific outcome rate) is not intended to provide patients with information about a hospital's volume of patients with social risk factors but instead to provide specific outcome rates for patients with certain risk factors at the hospital level. It says that preliminary results have shown that hospitals caring for a low or a high proportion of patients with social risk factors can perform well or poorly on this measure.

Regarding the dual-eligible stratified pneumonia readmission measure data, CMS says that confidential reports will be provided to hospitals to preview from August 24-September 24, 2018. Hospitals will be given educational material to help them interpret the results. Plans for public reporting are not yet determined. CMS will engage with hospitals and other stakeholders before proposing public display of the stratified data, which would occur through notice and comment rulemaking.

Throughout its responses CMS emphasizes its commitment to continuing to engage stakeholders on these issues.

6. Form, Manner and Timing of Data Submission

CMS reviews procedural and data submission requirements for the Hospital IQR Program; no changes were proposed to most of these policies involving procedural requirements, data submission for chart-abstracted measures, data submission deadlines, sampling and case thresholds, HCAHPS administration and submission requirements, data accuracy and completeness acknowledgement, public display of measures on *Hospital Compare*, reconsideration and appeals, and the extraordinary circumstances exception policy. However, a clarification and several changes apply to the reporting of eCQMs.

Clarification of eCQM Measure Logic. CMS discusses the measure logic used in eCQM development. Although this aspect of eCQMs is not part of rulemaking, CMS wants the public to know that all eCQM specifications beginning with the Annual Update that will be published in Spring 2018 for implementation in 2019 reporting will use the Clinical Quality Language (CQL). CQL is described as a Health Level Seven (HL7) International standard and aims to unify the expression of logic for eCQMs and Clinical Decision Support (CDS). It provides the ability to express logic defining measure populations to improve the accuracy and clarity of eCQMs and is intended to be human-readable which allows measure developers to express data criteria and represent it in a manner suitable for language processing. Prior to 2017, eCQM logic was defined by Quality Data Model (QDM) Logic, which CMS believes is more complex and difficult to compute. Other benefits of CQL are described and readers are referred for more information to https://ecqi.healthit.gov/cql.

CMS reports that eCQM developers successfully tested CQL for expressing eCQMs from 2016 through 2017. Based on the results, the Measure Authoring Tool (MAT) and the Bonnie tool have been updated to use CQL. CMS believes that the change from QDM to CQL will enable measure developers to engineer more precise, more interoperable measures that interface with CDS tools, and will result in availability of better measures of patient outcomes.

Reporting of eCQMs for FY 2021 Payment. CMS finalizes its proposal to extend for the 2019 reporting year (FY 2021 payment) the same eCQM reporting and submission requirements in place for the 2018 reporting year (2020 payment determinations). Under these requirements, hospitals must report on four eCQMs for one self-selected quarter of data. These reporting and data submission requirements are also adopted for the Medicare EHR Incentive Program (now Promoting Interoperability Program. See section VIII.D below.) Responding to comments, CMS says it will continue to engage in discussion with hospitals and health IT vendors as it considers eCQM reporting for future rulemaking.

Certification Requirements for 2019 Reporting (FY 2021 payment). Under this final rule, hospitals must use only the 2015 Edition for the 2019 reporting period (FY 2021 payment). This requirement was finalized in previous rulemaking for both the Hospital IQR Program and the newly-named Promoting Interoperability Program, and CMS is proposing to retain it. For the 2018 reporting period (FY 2020 payment) hospitals retain the flexibility to use EHR technology certified to the 2014 Edition or the 2015 Edition or a combination of these Editions. The advantages of the 2015 Edition are enumerated including up-to-date standards-based structured data capture to support electronic clinical quality measurement; improved health information exchange; more robust testing coverage; capacity for providers to export data without the vendor; and support for electronic clinical quality data reporting.

Responding to comments opposing this requirement, CMS believes that a majority of health IT vendors have completed or are in the process of completing certification under the 2015 criteria and that 2019 is the right time to require the transition to the 2015 Edition. It reminds readers of previous delays and says it does not believe that this requirement will materially impact the percentage of hospitals able to successfully report eCQM data. Hospitals unable to migrate to the 2015 Edition due to vendor backlogs should consider whether to submit an Extraordinary Circumstances Exception, which CMS will consider on a case-by-case basis. CMS believes that this requirement will expedite the development of products certified to the 2015 Edition. CMS clarifies that the hospital certification should be obtained prior to the end of the eCQM reporting period to meet program requirements (e.g., December 31, 2019 for the 2019 reporting period.) CMS also notes that while it has aligned IQR Program requirements with the Promoting Interoperability Program, for statutory reasons it is not able to align the IQR Program with the Promoting Interoperability Program's requirements for attesting to measures and objectives, which allow for one consecutive 90-day reporting period. The IQR Program is limited to measures appropriate for the measurement of quality of care and does not allow for an attestation option.

CMS also says it will consult with ONC regarding interoperability and linking EHRs to application programming interfaces such as the Fast Healthcare Interoperability Resources

IFHIR), a standards framework developed by HL7 that is designed to enable information exchange.

Other Data Submission Requirements. While no changes are made to the data submission requirements for the structural measures, CMS notes that under this final rule these measures will be removed, and no structural measure reporting will be required beginning with the 2019 reporting period/FY 2021 payment determination. Likewise, CMS notes the removal of five healthcare-associated infection measures from the Hospital IQR Program beginning with 2020 reporting (FY 2022 payment determination); at that point data on these measures will be reported through the HAC Reduction Program as described in section IV.J above.

7. Data Validation

No changes are made to the data validation process, but CMS notes that under the final rule there would be fewer IQR Program measures requiring validation. By the FY 2022 payment determination, only two chart abstracted measures and the five NHSN measures will be subject to validation, and by FY 2023 only one chart abstracted measure (sepsis measure) will remain. CMS will continue to sample up to 8 cases for each measure, and will evaluate its scoring methodology to ensure the continued reliability of the Hospital IQR Program measures. Validation of the NSHN infection measures will be shifted to the HAC Reduction Program as described in section IV.J above.

8. Impact Analysis

In the Regulatory Impact Analysis section of the final rule, CMS estimates that for FY 2019, 49 hospitals will fail to meet the requirements of the Hospital IQR Program and be subject to a payment reduction of 0.725 percentage points (one quarter of the market basket update of 2.9 percent). Some 40 of these hospitals are also estimated to fail to meet the requirements of the Medicare Promoting Interoperability Program and therefore be subject to a combined 1.55 percentage point reduction for FY 2019 (0.725 percentage points and another 2.175 percentage points, or three-quarters of the market basket update for failure to comply with the Promoting Interoperability Program).

In the Collection of Information requirements section of the final rule, CMS estimates the potential reduced burden on hospitals associated with the removal of measures. Removal of the three chart abstracted measures IMM-2, ED–1, and VTE–6 would result in an information collection burden reduction of 1,046,071 hours (-741,074 hours for ED-1 and IMM-2 removal and -304,997 hours for VTE-6 removal) and approximately $38.3 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the 2019 reporting period/FY 2021 payment determination. Reduction of 67 hours is included for the end of the voluntary reporting period for the hybrid hospital-wide readmissions measure.

In addition, removal of ED–2 results in an estimated collection burden reduction of 858,000 hours and approximately $31.4 million across all 3,300 IPPS hospitals participating in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination.

Additional burden reduction will occur because these measures are no longer subject to data validation; no specific estimates are provided for that. CMS estimates savings from eliminating the NSHN measures from the Hospital IQR Program but notes that this burden is only shifted to the HAC Reduction Program.

Under the final rule the eCQM reporting requirement for the 2019 reporting period/FY 2021 payment determination is unchanged from 2018 reporting/2020 payment. CMS estimates this burden associated with eCQM reporting requirements to be 40 minutes per hospital per year (10 minutes per record x 4 eCQMs x 1 quarter).

<table>
<tr><th colspan="6">Summary Table: IQR Program Measures by Payment Determination Year
X= Mandatory Measure</th></tr>
<tr><th></th><th>2018</th><th>2019</th><th>2020</th><th>2021</th><th>2022+</th></tr>
<tr><td colspan="5">Chart-Abstracted Process of Care Measures</td><td></td></tr>
<tr><td>STK-4 Thrombolytic therapy for acute ischemic stroke</td><td>X</td><td>Removed</td><td></td><td></td><td></td></tr>
<tr><td>VTE-5 VTE discharge instructions</td><td>X</td><td>Removed</td><td></td><td></td><td></td></tr>
<tr><td>VTE-6 Incidence of potentially preventable VTE</td><td>X</td><td>X</td><td>X</td><td>Removed</td><td></td></tr>
<tr><td>Severe sepsis and septic shock: management bundle (NQF #500)</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital (NQF #0495)</td><td>X</td><td>X</td><td>X</td><td>Removed</td><td></td></tr>
<tr><td>ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status (NQF #0497)</td><td>X</td><td>X</td><td>X</td><td>X</td><td>Removed</td></tr>
<tr><td>IMM-2 Immunization for influenza (NQF #1659)</td><td>X</td><td>X</td><td>X</td><td>Removed</td><td></td></tr>
<tr><td>PC-01 Elective delivery < 39 weeks gestation (NQF#0469)</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td colspan="5">Electronic Clinical Quality Measures</td><td></td></tr>
<tr><td>AMI-2 Aspirin prescribed at discharge for AMI
AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival
AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) (NQF #0163)
AMI-10 Statin at discharge
PN-6 Appropriate initial antibiotic selection
STK-2 Antithrombotic therapy for ischemic stroke (NQF #0435)
STK-3 Anticoagulation therapy for Afib/flutter (NQF #0436)
STK-4 Thrombolytic therapy for acute ischemic stroke
STK-5 Antithrombotic therapy by end of hospital day 2 (NQF #0438)
STK-6 Discharged on statin (NQF #0439)
STK-8 Stroke education
STK-10 Assessed for rehabilitation services (NQF #0441)
VTE-1 VTE prophylaxis (NQF #0371)
VTE-2 ICU VTE prophylaxis (NQF #0372)</td><td>Must report at least 4 of 28 eCQMs</td><td colspan="3">For FY 2019-2021 must report 4 of the following 15 eCQMs:
AMI-8a
CAC-3
ED-1
ED-2
EHDI-1a
PC-01
PC-05
STK-02
STK-03
STK-05
STK-06
STK-08
STK-10
VTE-1
VTE-2</td><td>For FY 2022 payment, (2020 reporting) report 4 of the following 8 eCQMs:
ED-2
PC-05
STK-02
STK-03
STK-05
STK-06
VTE-1
VTE-2

