**Fiscal Year 2019 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule**

## SUMMARY

On April 24, 2018, the Centers for Medicare & Medicaid Services (CMS) released its proposed 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).

On the same day, CMS also released a notice advising the public of its implementation of sections 50204 and 50205 of the Bipartisan Budget Act (BBA) of 2018 extending the statutory deadline and making changes to the low volume hospital adjustment and the Medicare Dependent Hospital (MDH) programs. **Of the most significance in these notices is the deadline for hospitals eligible for the low volume hospital program to notify its Medicare Administrative Contractor (MAC) that it meets or continues to meet the distance requirements to be a low-volume hospital by May 29, 2018**. More details are provided in section IV. 4. of this summary.

The payment rates and policies described in the IPPS/LTCH proposed rule (CMS-1694-P) 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 proposed rule also sets forth rate-of-increase limits for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals, and religious nonmedical health care institutions, which are paid based on reasonable costs.

The proposed rule will be published in the *Federal Register* on May 7, 2018. **Written or electronic comments on the proposals must be submitted to CMS by close of business June 25, 2018**. A final rule will be published around August 1, 2018, with the rates and policy changes generally taking effect on October 1, 2018.

CMS makes many data files available to support analysis of the proposed rule. These data files are generally available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Proposed-Rule-Home-Page-Items/FY2019-IPPS-Proposed-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.

Numbered tables that were historically included in the IPPS but are now only available on the CMS website can be found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Proposed-Rule-Home-Page-Items/FY2019-IPPS-Proposed-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.

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

CMS estimates that policies and rates in the proposed rule would increase combined operating and capital payments to the approximately 3,257 acute care hospitals paid under the IPPS by about $4.1 billion in FY 2019 compared to FY 2018 or 3.4 percent. Approximately, 3.2 percentage points of this estimated increase is due to the proposed change in operating payments, including uncompensated care while the remaining 0.2 percentage points is due to the increase in capital and low-volume hospital payments. CMS estimates that capital payments will increase 1.7 percent or about $146 million. Low volume hospital payments are estimated to increase $72 million.

## A. Inpatient Hospital Operating Update

The proposed rule would increase IPPS operating payment *rates* by 1.75 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 1.75 percent rate increase is the net result of a market basket update equal to 2.8 percent; an annual multi-factor productivity (MFP) adjustment of -0.8 percentage points[1]; an ACA required statutory update adjustment of -0.75 percentage points; and an adjustment of +0.5 percentage points required under section 414 of the MACRA (described in sections II.D and IV.B below). 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 MDHs are paid. The documentation and coding adjustment does not apply to the hospital-specific rates resulting in a 1.25 percent increase rather than the 1.75 percent increase applicable to the national standardized operating amounts.

| Factor | Percent Change |
|---|---|
| FY 2019 Market Basket | 2.8 |
| Multifactor productivity adjustment | -0.8 |
| ACA Adjustment | -0.75 |
| Subtotal | 1.25 |
| MACRA Documentation and Coding Adjustment | +0.5 |
| Net increase before application of budget neutrality factors | 1.75 |

Hospitals that fail to participate successfully in the Hospital Inpatient Quality Reporting (IQR) Program or are not meaningful users of EHR do not receive the full payment rate increase. For FY 2019, hospitals that choose not to participate in the IQR Program or do not successfully submit the required quality data are subject to a one-fourth reduction of the market basket update or ¼ of the full market basket of 2.8 percent or -0.7 percentage points. The statute additionally requires that the update for any hospital that is not a meaningful EHR user be reduced by three-quarters of the market basket update or 2.1 percentage points.

CMS estimates that 54 hospitals will not receive the full market basket rate-of-increase because they failed the quality data submission process or chose not to participate in IQR; 148 hospitals because they are not meaningful EHR users; and 43 hospitals are estimated to be subject to both reductions.

[1] The Bureau of Labor Statistics publishes the official measure of private nonfarm business MFP; historical data on this series are available at http://www.bls.gov/mfp. Projections of MFP for IPPS payment updates are developed by IHS Global Insight, Inc. an economic forecasting firm which also prepares the market basket forecasts, using a methodology described in the proposed rule. More technical information on the MFP is available from BLS: http://www.bls.gov/mfp/mprtech.pdf. The final rule will reflect more recent projections of the market basket and productivity adjustments.

Hospitals that have not successfully submitted quality data will receive a proposed update of 0.55 percent for FY 2019. The reduction to the update is applied before application of the MACRA documentation and coding adjustment and equals the subtotal in the above table of 1.25 less 0.7 percentage points.

Hospitals that do not qualify as meaningful EHR users will receive an update of -0.85 percent for FY 2019. This update is also applied before application of the MACRA documentation and coding adjustment and equals the subtotal of 1.25 percent in the above table less 2.1 percentage points.

Hospitals that have neither successfully submitted quality data or qualified as meaningful EHR users will receive an update of -1.55 percent (1.25 percent less 2.8 percentage points prior to the MACRA documentation and coding adjustment).

**B. Payment Impacts**

CMS' impact table for IPPS operating costs shows proposed FY 2019 payments increasing 2.1 percent. Not all policy changes are reflected in this total. For example, increases in payment due to the effects of proposed policy changes related 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 proposed payment rates | +1.7[1] |
| Frontier hospital wage index floor and out-migration wage adjustment | +0.1[2] |
| Residual | +0.3[3] |
| Total | +2.1 |

[1]Weighted average of the updates of 1.25 percent for hospitals that receive payment in full or in part based on hospital-specific rates and 1.75 percent for all other hospitals.
[2]The frontier hospital wage index floor increases payments about $61 million to 50 hospitals and the out-migration adjustment increases payments about $36 million to 220 providers.
[3]This residual is unexplained. There is some implication that the residual is accounted for by increased outlier payments relative to the amount removed from IPPS rates in FY 2018. CMS is required to simulate its estimates of FY 2018 and FY 2019 outlier payments to set the FY 2019 outlier threshold. However, CMS has no actual FY 2018 claims data upon which to make an estimate of its FY 2018 outlier payments.