These 7 eCQMs are removed:</td></tr>
</table>

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure					
	2018	**2019**	**2020**	**2021**	**2022+**
VTE-3 VTE patients with anticoagulation overlap therapy VTE-4 VTE patients receiving un-fractionated Heparin with doses/labs monitored by protocol VTE-5 VTE discharge instructions VTE-6 Incidence of potentially preventable VTE SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision SCIP-INF-2 Prophylactic antibiotic selection for surgical patients SCIP–INF-9 Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital (NQF#0495) ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status (NQF #0497) PC-01 Elective delivery < 39 completed weeks gestation (NQF #0469) PC-05 Exclusive breast milk feeding (NQF #0480) Healthy term newborn EDHI-1a Hearing screening prior to hospital discharge CAC- 3 Children's asthma care – 3					AMI-8a CAC-3 ED-1 EHDI-1a PC-01 STK-08 STK-10
Healthcare-Associated Infection Measures					
Central Line Associated Bloodstream Infection (CLABSI)	X	X	X	X	**Removed**
Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy	X	X	X	X	**Removed**
Catheter-Associated Urinary Tract Infection (CAUTI)	X	X	X	X	**Removed**
MRSA Bacteremia	X	X	X	X	**Removed**
Clostridium Difficile (C. Diff)	X	X	X	X	**Removed**
Healthcare Personnel Influenza Vaccination	X	X	X	X	X
Claims-Based Measures					
Mortality					
AMI 30-day mortality rate	X	X	**Removed**		
Heart Failure (HF) 30-day mortality rate	X	X	**Removed**		
Pneumonia 30-day mortality rate	X	X	X	**Removed**	
Stroke 30-day mortality rate	X	X	X	X	X
COPD 30-day mortality rate	X	X	X	**Removed**	
CABG 30-day mortality rate	X	X	X	X	**Remove**
Readmission/ Coordination of Care					
AMI 30-day risk standardized readmission	X	X	**Removed**		
Heart Failure 30-day risk standardized readmission	X	X	**Removed**		
Pneumonia 30-day risk standardized readmission	X	X	**Removed**		
TKA/THA 30-day risk standardized readmission	X	X	**Removed**		
Hospital-wide all-cause unplanned readmission	X	X	X	X	X

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure					
	2018	**2019**	**2020**	**2021**	**2022+**
Stroke 30-day risk standardized readmission	X	X	**Removed**		
COPD 30-day risk standardized readmission	X	X	**Removed**		
CABG 30-day risk standardized readmission	X	X	**Removed**		
Hybrid (claims+EHR) hospital-wide readmission			Voluntary		
Excess days in acute care after hospitalization for AMI	X	X	X	X	X
Excess days in acute care after hospitalization for HF	X	X	X	X	X
Excess days in acute care after hospitalization for PN		X	X	X	X
Patient Safety					
PSI-90 Patient safety composite (NQF #0531)	X	X	**Removed**		
PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351)	X	X	X	X	X
THA/TKA complications	X	X	X	X	X **Removed in FY 23**
Efficiency/Payment					
Medicare Spending per Beneficiary	X	X	**Removed**		
AMI payment per 30-day episode of care	X	X	X	X	X
Heart Failure payment per 30-day episode of care	X	X	X	X	X
Pneumonia payment per 30-day episode of care	X	X	X	X	X
THA/TKA payment per 30-day episode of care	X	X	X	X	X
Kidney/UTI clinical episode-based payment		X	**Removed**		
Cellulitis clinical episode-based payment		X	**Removed**		
Gastrointestinal hemorrhage clinical episode-based payment		X	**Removed**		
Aortic Aneurysm Procedure clinical episode-based payment		X	**Removed**		
Cholecystectomy/Common Duct Exploration episode-based payment		X	**Removed**		
Spinal Fusion clinical episode-based payment		X	**Removed**		
Patient Experience of Care					
HCAHPS survey + 3-item Care Transition Measure	X	X	X	X	X
Structural Measures					
Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	X	Removed			
Participation in a Systematic Clinical Database Registry for General Surgery	X	Removed			
Safe Surgery Checklist Use	X	X	**Removed**		
Hospital Survey on Patient Safety Culture	X	X	**Removed**		

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

The PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program began in FY 2014 and follows many of the policies established for the Hospital IQR Program, including the principles for selecting and removing measures and the procedures for hospital participation in the program.

Currently, there are 11 PPS-exempt cancer hospitals.[27] No policy was adopted on the consequences if a PCH fails to meet the quality reporting requirements; CMS has indicated its intention to address the issue in future rulemaking. Five initial measures were adopted for FY 2014, and subsequent rulemaking has added and removed measures. A total of 18 measures were previously adopted for FY 2020. Technical specifications for PCHQR Program measures are available on the QualityNet.org website.

In this rule, CMS discusses its Meaningful Measure Initiative and adopts the same new cost-related eighth measure removal criterion that is added in this rule to the Hospital IQR Program (see IV.A above). CMS further finalizes its proposal to remove the following measures from the PCHQR Program beginning with FY 2021. The four cancer-related measures are removed because CMS has found that performance on these measures is topped out. In the impact analysis section of the proposed rule CMS estimates that the removal of these four measures from the PCHQRP will reduce burden for the 11 PPS-exempt cancer hospitals by 1 hour each annually.

- Oncology-Radiation Dose Limits to Normal Tissues (NQF #0382)
- Oncology: Pain Intensity Quantified (NQF #0384)
- Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients (NQF #0389)
- Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients (NQF #0390)

Two NHSN infection measures (listed below) were also proposed for removal under the new cost removal factor 8; CMS believed that the burden of reporting these measures outweighs the benefits, especially because the volume of results is too low for public reporting and therefore of no use to beneficiaries. However, a final decision on removal of these measures is deferred until a later 2018 final rule, most likely the 2019 Hospital Outpatient Prospective Payment System (OPPS) final rule. In the interim CMS is conducting additional data analyses to assess measure performance based on new information provided by the CDC; it wants to be cautious and not prematurely remove these measures from the PCHQR Program.

- NHSN CLABSI (NQF #0139)
- NHSN CAUTI (NQF #0138)

CMS finalizes addition of one new claims-based measure to the program, 30-Day Unplanned Readmissions for Cancer Patients (NQF #3188). The final rule provides background on the problem of readmissions for this population and details the measure data sources, calculation and risk adjustment. The MAP supported inclusion of this measure in the PCHQR Program. CMS directs readers to the NQF website for measure specifications (the link provided appears broken.) The data collection for this measure will be for a period of October 1 through September 30. For the initial FY 2021 program year, this period is October 1, 2018 through September 30, 2019. For FY 2022 it will be October 1, 2019 through September 30, 2020, and so on for subsequent years.

[27] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html

Public reporting of four measures is deferred until 2019 because CMS says there is not sufficient data at this point to draw conclusions on performance and because for some measures the NHSN baseline reference period was changed. By 2019 CMS will have 2 years of comparable data to properly assess trends. The table below shows the finalized public reporting dates for each measure.

CMS discusses issues regarding accounting for social risk factors in the PCHQR Program. This discussion is similar to the one summarized with respect to the HRRP in item IV.H.4 above.

In the proposed rule, CMS sought comments on two possible future measures: Risk-Adjusted Mortality for Lung Resection for Lung Cancer (NQF # 1790), which assesses postoperative complications and operative mortality, and Shared Decision Making Process (NQF #2862), a patient-reported outcome measure which asks patients who had specific surgical interventions to report on the interactions they had with their providers when the decision was made to have the surgery. Comments were also sought on whether the PCHQR Program would benefit from the inclusion of more quality measures that examine general cancer care or more measures that examine cancer-specific clinical conditions.

Commenters raised several concerns with respect to the shared decision-making measure, and CMS commits to ensuring adequate reliability and validity testing has been conducted should it move forward with this measure in the future. In addition, it will communicate to the measure steward the possibility of adding lung cancer screening to the measure's list of procedures as a future refinement and will share suggested revisions to the wording of measure questions.

PCHQR Program Measures for 2021	
Measure	**Public Display**
Safety and Healthcare Associated Infection	
Colon/Abdominal Hysterectomy SSI (NQF #0753)	Deferred*
NHSN CDI (NQF #1717)	Deferred*
NSHN MRSA bacteremia (NQF #1716)	Deferred*
NHSN Influenza vaccination coverage among health care personnel (NQF #0431)	Deferred*
NHSN CLABSI (NQF #0139)**	Deferred*
NHSN CAUTI (NQF #0138)**	Deferred*
Clinical Process/Oncology Care	
Oncology: Plan of Care for Pain (NQF #0383)	2016
The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOLChemo) (NQF #0210)	
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215)	
Intermediate Clinical Outcomes	
The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216)	
The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL-ICU) (NQF #0213)	
Patient Experience of Care	
HCAHPS (NQF #0166)	2016
Clinical Effectiveness	

PCHQR Program Measures for 2021	
External Beam Radiotherapy for Bone Metastases (NQF#1822)	2017
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	
30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188)	
Previously Adopted Measures Removed Beginning with 2021 Payment	
Oncology-Radiation Dose Limits to Normal Tissues (NQF #0382)	*2016*
Oncology: Pain Intensity Quantified (NQF #0384)	*2016*
Prostate Cancer-Avoidance of Overuse Measure-Bone Scan for Staging Low-Risk Patients (NQF #0389)	*2016*
Prostate Cancer-Adjuvant Hormonal Therapy for High-Risk Patients (NQF #0390)	*2016*
*CMS had proposed public display of these measures to begin in 2019; the final rule provides for public display as soon as practicable. If useable data is available prior to 2019 it will be posted on the next available *Hospital* Compare release. **Removal of these measures was proposed beginning with the 2019 payment but CMS has deferred a final decision to a future 2018 final rule, most likely the 2019 OPPS/ASC final rule.	

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In the FY 2012 IPPS/LTCH final rule, CMS established a quality reporting program beginning in FY 2014 for LTCHs, as required under section 1886(m) of the Act as added by section 3004 of the ACA. Further developed in subsequent rulemaking, the LTCH QRP follows many of the policies established for the IQR Program, including the principles for selecting measures and the procedures for hospital participation in the program. An LTCH that does not meet the requirements of participation in the LTCH QRP for a rate year is subject to a 2.0 percentage point reduction in the update factor for that year. In the regulatory impact analysis section of the final rule, CMS says that it does not have information to estimate the number of LTCHs that would fail to meet the LTCH QRP requirements for FY 2019.

1. Removal of LTCH QRP Measures

CMS finalizes its proposal to add to the LTCH QRP a new removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. (This new removal factor is identical to the one adopted for the Hospital IQR Program as described above.) The other seven removal factors for the LTCH QRP differ slightly from the Hospital IQR Program removal factors. They are: (1) measure performance among LTCHs is topped out; (2) performance or improvement on a measure does not result in better patient outcomes; (3) measure does not align with current clinical guidelines or practice; (4) a more broadly applicable measure for the topic is available; (5) a measure that is more proximal in time to desired patient outcomes for the particular topic is available; (6) a measure that is more strongly associated with desired patient outcomes for the topic is available; and (7) collection or public reporting of a measure leads to negative unintended consequences other than patient harm. The final rule codifies all eight factors in regulatory text at §412.560(b)(3).

Three measures are finalized for removal from the LTCH QRP measure set. In discussing comments, CMS notes that MedPAC supported removal of all three measures.

- The NSHN MRSA infection measure is removed based on factors 6 and 8. CMS believes that the NSHN CLABSI measure is more strongly associated with desired patient outcomes for bloodstream infections than the MRSA measure, and CLABSI also captures the same type of MRSA infection so the measures are duplicative. Removal is effective beginning with FY 2020 payment determination, and reporting is no longer required beginning with October 1, 2018 admissions and discharges.
- The NHSN Ventilator-Associated Event (VAE) Outcome measure is removed based on factor 6 because CMS believes that the three other LTCH QRP measures addressing ventilator support together have reduced poor outcomes associated with complications of ventilator care, which is the same focus of the NHSN VAE outcome measure. (Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632); Compliance with Spontaneous Breathing Trials by Day 2 of the LTCH Stay; and (3) Ventilator Liberation Rate. Removal is effective beginning with FY 2020 payment determination, and reporting is no longer required beginning with October 1, 2018 admissions and discharges.
- Percent of Residents or Patients Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) is removed based on new factor 8, because most patients have been found to have been vaccinated prior to admission and therefore the reporting burden outweighs any benefit from continuing the measure. Removal is effective with FY 2021 payment determination and LTCHs no longer have to report the associated data elements beginning with October 1, 2018 admissions and discharges.

In the Collection of Information requirements section of the proposed rule, CMS estimates that removal of these measures will reduce costs by $1,149 per LTCH annually or $482,469 for all LTCHs.

2. Update on IMPACT Act Implementation

The Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, enacted on October 6, 2014, requires the Secretary to implement quality measures for five specified quality measure domains using standardized data elements to be nested within the assessment instruments currently required for submission by LTCHs and other post-acute care providers (IRFs, SNFs, and HHAs). Other measures are to address resource use, hospitalization, and discharge to the community. The intent of the Act is to enable interoperability and access to longitudinal information among post-acute providers to facilitate coordinated care, improve outcomes, and provide for quality comparisons across providers.

In the FY 2018 LTCH/IPPS proposed rule and related post-acute care rules, CMS proposed the adoption of standardized patient assessment data that would form the foundation of cross-cutting quality measures. These data elements were not finalized, however, due to commenter concerns about reporting burden.

CMS reports on its ongoing work on developing two measures that would satisfy the IMPACT Act domain of accurately communicating the existence and provision of the transfer of health information and care preferences. It plans on reconvening a TEP in mid-2018 and specifying the

measures no later than October 1, 2019. CMS intends then to propose adoption beginning with the FY 2022 LTCH QRP. CMS says information on pilot measure testing 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.

3. Accounting for Social Risk Factors

CMS discusses issues regarding accounting for social risk factors in the LTCH QRP. This discussion is like the one summarized with respect to the HRRP in item IV.H.4 above.

4. Data Submission under the LTCH QRP

In the proposed rule, CMS sought comments on whether in the future it should move the implementation date of any new version of the LTCH CARE Data Set from the usual release date of April to October. In this rule, CMS clarifies that any proposed updates to the LTCH CARE Data Set would be implemented in the following year at the earliest. For example, if the date change were proposed in the FY 2020 IPPS/LTCH proposed rule issued in April 2019, implementation of the new version of the LTCH CARE Data Set would not occur until October 1, 2020 at the earliest. CMS believes this would give LTCHs an additional 6 months (April-October) to update their systems so to comply with new reporting requirements.

5. Changes to Reconsideration Requirements

Changes to the regulatory text at 42 CFR 412.560(d) are finalized regarding reconsiderations. Instead of notifying an LTCH that it is noncompliant with LTCH QRP requirements through the QIES ASAP system, CMS will notify LTCHs of noncompliance via a letter sent through one or more of the following: the QIES ASAP system, the United States Postal Service, or via an email from the Medicare Administrative Contractor (MAC). CMS believes this responds to providers requesting additional modes of notification. The same notification processes will be used to communicate CMS' final decision regarding any reconsideration request.

Providers will be notified of the method of communication that CMS will use via the LTCH QRP Reconsideration and Exception and Extension website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/LTCH-Quality-Reporting-Reconsideration-and-Exception-and-Extension.html. Announcements will be posted annually following the May 15th data submission deadline and prior to the distribution of the initial notices of non-compliance determination. The messaging will include the method of communication of the notices and instructions and deadlines for submitting a reconsideration request. Notifications are sent to the point of contact on file in the QIES database, and it is the responsibility of the facility to ensure the information is up to date.

LTCH QRP Measures, by Year			
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139)	X	X	X
Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678)	X	Replace	
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury		X	
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)	X	X	Removed
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	X	X	X
NHSN Facility-Wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)	X	X	Removed
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717)	X	X	X
All-Cause Unplanned Readmissions for 30 Days Post Discharge from LTCHs (NQF #2512)	Removed		
Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (Application of NQF #0674)	X	X	X
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)	X	X	X
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)	X	X	X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632)	X	X	X
NHSN Ventilator Associated Event Outcome Measure	X	X	Removed
Medicare spending per beneficiary MSPB-PAC LTCH	X	X	X
Discharge to Community PAC LTCH	X	X	X
Potentially Preventable Readmissions 30 Days Post LTCH Discharge	X	X	X
Drug Regimen Review Conducted with Follow-up		X	X
Mechanical Ventilation Process Measure: Compliance with Spontaneous Breathing Test by Day 2 of the LTCH Stay		X	X
Mechanical Ventilation Outcome Measure: Ventilator Liberation Rate		X	X

D. Changes to the Medicare and Medicaid EHR Incentive Programs

In the proposed rule, CMS announced that it has renamed the Medicare and Medicaid EHR Incentive Programs as the Medicare and Medicaid Promoting Interoperability Programs, a name that will apply to fee-for-service Medicare, Medicare Advantage, and Medicaid. It believes this new name better reflects the goals of the program, and that references to Medicare incentive payments are no longer appropriate as these no longer apply outside of Puerto Rico and will end for Medicaid in 2021.

A hospital that is not identified as a meaningful EHR user under the Medicare Promoting Interoperability Program is subject to a reduction of 2.175 percentage points in the update factor for FY 2019. In the impact analysis section of this final rule, 137 hospitals are estimated to not meet the meaningful use requirements for FY 2019 payment; 40 hospitals are estimated to fail to meet both the meaningful use and Hospital IQR Program requirements and therefore be subject to a total update factor reduction of 2.9 percentage points.

In this final rule CMS addresses certification requirements and adopts substantial changes to program policies including reporting periods and the scoring methodology used in determining whether hospitals have met the meaningful use requirements under the Medicare Promoting Interoperability Program.

1. Certification Requirements Beginning in 2019

CMS proposed no changes to its previously finalized policy for 2019 under which eligible hospitals and CAHs must use EHR technology certified to the 2015 Edition of Certified EHR Technology (CEHRT). (For 2018, eligible hospitals and CAHs may use EHR technology certified to the 2014 Edition, the 2015 Edition, or a combination of both Editions.) Although no changes were proposed, CMS discussed in the proposed rule why it believes it would be beneficial to IT developers and health care providers to move to more up-to-date standards and functions that better support interoperable exchange of health information and improve clinical workflows. It believes that the 2014 Edition includes standards that are significantly out of date, and that the marketplace is shifting away from 2014 Edition products. CMS also cites the costs associated with market fragmentation and recertification of older products which divert resources from advancing technologies including the 2015 Edition of CEHRT.

In addition, CMS lists numerous advantages to using the 2015 Edition. Among these is the application programming interface (API) functionality, which it believes will assist patients in making decisions and contribute to quality improvement and greater interoperability among systems. Further, CMS references the Common Clinical Data Set specified in the 2015 Edition which is a critical element to interoperability, and upon which the US Core Data for Interoperability (USCDI) was built. The USCDI is further referenced by the Draft Trusted Exchange Framework for secure exchange of electronic health information. Other advantages of the 2015 Edition described by CMS relate to improved patient access to their health information and the ability of providers to export data without intervention by the vendor.

CMS believes that the transition from the 2014 Edition to the 2015 Edition is on schedule for the 2019 reporting period. In the proposed rule it identified 90 percent of eligible hospitals and CAHs and 66 percent of eligible clinicians as having 2015 Edition available to them at the beginning of 2018 based on previous attestation data. CMS acknowledges the burden of deploying new technology but believes that the 2015 Edition provides key updates to functions and standards to support interoperability and clinical effectiveness.

Despite receiving many comments on the requirement to use 2015 CEHRT, CMS says the issue was not a subject of rulemaking and does not respond to the comments in this final rule. It will use the comments to inform future policymaking.

2. Reporting Periods for 2019 and 2020

CMS finalizes that for 2019 and 2020, Medicare and Medicaid Promoting Interoperability Program participants must attest to meaningful use to CMS or to the state for a minimum reporting period of any continuous 90-day period during the calendar year (2019 or 2020, respectively). This replaces the previous requirement that beginning in 2019 the EHR reporting period would be the full calendar year. CMS believes this change will allow providers to test systems and make adjustments to fully implement the 2015 Edition as well as to meet the requirement for use of an API to incorporate patient data. Furthermore, under this final rule eligible hospitals and CAHs face a new scoring methodology and new measures, and CMS says it wants to provide flexibility to providers in becoming familiar with these changes. The definition of reporting period at 42 CFR 495.4 is modified with respect to eligible providers (EPs) as well as eligible hospitals and CAHs.

Responding to requests for clarification, CMS states that the 2015 Edition of CEHRT must be implemented for an EHR reporting period of at least 90 days during 2019. It does not need to be implemented on January 1, 2019. Further, CMS states that it is premature to establish policy beyond 2020, and therefore declines the suggestion of extending the 90-day reporting period into 2021.

3. Scoring Methodology for Eligible Hospitals and CAHs

Under the Medicare Promoting Interoperability Program, providers are required to demonstrate meaningful use of EHRs, and until recent statutory amendments the Secretary was required to impose increasingly stringent measures of meaningful use over time. The proposed rule briefly reviews the regulatory history of the Stage 1 (2010), Stage 2 (2012) and Stage 3 (2015) meaningful use requirements. CMS notes that the requirement for increasingly stringent meaningful use measures was removed by the Bipartisan Budget Act of 2018.

In this rule, CMS adopts major changes to the scoring system used to determine whether an eligible hospital or CAH has met the meaningful use requirements beginning with the 2019 reporting period. The intention of the changes is to reduce burden and increase flexibility for hospitals while focusing on interoperability and patient access. CMS says the views of hospitals with respect to the burdens of complying with meaningful use requirements were taken into account. In particular, CMS notes the concerns raised with the View, Download or Transmit (VDT) measure because success on that measure requires hospitals to rely on actions of patients.

The current meaningful use scoring system requires eligible hospitals and CAHs to report on six objectives and 16 measures. In order to qualify as a meaningful user of EHRs, performance on the objectives is scored on a pass/fail basis, and in order to pass, performance thresholds must be met for most measures unless an exclusion is claimed.

The newly finalized scoring system relies on fewer measures and eliminates the current threshold-based methodology. It will apply to eligible hospitals and CAHs that participate only in the Medicare Promoting Interoperability Program and those that participate in both the

Medicare and Medicaid Promoting Interoperability Programs. For hospitals that are eligible for the Medicaid Promoting Interoperability Program but not the Medicare version, CMS defers to the states. States have the option to use the measures and scoring as finalized in this rule. This is discussed further in section VIII.D.10 below. The new methodology for eligible hospitals and CAHs attesting to CMS beginning with 2019 reporting is codified in a new section §495.24(e). Other conforming changes are made to regulatory text.

The new methodology requires eligible hospitals and CAHs to report on four objectives and six measures. Instead of pre-defined performance thresholds, points will be awarded for individual measures based on performance or participation. A score of 50 points or more will satisfy the meaningful use requirement; eligible hospitals and CAHs earning a score of less than 50 points will not be considered meaningful users. CMS believes the new scoring approach will allow hospitals and CAHs flexibility to emphasize measures that are most applicable to them while putting less emphasis on other measures. Providers might be considered meaningful users due to strengths in some areas while continuing to improve in others. The table below combines two tables from the final rule to display the final objectives, measures and points for meaningful use scoring for 2019 and 2020.

The final methodology makes three modifications to what was proposed: (1) the new Verify Opioid Treatment Agreement measure will be a bonus measure for both 2019 and 2020 (instead of a bonus measure in 2019 and a required measure in 2020); (2) the Syndromic Surveillance Reporting measure is not required for all hospitals and CAHs but is one of a list from which two measures must be reported; (3) the maximum points for the Provider to Patient Exchange objective remains at 40 points for both 2019 and 2020 (instead of dropping to 35 points in 2020 as proposed to accommodate making the opioid treatment agreement measure mandatory).

Final Performance-Based Scoring Methodology for EHR Reporting Periods in 2019 and 2020

Objectives	Measures	Maximum Points 2019	Maximum Points 2020
e-Prescribing	e-Prescribing	10 points	5 points
	Bonus in 2019, Required in 2020: Query of Prescription Drug Monitoring Program (PDMP)	5 points (bonus)	5 points
	Bonus in 2019 and 2020 Verify Opioid Treatment Agreement	5 points (bonus)	5 points (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points	40 points
Public Health and Clinical Data Exchange	Choose any two of the following: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting	10 points	10 points

Objectives	Measures	Maximum Points 2019	Maximum Points 2020
	Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting		

Overall, in order to be considered a meaningful user beginning with the 2019 reporting year under the new scoring methodology, an eligible hospital or CAH must meet all of the following requirements:

- ☐ Report on all the required measures across all four objectives, unless an exclusion applies*
- Report "yes" on all required yes/no measures, unless an exclusion applies*
- ☐ Attest to completing the actions included in the Security Risk Analysis measure*
- ☐ Achieve a total score of at least 50 points

*failure on this requirement results in a total score of zero

The requirements for scoring each objective follow.

e-Prescribing Objective (1 to 3 measures; 5 to 15 points). For 2019 reporting, the e-Prescribing objective includes the existing e-prescribing measure, weighted at 10 points, and two optional new measures (discussed in section VIII.D.5 below) worth five bonus points each. If an eligible hospital or CAH meets the criteria for exclusion for the e-prescribing measure in 2019, the 10 points for this objective will be redistributed equally between the two measures in the Health Information Exchange objective. The exclusion criteria are unchanged from current regulations. For 2020, the new Query of Prescription Drug Monitoring Program (PDMP) measure becomes required, and a hospital or CAH that qualifies for the e-prescribing measure exclusion is also excluded from this required measure. A separate exclusion is also available for the new measure. In a case where the hospital or CAH claims an exclusion for both required measures in this objective, the 10 points would be divided equally between the two measures in the Health Information Exchange objective. If the exclusion applies only to the Query of PDMP measure, the five points will be added to the e-prescribing measure. The addition of the Query of PDMP measure as a requirement in 2020 is accompanied by a decrease in the points for the e-prescribing measure (from 10 to 5 points).

Health Information Exchange Objective (2 measures; 40 points). For this objective CMS adopts two measures worth 20 points each. The heavy weighting of this objective is intended to emphasize the sharing of health information through interoperable exchange to promote care coordination and better patient outcomes. CMS changes the name of one measure (from Send a Summary of Care to Support Electronic Referral Loops) and adds a new measure Support Electronic Referral Loops by Receiving and Incorporating Health Information, which combines the existing Request/Accept Summary of Care and Clinical Information Reconciliation measures. The new measure is discussed in section VIII.D.6 below. Each measure is worth 20 points. An exclusion applies to the new Support Electronic Referral Loops by Receiving and Incorporating Health Information measure for eligible hospitals and CAHs that are unable to implement the measure for the 2019 reporting period. If the exclusion is claimed the Support Electronic Referral Loops measure will be worth all 40 points.

Provider to Patient Exchange Objective (1 measure; 40 points). CMS considers the objective of improved access and exchange of patient data to be "the crux of the Medicare Promoting Interoperability Program." Hence, the Provide Patients Electronic Access to Their Health Information measure will be worth 40 points to emphasize the importance of patients having control over their own health information. No exclusions are available for this measure. (Under the proposed rule the points for this measure would have dropped to 35 points in 2020 to account for the additional mandatory e-prescribing measure. Because that policy is not finalized, this objective will remain at 40 points in 2020.)

Public Health Data Exchange Objective (2 measures; 10 points). These measures cannot be scored on performance and will be reported using a yes/no response. While CMS had proposed that all eligible hospitals and CAHs be required to report the Syndromic Surveillance Reporting measure and one other of their choice from a specified list (shown in the table above), it is persuaded by commenters that hospitals and CAHs should be allowed to choose two measures from the list including Syndromic Surveillance Reporting. (This is discussed further below.) In order to receive the 10 points for this measure and be eligible as a meaningful user the eligible hospital or CAH would need to report yes on both measures. No additional points are available for reporting more than two measures. Reporting 'yes' on only one measure for this objective will result in a score of zero for the objective and also for the total Promoting Interoperability score. Previously finalized exclusions for these measures are continued. If an eligible hospital or CAH claims an exclusion for one or both measures required for this objective, the 10 points are redistributed to the Provider to Patient Exchange objective, raising that maximum weight to 50 points.

Attestation to Stage 3 Objective: Protect Patient Health Information. In order to receive any Promoting Interoperability score, eligible hospitals and CAHs must attest that they have completed the actions included in the Security Risk Analysis measure at some point during the reporting year. CMS expects that every hospital is already meeting the requirements of this objective and measure as a result of requirements under the Health Insurance Portability and Accountability Act (HIPAA).

Assignment of Performance Points. Performance points will be assigned for each measure as follows. As a requirement for receiving a score, each eligible hospital and CAH must submit complete numerator/denominator and yes/no data for all required measures. For measures that include a numerator and denominator, the eligible hospital or CAH must submit a numerator of at least one patient. The numerator and denominator translate into a performance rate which is multiplied by the total points for the measure (e.g., for a measure worth 10 points on which a hospital's performance rate is 80 percent, 8 points are awarded). CMS will generally round scores to the nearest whole number, with a minimum score of 1 point awarded for a measure even if the score is less than 0.5 as long as the hospital reported on at least one patient for the measure. Scores for each measure are summed into the total score.

Minimum Score for Meaningful User Designation. In finalizing a 50-point minimum score for determining meaningful use, CMS says it believes this encourages progress in interoperability but allows eligible hospitals and CAHs to achieve high performance in one area to offset performance where improvement is needed. Most commenters supported the 50-point minimum.

CMS may propose to adjust the minimum score over time as eligible hospitals and CAHs adjust to the program's new focus and scoring methodology.

4. Measures for Eligible Hospitals and CAHs under the Medicare Promoting Interoperability Program

In constructing the scoring methodology described immediately above, CMS reduces the number of measures required for a hospital or CAH attesting to meaningful use under the Medicare Promoting Interoperability Program. CMS believes that the smaller number of required measures will focus the program on interoperability and patient access.

Some existing measures are modified, others are removed and new measures are added; these changes are detailed below. In addition, some remaining objectives and measures are renamed. CMS notes that the recent elimination of the statutory provision requiring more stringent measures of meaningful use allows it to reduce burden and offer flexibilities.

Exclusion criteria are removed from most of the retained Stage 3 measures. The finalized measures with exclusion criteria are those associated with the e-Prescribing objective, the Public Health and Clinical Data Exchange objective, and the new measure under the Health Information Exchange objective. The exclusion criteria related to broadband availability are removed because the Federal Communications Commission indicates that no counties have less than 4 Mbps of broadband availability and no eligible hospital or CAH has claimed the exclusion.

Responding to commenters suggesting that some exclusion criteria be retained or new exclusion criteria added, CMS notes that eligible hospitals and CAHs may request a significant hardship exception based on extreme and uncontrollable circumstances (e.g., insufficient internet connectivity).

CMS reiterates that the changes to measures apply only with respect to the Medicare Promoting Interoperability Program and do not apply to Medicaid-only eligible hospitals that submit an attestation to their state Medicaid agency for the Medicaid Promoting Interoperability Program.

The final rule includes the following table which summarizes the final policies for retaining, modifying, removing and adding measures.

Measure Status	**Measure**
Measures retained from Stage 3 with no modifications (The Security Risk Analysis measure is retained as a requirement but is not included in the scoring methodology.)	e-Prescribing Immunization Registry Reporting Syndromic Surveillance Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting
Measures retained from Stage 3 with modifications	Send a Summary of Care (Renamed: Supporting Electronic Referral Loops by Sending Health Information) Provide Patient Access (Renamed: Provide Patients Electronic Access to Their Health Information)
Removed measures	Request/Accept Summary of Care Clinical Information Reconciliation

Measure Status	Measure
	Patient-Specific Education Secure Messaging View, Download or Transmit Patient Generated Health Data
New measures	Query of Prescription Drug Monitoring Program (PDMP) Verify Opioid Treatment Agreement Support Electronic Referral Loops by Receiving and Incorporating Health Information

5. New e-Prescribing Measures

CMS adopts, with a modification, its proposal to add two new measures which it believes align with the HHS Opioid Strategy by increasing use of Prescription Drug Monitoring Programs (PDMPs) in order to reduce inappropriate prescriptions, improve patient outcomes and promote informed prescribing practices. The two new opioid measures summarized briefly here are described in detail in the final rule, and the specific requirements are spelled out in regulatory text at §495.24(e)(5)(iii). For both measures, opioids are defined as Schedule II controlled substances and existing policies for the e-prescribing measure apply, including the requirement that CEHRT be used as the sole means of creating the prescription and transmitting it to the pharmacy. Responding to comments, CMS says that the certification criteria allow a health care provider to create a new prescription, change, cancel or refill a prescription, request fill status notifications and request and receive medication history information which it believes could support the query for a prescription drug history for a patient.

Both measures are optional in 2019, and worth 5 bonus points each. While CMS had proposed that both measures would be required beginning in 2020, this is finalized for only one of the measures; the other will remain optional in 2020, as discussed further below.

Query of PDMP assesses the number of Schedule II opioid prescriptions for which CEHRT data are used to conduct a query of a PDMP for prescription drug history (except where prohibited and in accordance with applicable law) as a percentage of the number of all Schedule II opioids electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period. The PDMP query must be conducted before the electronic transmission of the prescription. Like the current e-prescribing measure, this measure may be calculated to include only actions for patients whose records are maintained using CEHRT rather than for all patient records.

In the proposed rule CMS sought comment on a number of specific issues regarding this measure, and in the final rule responds to many comments, which are highlighted here.

Many commenters requested that this measure remain optional in 2020 because the timeline for implementation is viewed as unreasonable without certification criteria and standards. Responding, CMS acknowledges that both the new measures may require eligible hospitals and CAHs to incur additional burden due to workflow changes at the point of care. In this case, it says that eligible hospitals and CAHs that have integrated PDMPs within an EHR may still have to manually calculate the measure because automated functionality for this measure is not currently supported through certification criteria for Health IT Modules.

Despite acknowledging the work that must be done to fully operationalize the Query of PDMP measure, CMS is finalizing it because it believes that integration of PDMPs into the EHR will become more widespread, and that requiring the Query of PDMP measure for 2020 promotes HHS priorities in combatting the opioid crisis. It believes that use of structured data in CEHRT could support querying through broader use of health IT. Under the final rule, healthcare providers have the flexibility to query the PDMP in any manner allowed as legal and practicable under state law, which CMS believes provides more flexibility for providers to report this measure beginning in 2020. The optional reporting in 2019, CMS believes, will allow for expansion of PDMP integration into EHRs and for health IT developers to work with providers on methods for using CEHRT to capture and calculate PDMP query actions. CMS notes that using a health information exchange to access Schedule II opioid prescription drug history is acceptable in meeting this measure requirement.

CMS finalizes that the exclusion for the e-prescribing measure will also apply to Query of PDMP measure. (The exclusion provides that an eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of the EHR reporting period). CMS says that it will review variations in state laws and technical approaches over the next year and will consider whether additional exclusion criteria are needed.

Further, in next year's rulemaking CMS intends to propose that EHR-integrated PDMP querying be required beginning in CY 2020 as part of this measure. In connection with that proposal, CMS also intends to propose an additional exclusion for providers in states where integration with a statewide PDMP is not yet feasible or widely available.

In sum, CMS understands the lack of certification criteria and standards that are currently available as it relates to the Query of PDMP measure, but believes that this measure is essential to combatting the opioid crisis. It will continue to collaborate with other federal agencies and stakeholders to advance the capabilities, standards and functionalities for querying PDMPs as well as to facilitate more informed prescribing practices and improvement of patient outcomes. CMS appreciates the feedback from commenters on the questions it posed in the proposed rule and in general regarding the challenges and barriers to successfully implementing this measure, which it says will inform its future work.

Verify Opioid Treatment Agreement is finalized as an optional measure in both 2019 and 2020; it had been proposed to be a required measure beginning in 2020. The measure assesses the percentage of patients for whom a Schedule II opioid was prescribed during the EHR reporting period and for whom the eligible hospital or CAH sought to identify a signed opioid treatment agreement and then incorporated any agreement found into CEHRT. The measure is limited to patients for whom the total duration of Schedule II opioid prescriptions is at least 30 cumulative days within a six-month look-back period beginning on the date the hospital or CAH electronically transmits the Schedule II opioid prescription using CEHRT. The look-back period is required to use at a minimum the industry standard NCDCP SCRIPT v10.6 medication history request and response transactions codified at 42 CFR 170.205(b)(2). In proposing this measure

CMS acknowledged the debate over the value of opioid treatment plans, and sought specific comment on a number of issues.

Many commenters requested that the Verify Opioid Treatment Agreement measure not be finalized due to the lack of defined data elements, structure, or standards and certification criteria and for other reasons. CMS acknowledges the lack of definition for this measure and the concerns regarding unintended consequences and administrative burden.

CMS is finalizing the addition of this measure but as an optional measure only for 2019 and 2020. CMS says that there are providers who are already verifying if there is an opioid treatment agreement in place before prescribing opioids, and it believes that the measure may help lead to improvements in prescribing practices. It could, CMS says, encourage discussion and additional treatment options between health care providers and patients. Because the denominator is limited to patients with at least 30 cumulative days of Schedule II opioid prescriptions within the 6-month look-back period, it rules out issues related to pain management for certain patients who are post-surgery or recovering from acute illnesses. Since this is an optional measure, no exclusions are finalized.

Although the measure would be technically complex and potentially burdensome for providers to implement, CMS believes that it is possible for providers to implement the measure. It states that developers could incorporate technology standards or services that are not currently required in their health IT product to develop a workflow that healthcare providers are currently using to verify whether there is an opioid treatment agreement. CMS expects that the measure would only be adopted by a limited set of providers that already possess the infrastructure to support capture and calculation of this measure. CMS intends to revisit the measure in future rulemaking.

6. Modifications to the Health Information Exchange Objective Measures

CMS adopts without change its proposals to make a number of changes to the measures associated with this objective, including renaming, combining, and adding measures. The changes are intended to respond to stakeholder concerns regarding implementation of effective health IT-supported workflows, complexity and burden associated with manual tracking of workflows to support health IT measures.

Under the finalized changes, eligible hospitals and CAHs may use any document template within the Consolidated Clinical Document Architecture (CCDA) standard for purposes of the measures under this objective. Eligible hospitals' and CAHs' CEHRT must be able to send the full CCDA upon request, but CMS believes this new flexibility will support efforts to ensure that the information provided during a care transition is relevant.

Like the current measures associated with the Health Information Exchange objective, both measures finalized for this objective can be calculated to include only actions for patients whose records are maintained using CEHRT rather than for all patient records.

Modifications to the Send a Summary of Care Measure. CMS renames this measure "Support Electronic Referral Loops by Sending Health Information," which it believes better emphasizes

completing the referral loop and improving care coordination. Consistent with the new scoring methodology, the existing 10 percent threshold for this measure is removed, and the measure is required for at least one transition of care or referral.

Removal of the Request/Accept Summary of Care Measure and the Clinical Information Reconciliation Measure. These measures are removed based on stakeholder input and CMS' own analysis. The summary of care measure is intended identify when health care providers are engaging with others to obtain patient health information and incorporate relevant data into the patient record. Stakeholders reported that the measure results in undesirable outcomes of burdensome workflow to document the manual action to request or obtain a record or workflows limited to querying internal resources only. In addition, CMS has discovered that the requirement for "incorporating" data into the record is unclear and not exclusively performed through use of CEHRT. For similar reasons, CMS believes that removal of the clinical information reconciliation measure would reduce redundancy, complexity and provider burden.

Addition of Measure: Support Electronic Referral Loops by Receiving and Incorporating Health Information. This newly finalized measure replaces the two measures removed from this objective. The measure assesses the proportion of electronic summary of care records for transition of care, referral or new patients received using CEHRT by the eligible hospital for which it conducts clinical information reconciliation for medication, medication allergy and current problem list. CMS notes that in combining the measures, the eligible hospital or CAH no longer is required to manually count each individual non-health-IT related action to engage other providers. The new measure focuses on the result of the actions when a summary of care record is successfully received and reconciled with the patient record. An exclusion is finalized for eligible hospitals and CAHs that cannot implement the new measure for an EHR reporting period in CY 2019. CMS sought comments on a number of specific issues regarding this measure and the two it is replacing.

To commenters that did not support the replacement of the measures because it would complicate workflows and not result in improved interoperability, CMS says that the current separation of the measures is burdensome and redundant in the action of incorporation of the summary of care record. In addition, the combined measure addresses stakeholder concerns that the separation between receiving and reconciling patient health information is not reflective of clinical and care coordination workflows. CMS acknowledges that the process of clinical information reconciliation includes both automated and manual reconciliation to allow the receiving health care provider to work with the electronic data provided and to work directly with the patient to reconcile their health information. CMS also reiterates that if no update is needed, the process of reconciliation may consist of verifying that fact or determining that information received on referral duplicates existing information in the patient record, which it believes reduces burden.

Further, CMS discusses the need for providers to pursue closing the referral loop. It notes that the denominator for this measure includes only the summary of care records received using CEHRT, so an eligible hospital or CAH does not therefore count in the denominator if a summary of care record is not received. However, CMS encourages the eligible hospital or CAH to make a reasonable effort to acquire the summary of care, such as a request to the referring

provider and a query of any health information exchange or service. If information is not received after a referral, the eligible hospital or CAH who referred the patient should also make a reasonable effort to acquire the summary of care from the referral. CMS believes the finalized measure will help incentivize further innovation around interoperable exchange of information. It plans to continue to work with ONC in future rulemaking on possible functionalities to support automated processes for closing the referral loop.

7. Measures for the Provider to Patient Exchange Objective

CMS changes the name of this objective to "Provide Patients Electronic Access to Their Health Information" to better emphasize patient engagement and access of health information through APIs. The Patient Specific Information measure is removed from this objective, along with the Coordination of Care Through Patient Engagement objective and three associated measures.

Modifications to the Provide Patient Access Measure. The one measure remaining in this objective is renamed "Provide Patients Electronic Access to Their Health Information" and the current 50 percent threshold is removed consistent with the finalized changes in the scoring methodology. This measure requires that patients be provided timely access to view online, download, and transmit their health information and that the eligible hospital or CAH ensure a patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the eligible hospital's or CAH's CEHRT.

Responding to a commenter suggestion that the previously finalized definition of "timely access" by patients (80 FR 62813) under this measure be changed from 36 hours to 72 hours, CMS says that it has not received compelling evidence that 36 hours is unreasonable, and that this timeline gives a reasonable amount of time for providers to review information if necessary before it is made available to patients.

Commenters were concerned that healthcare providers should be able to limit patient access to their data via applications that the provider deems secure rather than be required to provide access via any application configured to meet the technical specifications of the API in the CEHRT. CMS states that it did not intend to imply that eligible hospitals and CAHs and their technology suppliers are not permitted to take reasonable steps to protect the privacy and security of patient information. This might include vetting of application developers before allowing their applications to connect to the API functionality in the provider's health IT. Also, CMS says that applications are not given unmitigated access to data in the healthcare provider's CEHRT; each application should be registered and identifiable so the health care provider or the vendor that supplies the API technology can deactivate any application's access if it functions in anomalous or malicious ways. Patients seeking access to their data using an application may need to authenticate and authorize the application to connect to the provider's API. CMS further clarifies that the measure does not require that the eligible hospital or CAH provide an application for its patients to use.

For guidance on privacy in the case of patients who choose to access their health information through an API, readers are referred to "Key Privacy and Security Considerations for

Healthcare Application Programming Interfaces (APIs)" dated December 2017 which is available on ONC's website: https://www.healthit.gov/sites/default/files/privacy-security-api.pdf.

Some commenters requested additional guidance on how information blocking requirements are viewed in relation to system security, specifically whether a provider's determination of an unsecure API should not be considered information blocking. CMS thanks commenters and says it will continue to consider how any policy related to information blocking should treat issues involving the use of APIs.

Removal of the Patient Specific Education Measure. CMS removes this measure because it says it has proven burdensome and detracts from program priorities. CMS believes this measure does not align with current program goals of improving interoperability, prioritizing actions completed electronically, and use of advanced CEHRT functions. For example, the patient education resources do not need to be maintained within or generated through CEHRT. CMS expects there are different resources and materials otherwise available to patients and the measure could increase the burden on providers in seeking additional materials. Responding to comments, CMS notes that providers may choose to continue to use the functionalities that support this measure even though it is no longer required.

Removal of Patient Generated Health Data Measure. CMS removes this measure to reduce complexity. It notes that the measure is not fully health-IT based, as CMS did not specify the manner in which health care providers would incorporate the data they receive, which therefore may not require advanced use of CEHRT. CMS believes the measure does not align with current program goals of improving interoperability, prioritizing actions completed electronically, and use of advanced CEHRT functions.

Removal of Secure Messaging Measure. CMS removes this measure because it believes the measure does not align with the current program emphasis on interoperability. Further, CMS notes the burden associated with tracking secure messages and the unintended consequences of creating new workflows designed for the measure rather than clinical or administrative effectiveness. Furthermore, the measure may not be practical as the patient is more likely to receive follow-up care after discharge from other providers.

Removal of View, Download or Transmit Measure. CMS removes this measure based on the feedback it received from stakeholders about requiring patient actions for successful provider attestation. Many commenters supported removal of this measure.

8. Measures for the Public Health and Clinical Data Registry Reporting Objective

This objective is finalized with modification from the proposed rule. CMS finalizes changing the name of this objective to "Public Health and Clinical Data Registry Reporting" and requires eligible hospitals and CAHs to report two measures chosen from a list of six (shown in the final performance scoring methodology table above). CMS had proposed that eligible hospitals and CAHs all report on the Syndromic Surveillance Reporting measure and one other measure selected from the list. However, many commenters requested the change because some states do not accept syndromic surveillance files, and CMS understands this to be the case in Oklahoma,

Iowa, Minnesota and parts of Colorado. CMS will continue to monitor the ability of providers to report on syndromic surveillance measures and may consider requiring such reporting in the future. Existing exclusions for this measure will continue.

CMS clarifies that providers are only required to attest to two measures total, regardless of whether an exclusion is claimed. Attesting to more than two measures is possible but will not increase the score on this objective.

Furthermore, CMS states its intention to propose removal of this objective from the Promoting Interoperability Programs no later than the 2022 reporting year, and in the proposed rule sought comments on identifying other appropriate venues in which reporting to public health and clinical data registries could be encouraged.

9. Request for Comment on Potential New Health Information Exchange Measures

In the proposed rule CMS requested comment on two potential measures that address health information exchange across the care continuum, including other providers such as long-term care, post-acute care and behavioral health settings. It believes the addition of such measures would offer eligible hospitals and CAHs more flexibility in identifying measures that are most appropriate to their setting, patient population and clinical improvement goals. The measure "Support Electronic Referral Loops by Sending Health Information Across the Care Continuum" would assess the percentage of patients referred by the eligible hospital or CAH to a provider other than a hospital or CAH for whom the eligible hospital or CAH created and exchanged a summary of care record electronically using CEHRT. The measure "Support Electronic Referral Loops by Receiving and Incorporating Health Information Across the Care Continuum" would assess the percentage of patients referred to the eligible hospital or CAH by a provider other than a hospital or CAH for whom the eligible hospital or CAH completed an information reconciliation regarding medication, medication allergy and a current problem list.

Many commenters opposed the addition of these measures as redundant to the existing health information exchange measures, or suggested ongoing stakeholder discussions. CMS will take the comments into account in developing future policy.

10. Application of Scoring Methodology to the Medicaid Promoting Interoperability Program

As noted earlier, CMS finalizes its proposal to give states the option to adopt the new scoring methodology, objectives and measures for their Medicaid Promoting Interoperability Programs. A state wishing to do so would submit a change to its state Medicaid HIT Plan for CMS approval. CMS expects that states are unlikely to choose this option due to the cost of implementing changes and in light of the small number of providers eligible for an incentive payment under the programs in 2019 and later years. CMS clarifies that states can either (1) continue with the existing meaningful use measures or (2) adopt the new measures, but they may not adopt some of the revisions but not others.

Under this final rule, eligible hospitals and CAHs that participate in both the Medicare and Medicaid Promoting Interoperability Programs will demonstrate meaningful use to CMS and not

their state Medicaid agency. If they meet the Medicare definition they are deemed to be meaningful users for purposes of Medicaid incentive payments. This change is made because under the new scoring methodology there is no longer a common definition of meaningful use between the two programs.

CMS also finalizes that states no longer have to report provider level attestation data to CMS for program years after 2018.

11. Future Directions

CMS sought public comment on the future direction of the Promoting Interoperability Programs. One activity it is considering is creating a set of priority health IT activities as alternatives to the traditional program measures. For example, CMS sought public comment on whether participation in the Trusted Exchange Framework and Common Agreement (TEFCA) should be considered in lieu of reporting on measures within the Health Information Exchange objective. Another consideration is whether eligible hospitals and CAHs could obtain credit for the patient access objective if they maintain an open API which allows patients to access their health information through a preferred third party. A third activity would allow eligible hospitals and CAHs to obtain credit under the Public Health and Clinical Data Exchange objective for piloting emerging technology standards. Additional questions were specified in the proposed rule.

CMS says that many commenters support introducing health IT activities in lieu of reporting on measures, noting that this would reduce provider burden. Others disagreed and other comments were received. CMS will consider these in future policymaking.

12. eCQM Reporting for Hospitals and CAHs

As part of being a meaningful user under the Medicare and Medicaid Promoting Interoperability Programs, eligible hospitals and CAHs must report on eCQMs selected by CMS. For the 2018 reporting period, sixteen eCQMs are available for reporting by eligible hospitals and CAHs. They must report on four of these sixteen measures for one self-selected quarter of data during the calendar year. These requirements are in alignment with those for eCQM reporting under the Hospital IQR Program as described in section VIII.A above.

Beginning with the 2020 reporting period, CMS reduces the number of available eCQMs from sixteen to eight. The eCQMs are removed in an effort to reduce certification burden on hospitals and improve the quality of reported data by allowing providers to focus on a smaller subset of eCQMs. The eCQMs being removed are:

- ☐ Primary PCI Received Within 90 Minutes of Hospital Arrival (NQF #0163) (AMI-8a)
- ☐ Home Management Plan of Care Document Given to Patient/Caregiver (CAC-3)
- ☐ Median Time from ED Arrival to ED Departure for Admitted ED Patients (NQF #0495) (ED-1)
- ☐ Hearing Screening Prior to Hospital Discharge (NQF #1354) (EHDI-1a)
- ☐ Elective Delivery (NQF #0469) (PC-01)
- ☐ Stroke Education (STK-08)

- ☐ Assessed for Rehabilitation (NQF #0441) (STK-10)
- ☐ Median Time from ED Arrival to ED Departure for Discharged ED Patients (NQF 0496) (ED-3)

This list is almost identical to the seven out of fifteen eCQMs removed from the Hospital IQR Program except that the last measure (ED-3) is an outpatient measure and therefore not part of the Hospital IQR Program measure set. By removing this measure, the eCQMs for the two programs will perfectly align. Removal is effective beginning with FY 2022 payment (CY 2020 reporting).

2019 Reporting Period. For 2019, CMS finalizes continuation of the policies in place for reporting during 2018. That is, eligible hospitals and CAHs that report eCQMs electronically must report for one self-selected calendar quarter of 2019 data, with a submission deadline of February 29, 2020. For eligible hospitals and CAHs that report by attestation because electronic reporting is not feasible, and for those that report by attestation under the state Medicaid Promoting Interoperability Program, the reporting period is the full calendar year 2019 unless they are demonstrating meaningful use for the first time under the state program. In that case, the reporting period is any continuous 90-day period within 2019. For all eligible hospitals and CAHs reporting for the Medicare program by attestation the reporting deadline is also February 29, 2020. States have the flexibility to determine the method of reporting and submission periods for the Medicaid program, subject to CMS approval.

Further, for 2019 eligible hospitals and CAHs reporting electronically will continue to report on 4 selected eCQMs from the current list of 16 available measures. Those reporting by attestation must report on all 16 available eCQMs. The form and manner of reporting are explained in subregulatory guidance and documents available from the eCQI Resource Center webpage at https://ecqi.healthit.gov/. Reporting for 2019 will continue through the QualityNet Portal, and CMS also continues to require use of the most recent eCQM specifications for each eCQM to which the EHR is certified. This means that for 2019 electronic reporting of eCQMs, eligible hospitals and CAHs must use the Spring 2017 version of the eCQM electronic specifications and any applicable addenda available at the eCQI Resource Center website above. Further, the EHR technology must be certified to all 16 of the available eCQMs. As previously finalized and discussed in section VIII.A above, eligible hospitals and CAHs must use the 2015 Edition CEHRT for 2019. Recertification for the 2015 Edition is not required each time it is updated to reflect more recent versions of the eCQMs.

In the proposed rule, CMS discussed stakeholder concern about the burdens of eCQM reporting, and invited comment on a series of questions. CMS reports that commenters identified the following possible improvements: uniform calculation of eCQMs across various CEHRT systems and practices; addressing vendor misalignment of eCQM reporting requirements and availability of eCQMs; improved methods of reporting; application of the Meaningful Measures framework to eCQMs; development of metrics that inform readiness of eCQM data for public reporting; and increased participation of hospitals and CAHs in eCQM testing and innovated use of health IT.

13. Participation of Subsection (d) Puerto Rico Hospitals

CMS codifies in regulatory text the program instructions it has issued regarding the participation of subsection (d) Puerto Rico hospitals in the Medicare and Medicaid Promoting Interoperability Programs. These provisions identify subsection (d) Puerto Rico hospitals as eligible hospitals effective with FY 2016 and specify the reporting periods for these hospitals adopted for past years as well as propose the reporting periods for 2018 through 2020 as any continuous 90-day period during the calendar year. Under the statute, payment reductions for subsection (d) Puerto Rico hospitals that are not meaningful users apply beginning with FY 2022 payment, and conforming changes are made to various regulations to reflect this. General deadlines for hardship exception requests also apply to these hospitals. Following statutory requirements, transition periods and transition factors that apply to incentive payments for these hospitals are specified through 2020.

14. Modification to the MA Promoting Interoperability Program

The statute provides for incentive payments to qualifying Medicare Advantage organizations for certain affiliated hospitals that meaningfully use CEHRT and for application of the downward payment adjustment for MA organizations with affiliated hospitals that are not meaningful users of CEHRT. CMS changes the implementing regulations to reflect that subsection (d) Puerto Rico hospitals are potentially eligible as MA-affiliated hospitals for purposes of these adjustments.

15. Modification to the Medicaid Promoting Interoperability Program

CMS finalizes changes to the regulatory text to minimize state burden and align with prior approval policies used for automated data processing and the Medicaid Management Information System. Further, because state Medicaid Promoting Interoperability Program incentive payments to Medicaid eligible professionals and hospitals may not be made after December 31, 2021, CMS finalizes its proposal to end 90 percent federal matching payments to states for most purposes of the program on September 30, 2022. However, the date for expenditures associated with appeals and audits is extended to September 30, 2023.

To receive the federal matching payments, states will have to ensure that goods and services are provided before these deadlines. CMS says that as 2021 and 2022 approach it will use these finalized deadlines in setting reporting requirements and deadlines so that states will be able to conclude administrative activities by the September 30, 2022 deadline in a manner that will allow them to claim the 90 percent federal matching payment.

16. Other Comments

CMS reports receiving comments that were outside the scope of the proposed rule. These include comments addressing the Merit-based Incentive Payment System, regulation of vendors, information blocking, functionality requirements for APIs, the 2015 Edition of CEHRT, issuance of Medicaid incentive payments in 2021. It does not further describe or respond to these comments in the final rule.

IX. Revisions to Requirements for Submitting a Medicare Cost Report

A. Background

Under the regulations at 42 CFR §§ 413.20(b) and 413.24(f), providers are required to submit cost reports annually with the supporting documentation specified in 42 CFR §413.24(f)(5)(i). A cost report submitted without the required supporting documentation is rejected. Several provisions in the regulations requiring supporting documentation for the Medicare cost report to be acceptable need to be updated to reflect current practices, to improve the accuracy and to facilitate more efficient contractor review of cost reports. For instance:

- The regulations require that CMS Form-339 be submitted in addition to the cost report even though the cost report now incorporates this form.
- Teaching hospitals are required to provide a copy of the Intern and Resident Information System (IRIS) diskette. However, diskettes are no longer used by providers to furnish this data to contractors.
- Information from the provider relating to Medicaid days used in the calculation of DSH payments, charity care charges, uninsured discounts, and home office cost allocations are necessary to assure proper payment but are not included among the supporting documentation required with submission of the cost report which can delay payments and prolong audits.

B. Revisions to Regulations

1. Provider Cost Reimbursement Questionnaire

The Provider Cost Reimbursement Questionnaire, Form CMS-339, was incorporated into all Medicare cost reports as a worksheet except for the Organ Procurement Organization (OPO) and Histocompatibility Laboratory cost report, Form CMS-216. CMS is finalizing its proposal to:

- Incorporate the Provider Cost Reimbursement Questionnaire, Form CMS 339, into the OPO and Histocompatibility Laboratory cost report, Form CMS-216.
- Revise the regulations to no longer state that a cost report will be rejected for lack of supporting documentation if it does not include a Provider Cost Reimbursement Questionnaire (Form CMS-339).
- Clarify that a provider must submit all necessary supporting documents for its cost report consistent with recordkeeping requirements in 42 CFR §§413.20 and 413.24.

In each of the specific areas where CMS made a proposal, it indicated that the proposal would not be burdensome to hospitals because there is already a requirement for hospital to collect, maintain, and submit this data when requested. CMS indicates that a requirement to submit this supporting documentation with the cost report would facilitate the contractor's review and verification of the cost report without the need to request additional data from the provider.

Public comments supported the first two of the above three proposals. Some public comments objected to being required to furnish all necessary supporting documentation with the cost report indicating that the requirement would be burdensome and suggested that the provider should only be required to furnish supporting documentation in the event of an audit. This same comment was provided in the specific areas where CMS is requesting documentation such as the bad debt listing, uncompensated care reported on Worksheet S-10 of the Medicare cost report and Medicaid eligible days for the Medicare DSH adjustment.

CMS' response to this comment reiterated what was said in the proposed rule—the requirement is not burdensome because these data are recorded and maintained by the provider and are available to providers at the time of completion of the Medicare cost report. Because not all cost reports are audited, the submission of supporting documents that agree with the amounts reported in the cost report at the time of submission is necessary so that contractors can pay providers promptly and accurately.

2. IRIS Data

Teaching hospitals are paid by Medicare for their IME and direct GME costs based on the number of residents training in a hospital. Residents may train in more than one hospital. For purposes of IME and direct GME payment, no individual may be counted as more than one full-time equivalent (FTE). For each hospital where the resident trains, the resident counts as a partial FTE based on the proportion of time worked at the hospital to the total time worked. IRIS is used to collect and report information on residents training in approved residency programs and used by CMS to ensure that residents are not counted as more than one FTE.

At one time, CMS collected the IRIS data from hospitals on a diskette. Because diskettes are no longer used by providers to furnish these data to contractors, CMS is removing "diskette" from the regulations and instead requiring "Intern and Resident Information System data."

CMS further notes that two reports by the Office of the Inspector General (Report No. A-02-13-01014, August 2014 and OIG Report No. A-02-15-01027, July 2017) cited the need for CMS to develop procedures to ensure that no resident is counted as more than one FTE in the calculation of Medicare IME and direct GME payments. In response to these reports, effective for cost reports filed on or after October 1, 2018, CMS had proposed that the IRIS data contain the same total counts of residents as reported in the hospital's cost report or the cost report will be rejected for lack of supporting documentation. However, CMS is not finalizing this proposal because a new Extensible Markup Language (XML)-based IRIS file format that captures FTE resident count data consistent with how FTEs are reported on the Medicare cost report will not be completed prior CMS' proposed effective date for this new policy.

In addition to comments that CMS has addressed by not finalizing its proposal to provide total counts of residents, public commenters made a number of suggestions for improving IRIS and creating compatibility with information reported in the Medicare Cost Report e-Filing to facilitate auditing. CMS indicated it would explore these suggestions as it develops the XML-based IRIS program.

3. Medicare Bad Debt Reimbursement

Section 1861(v)(1) of the Act and the regulations at 42 CFR §413.89 provide authority for Medicare to reimburse a portion of Medicare uncollectible deductible and coinsurance amounts to those entities eligible to receive reimbursement for Medicare bad debt. The Provider Cost Reimbursement Questionnaire (Forms CMS-339 and 216) require the provider to submit supporting documentation with the cost report to substantiate its claims for Medicare bad debt reimbursement. That documentation, known as the "Medicare bad debt listing," requires information such as the patient's name, dates of service, the beneficiary's Medicaid status, if applicable, the date that collection effort ceased, and the deductible and coinsurance amounts.

Effective for cost reporting periods beginning on or after October 1, 2018, for providers claiming Medicare bad debt reimbursement, CMS will reject a cost report for lack of supporting documentation if it does not include a detailed bad debt listing that corresponds to the bad debt amounts claimed in the provider's cost report.

Commenters suggested standardizing the format of the bad debt listing so it corresponds to the bad debt amounts claimed in the provider's cost report. CMS indicated that it will continue to use the exhibit to CMS Form-339 which is being incorporated into the Medicare cost report as the standardized format of the bad debt listing.

Some commenters cited the need to revise the bad debt listing following the submission of the cost report and suggested that cost reports be permitted to be amended for this purpose. CMS disagreed indicating that uncollectible deductibles and coinsurance amounts are recognized as allowable bad debts in the reporting period in which the debts are determined to be worthless. Because cost reports are due on or before the last day of the fifth month following the close of the period covered by the report, CMS believes there is sufficient time for the provider to accurately report bad debts. CMS did acknowledge, however, that providers may request and contractors may grant a reopening to amend cost reports.

4. Disproportionate Share Hospital (DSH) Payment Adjustment

Medicare DSH payments are based, in part, on the hospital's number of inpatient days for patients who are eligible for Medicaid, but were not entitled to benefits under Medicare Part A. Effective for cost reporting periods beginning on or after October 1, 2018, a cost report will be rejected for lack of supporting documentation if it does not include a detailed listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report for determining the hospital's DSH payment adjustment. If the hospital submits an amended cost report that changes its Medicaid eligible days, an amended listing that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report would be required.

Some commenters pointed out that, in some instances, the state may not have made information regarding the Medicaid eligible days available to the provider at the time the cost report is submitted. These commenters indicated that CMS' policy would require the provider to submit knowingly incomplete information with the cost report and also would require a duplication of

efforts if an amended cost report is submitted with an updated listing of the Medicaid eligible days in the 12 months following the hospital's cost report due date.

CMS disagreed with this comment indicating that currently, the provider is required to submit the cost report with the known Medicaid eligible days for the hospital's fiscal year. The policy would require hospitals to substantiate those days by requiring the hospital to also submit a listing of the hospital's Medicaid eligible days that corresponds to the days claimed in the hospital's cost report. If the Medicaid eligible days change once the hospital receives the documentation from the state, the hospital may amend its cost report.

In response to a comment, CMS indicated that SCHs that would otherwise be eligible for DSH but for being paid on the basis of a hospital-specific rate would not be required to submit a listing of Medicaid eligible days. However, MDHs and SCHs claiming DSH and being paid based on the federal rate will be required to submit the Medicaid eligible days listing.

5. Charity Care and Uninsured Discounts

In addition to DSH payments, Medicare distributes an additional payment to hospitals for uncompensated patient costs. CMS establishes a national pool for uncompensated care that is distributed to each hospital. In FY 2018, these payments are partially distributed to hospitals based on Worksheet S-10 of the Medicare cost report. By FY 2020, uncompensated care payments will be completely distributed using data reported on Worksheet S-10.

Uncompensated care is defined as charity care plus non-Medicare bad debt. Charity care will include discounts from billed charges for patients eligible for the hospital's charity care or financial assistance policy. Effective for cost reporting periods beginning on or after October 1, 2018, CMS is requiring a detailed listing of charity care and/or uninsured discounts that contains information such as the patient name, dates of service, insurer (if applicable), and the amount of charity care and/or uninsured discount that corresponds to the amount claimed in the hospital's cost report as a supporting documentation with the hospital's cost report.

CMS agreed with commenters on developing standardized formats for reporting charity care and uninsured discounts and it will work on doing so for the future. Until a standard format is adopted, the regulation mandates the hospitals submit the required information that corresponds to the amounts claimed in the cost report in order for the cost report to be considered acceptable and not be rejected for lack of supporting documentation.

6. Home Office Allocations

A chain organization consists of a group of two or more health care facilities which are owned, leased, or otherwise controlled by one organization. When a provider claims costs on its cost report that are allocated from a home office (also known as a chain home office or chain organization), the home office cost statement is the supporting documentation as set forth in Section 2153, Chapter 21, of the Provider Reimbursement Manual Part 1. Section 2153 states that each contractor servicing a provider in a chain must be furnished with a detailed home office

cost statement as a basis for reimbursing the provider for cost allocations from a home office or chain organization.

CMS is concerned that:

- Many cost reports that have home office costs allocated to them are submitted without a home office cost statement as a supporting document;
- There are home offices or chain organizations that are not completing a home office cost statement to support the costs they are allocating to the provider cost reports; and
- Some providers paid under a PPS mistakenly believe that a home office cost statement is no longer required.

CMS indicates that home office costs reported in the provider's cost report may have an impact on future rate-setting and payment refinement activities.

CMS modified its proposed policy in the final rule to account for home offices that report costs on a different fiscal reporting period than a provider's cost reporting period and to clarify that the home office only needs to furnish one home office cost statement for all its providers and to each of its provider's servicing MACs effective for cost reporting periods beginning on or after October 1, 2018.

When a provider and its home office have different fiscal reporting periods, CMS is requiring that the provider's home office costs for a portion of the cost reporting period (as reflected on the home office cost statement) must correspond to a portion of the amount reported in the provider's cost report. When the provider and its home office have the same fiscal year end, the provider's home office costs for the same time period (as reflected on the home office cost statement) must correspond to the costs reported in the provider's cost report.

X. Hospital Requirements to Publicly List Standard Charges

The ACA established section 2718(e) of the Public Health Service Act. This provision requires each hospital operating within the United States make public a list of its standard charges for items and services including for diagnosis-related groups according to guidelines established by the Secretary. In the FY 2015 IPPS/LTCH rule (79 FR 50146), CMS reminded hospitals of their obligation to be in compliance with this provision by making public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry.

The rule describes CMS' concern that challenges continue to exist for patients due to insufficient price transparency. Such challenges include:

- Patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in network hospitals, and by facility and physician fees

for emergency room visits.
- Chargemaster data are not helpful to patients for determining what they are likely to pay for a particular service or hospital stay.

In order to promote greater price transparency for patients, CMS is updating its guidelines to require hospitals to make available a list of their current standard charges via the internet in a machine-readable format and to update this information at least annually, or more often as appropriate. CMS is finalizing this policy without change from the proposed rule. In response to comments, CMS reiterates several times that this change is the only one it is making at this time.

In the proposed rule, CMS asked a large number of questions about how hospitals and others can provide useful information to help consumers understand the costs of health care services. The following is a selection of public comments and CMS' responses.

- Many commenters indicated that many hospitals already make their standard charges available voluntarily or under applicable state law. CMS agreed and referenced the 2014 American Hospital Association State Transparency Survey data indicating that 35 states require hospitals to release information on some charges and 7 states rely on voluntary disclosure of charges.
- Some commenters stated that the information contained in the chargemaster would not be useful to patients as it would not inform them of their out-of-pocket costs for a particular service, depict negotiated discounts with insurers or provide context to make the information understandable. To the extent that such information would be published in a payer-specific manner, the commenters stated that such information is proprietary and confidential, and that publishing this information could undermine competition. CMS disagrees and noted that many hospitals have price transparency initiatives beyond the provision of the chargemaster that provide needed context for understanding hospital charges.
- Many commenters explained that, for insured patients, payers are a better source of information about the cost of care and should be the primary source of information for out-of-pocket costs for patients. For uninsured patients, commenters noted that many patients receive free or discounted care through the hospital's charity care policies. CMS responded that its guidelines do not preclude hospitals and payers from working together to provide information on out-of-pocket costs for patients and to improve price transparency for patients or change hospital policies on charity care to uninsured patients.
- Several commenters expressed concern about the updated guidelines conflicting with state requirements and increasing administrative burden if hospitals are required to report charge information in multiple incongruent ways. Other commenters noted that some state efforts are already providing patients with much more information than they could obtain from a chargemaster and suggested that CMS instead encourage state level price transparency efforts. CMS encourages state efforts on price transparency. As many hospitals that already make their standard charges publicly available either voluntarily or under applicable state law, disclosure of standard charges under CMS' updated guidelines can exist in a complementary manner with state regulatory initiatives.
- A few commenters expressed concern that patients may forgo needed care if they were informed of the charges in advance. Other commenters noted that price information in the absence of quality information can be misleading to patients in a variety of ways. CMS

disagrees that patients may forgo needed care if they were informed of the charges in advance if that information is placed in the proper context by hospitals. CMS agrees that price information and quality information is important indicators that hospitals are not precluded from providing quality information to patients under its guidelines.

XI. Revisions to Physician Certification of an Inpatient Stay

Sections 1814(a)(2) and 1835(a)(2) of the Act require a physician to certify and periodically recertify the medical necessity of certain types of covered services provided to Medicare beneficiaries. If the information can be found in the medical record, the information does not need to be repeated in the certification statement. 42 CFR §424.11(c) specifies it will suffice for the certification statement to indicate where in the medical record the information can be found.

CMS is concerned that requiring the certification statement to state where the information can be found is resulting in unnecessary denials of Medicare claims even when that information may be readily apparent to the reviewer. For this reason, CMS is eliminating that requirement. In addition, it is relocating the statement that supporting information contained elsewhere in the provider's records need not be repeated in the certification or recertification statement. The statement is being relocated to end of the immediately preceding paragraph (b), which describes similar kinds of flexibility that are currently afforded in terms of completing the required statement. Public comments supported the policy that CMS finalized without change.

XII. Request for Information on Promoting Electronic Interoperability

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20550 through 20553), CMS requested comments on promoting interoperability and electronic health care information exchange. It acknowledged receiving approximately 313 timely pieces of correspondence on this RFI but neither summarized nor responded to the comments.

Appendix: IPPS Regulatory Impact Analysis Table

TABLE I.—IPPS OPERATING IMPACT ANALYSIS: FINAL RULE FY 2019

	Number of Hospitals [1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Wage Data with Application of Wage Budget Neutrality (3)[4]	MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All FY 2019 Changes (7)[8]
All Hospitals	3,256	1.8	0	0	0	0	0.1	2.4
By Geographic Location:								
Urban hospitals	2,483	1.8	0	0	-0.1	0	0.1	2.5
Large urban areas	1,302	1.8	0.1	0	-0.7	0	0	2.4
Other urban areas	1,181	1.8	0	0	0.5	0.1	0.2	2.5
Rural hospitals	773	1.5	-0.3	-0.1	1.2	-0.2	0.1	1.2
Bed Size (Urban):								
0-99 beds	644	1.7	-0.5	0.1	-0.7	0.1	0.2	1.7
100-199 beds	763	1.8	0	0	-0.1	0.1	0.2	2.2
200-299 beds	433	1.8	0	0	0.1	0	0.1	2.3
300-499 beds	424	1.8	0.1	0	-0.1	0	0.1	2.5
500 or more beds	219	1.8	0.1	0	-0.2	0	0	2.9
Bed Size (Rural):								
0-49 beds	306	1.4	-0.5	0	0.3	-0.2	0.2	0.9
50-99 beds	274	1.3	-0.4	0	0.7	-0.1	0.2	1.1
100-149 beds	108	1.6	-0.5	-0.1	0.9	-0.2	0	1.2
150-199 beds	45	1.7	-0.1	-0.2	2	-0.2	0.3	1.4
200 or more beds	40	1.7	0.1	-0.2	2.4	-0.2	0	1.6
Urban by Region:								
New England	113	1.8	0.1	-0.5	2.6	2.5	0.1	4.7
Middle Atlantic	310	1.8	0.2	0	0.3	-0.4	0.1	2.3

	Number of Hospitals [1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Wage Data with Application of Wage Budget Neutrality (3)[4]	MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All FY 2019 Changes (7)[8]
South Atlantic	401	1.8	0	-0.1	-0.5	-0.3	0	2.1
East North Central	386	1.8	0.1	-0.2	-0.4	-0.4	0.1	2.1
East South Central	147	1.8	0	0	-0.4	-0.3	0	2.1
West North Central	158	1.8	-0.1	0	-0.8	-0.3	0.6	2.1
West South Central	379	1.8	0	0.2	-0.7	-0.3	0	2.3
Mountain	164	1.7	-0.1	-0.7	-0.2	1.1	0.3	2.1
Pacific	374	1.8	-0.1	0.8	0.1	0.2	0.1	3.2
Puerto Rico	51	1.8	0	-1.2	-1.2	0.1	0.1	0.8
Rural by Region:								
New England	20	1.5	0.1	-0.5	1.5	-0.3	0	0.9
Middle Atlantic	53	1.5	-0.2	-0.1	0.7	-0.2	0.1	1.4
South Atlantic	122	1.6	-0.2	-0.2	1.7	-0.2	0.1	1.2
East North Central	114	1.5	-0.3	0.1	0.9	-0.1	0	1.1
East South Central	150	1.7	-0.1	-0.2	2.5	-0.3	0.1	1.8
West North Central	94	1.3	-0.5	0	0.1	0	0.2	0.9
West South Central	145	1.5	-0.3	0.2	1.3	-0.3	0.2	1.5
Mountain	52	1.3	-1.1	-0.4	0	-0.1	0.8	0.8
Pacific	23	1.4	-0.4	-0.2	0.8	-0.1	0	1
By Payment Classification:								
Urban hospitals	2,264	1.8	0	0	-0.6	0	0.1	2.3
Large urban areas	1,317	1.8	0.1	0	-0.7	0	0	2.4
Other urban areas	947	1.8	0	0	-0.3	0.2	0.2	2.1
Rural areas	992	1.7	-0.1	0	1.9	-0.1	0.1	2.7
Teaching Status:								

	Number of Hospitals [1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Wage Data with Application of Wage Budget Neutrality (3)[4]	MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All FY 2019 Changes (7)[8]
Nonteaching	2,157	1.7	-0.1	0	0.1	0.1	0.1	2.1
Fewer than 100 residents	849	1.8	0	0	-0.2	-0.1	0.2	2.2
100 or more residents	250	1.8	0.2	0	0.1	-0.1	0	3.1
Urban DSH:								
Non-DSH	520	1.8	-0.3	-0.2	-0.2	-0.1	0.2	2.1
100 or more beds	1,462	1.8	0.1	0	-0.6	0.1	0.1	2.3
Less than 100 beds	367	1.7	-0.2	0.3	-0.6	0.1	0.1	1.9
Rural DSH:								
SCH	256	1.2	-0.6	-0.1	0	-0.1	0	0.7
RRC	382	1.7	0	0.1	2.3	-0.2	0.1	3.1
100 or more beds	33	1.8	0	-0.6	1	0.2	0.1	2.9
Less than 100 beds	236	1.6	-0.3	0	0.8	-0.2	0.3	1.5
Urban teaching and DSH:								
Both teaching and DSH	805	1.8	0.1	0	-0.6	-0.1	0.1	2.4
Teaching and no DSH	89	1.9	-0.1	-0.1	-0.5	-0.1	0	2.3
No teaching and DSH	1,024	1.8	0	0.1	-0.4	0.3	0.1	2.2
No teaching and no DSH	346	1.8	-0.3	-0.2	-0.6	-0.1	0.2	1.8
Special Hospital Types:								
RRC	327	1.8	0	0.2	2.5	-0.2	0.2	3.4
SCH	312	1.1	-0.5	0.1	-0.1	-0.1	0	0.8
MDH	140	1.5	-0.5	-0.1	0.8	0	0	1.2
SCH and RRC	134	1.4	-0.2	-0.2	0.3	0	0.1	1.2
MDH and RRC	16	1.5	-0.4	0	0.8	-0.1	0	1.1
Type of Ownership:								

	Number of Hospitals [1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Wage Data with Application of Wage Budget Neutrality (3)[4]	MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Frontier Wage Index and Outmigration Adjustment (6)[7]	All FY 2019 Changes (7)[8]
Voluntary	1,899	1.8	0	0	0	0	0.1	2.4
Proprietary	856	1.8	0	-0.1	-0.1	0	0.1	2.1
Government	501	1.7	0.1	0.2	-0.1	-0.1	0	2.5
Medicare Utilization as a Percent of Inpatient Days:								
0-25	602	1.8	0.1	-0.1	-0.5	0	0	2.3
25-50	2,139	1.8	0	0	0	0	0.1	2.5
50-65	421	1.7	-0.2	-0.1	0.6	0.2	0.1	1.7
Over 65	73	1.1	0.5	-0.1	-0.4	-0.3	0.1	2.5
Reclassifications by the Medicare Geographic Classification Review Board:								
All Reclassified Hospitals	856	1.8	0	0.1	2.4	-0.2	0	2.8
Non-Reclassified Hospitals	2,400	1.8	0	0	-1	0.1	0.1	2.2
Urban Hospitals Reclassified	585	1.8	0	0.1	2.4	-0.2	0	3
Urban Non-Reclassified Hospitals	1,838	1.8	0	0	-1.1	0.1	0.1	2.3
Rural Hospitals Reclassified Full	271	1.5	-0.2	-0.1	2.1	-0.2	0.1	1.5
Medicare Utilization as a Percent								
0-25	602	1.8	0.1	-0.1	-0.5	0	0	2.3
25-50	2,139	1.8	0	0	0	0	0.1	2.5
50-65	421	1.7	-0.2	-0.1	0.6	0.2	0.1	1.7
Over 65	73	1.1	0.5	-0.1	-0.4	-0.3	0.1	2.5

[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 2017, and hospital cost report data are from reporting periods beginning in FY 2016 and FY 2015.

[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 1.35 percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 2.9 percent market basket update reduced by 0.8 percentage point for the multifactor productivity adjustment and the 0.75 percentage point reduction under the Affordable Care Act), and the 0.5 percent adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 36 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2017 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.997192 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wage index data using FY 2015 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wage budget neutrality factor is 1.000748.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2019 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2019. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.985932.

[6] This column displays the effects of the rural floor and expiration of the imputed floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.993142.

[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2018 to FY 2019.