Table I Impact Analysis

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

| Hospital Type | All Proposed Rule Changes |
|---|---|
| All Hospitals | 2.1% |
| Large Urban | 2.1% |
| Other Urban | 2.1% |
| Rural | 1.1% |
| Major Teaching | 2.6% |

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 has not yet determined whether the 15 applications it received for FY 2019 meet the criteria for new technology add-on payments. Estimates will be included in the final rule if any are found to be eligible. New technology add-on payments for four technologies will expire at the end of FY 2018. CMS will continue to make new technology add-on payments for three technologies that remain eligible and estimates spending will be $8.4 million.

- Post-Acute Transfer Policy. CMS is proposing to make 10 proposed new or revised MS-DRGs subject to the post-acute transfer policy. One of these MS-DRGs will be subject to the special payment methodology. In addition, CMS's implementation of section 53019 of the BBA 2018 extends the post-acute transfer policy to pre-geometric mean length of stay IPPS discharges to hospice. CMS' Actuaries estimate that the BBA 2018 provision will result in annual savings of $240 million beginning in FY 2019 up to $540 million annually by FY 2028.

- Low Volume Hospitals. CMS estimates its proposed implementation of extensions and revisions to the low volume hospital policy required by section 50204 of BBA 2018 will increase Medicare payments by $72 million in FY 2019 compared to FY 2018. This estimate is based on 622 providers receiving approximately $417 million in FY 2019 compared to 606 providers receiving approximately $345 million in FY 2018.

- Medicare DSH and Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to increase 21.9 percent or $1.484 billion. This increase is due to changes in estimates in the number of uninsured individuals in FY 2019. More detail on these calculations is in section IV. F. While the total pool of uncompensated care payments is increased, the distribution of those payments will not be uniform and will reflect each hospital's share of national aggregate uncompensated costs (also detailed in section IV. F.). CMS estimates that traditional DSH payments will increase 4.8 percent or about $140 million. Traditional DSH payments are reconciled after the year is completed based on actual data. Uncompensated care payments are based on CMS estimates and not reconciled.

- Hospital Readmissions Reduction Program (HRRP). The HRRP program would reduce FY

2019 payments to an estimated 2,610 hospitals. This compares to 2,591 hospitals that were estimated to receive an HRRP penalty in FY 2018. CMS estimates savings from the HRRP will be approximately $566 million in FY 2019 or nearly the same as the $564 million estimated FY 2018.

- Hospital Value-Based Purchasing (HVBP) Program. The HVBP program is budget neutral but will redistribute about $1.9 billion (2 percent of base operating MS-DRG payments) based on hospitals' performance scores.

- Hospital Acquired Conditions (HAC) Reduction Program. CMS indicates that "any significant impact due to the proposed HAC Reduction Program changes for FY 2019, including which hospitals would receive the adjustment, would depend on actual experience."

- Capital IPPS Payments. CMS estimates capital payment per case will increase 1.7 percent. Of this increase, 1.2 percent is attributed to the capital payment rate update and another 0.5 percent is attributed to an increase in case mix. CMS does not provide the dollar increase in capital payments but the data provided with the rule suggests the increase will be about $180 million.

## C. IPPS Standardized Amounts

The following four rate categories continue in FY 2019:

- Hospital Submitted Quality Data and is a Meaningful EHR User (applicable percentage increase [i.e., before adjustments] = 1.25 percent
- Hospital did NOT submit quality data and is a meaningful EHR user (applicable percentage increase = 0.55 percent)
- Hospital submitted quality data and is NOT a meaningful EHR user (applicable percentage increase = -0.85 percent)
- Hospital did NOT submit quality data and is NOT a meaningful EHR user (applicable percentage increase = -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 proposed rule were calculated applying the additional 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, 0.997896 (a decrease of 0.21 percent);
- Wage index, 1.001182 (an increase of 0.12 percent);
- Geographic reclassification, 0.987084, a reduction of 1.3 percent; and
- Rural and imputed floor budget neutrality, 0.994733, a reduction of 0.5 percent applied to

hospital wage indices (68.3 percent of total payments for hospitals with a wage index of 1.0 or greater and 62 percent of total payments for hospitals with a wage index of less than 1.0).

- 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 proposed FY 2019 is about 1.5 percent including the IPPS update of 1.25 percent. There is an additional MACRA documentation and coding adjustment of +0.5 percent. The additional -0.25 percent residual in the change to the standardized amount is accounted for by the budget neutrality adjustment for MS-DRG recalibration (-0.21 percent) and a slight difference in the reclassification budget neutrality adjustment between FY 2018 and FY 2019.

Thus, the net increase in the operating standardized amounts from FY 2018 to proposed FY 2019 after applying all adjustments is about 1.5 percent for hospitals satisfying quality reporting and EHR meaningful use requirements. Including the proposed FY 2019 capital payment rate, which increases 1.2 percent, the operating plus capital standardized amounts will increase by approximately 1.48 percent in FY 2019 compared to FY 2018.

# FY 2019 RULE TABLES 1A-1D

| TABLE 1A. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS; LABOR/NONLABOR (68.3 PERCENT LABOR SHARE/31.7 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)—FY 2019 | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 1.25 Percent)** | | **Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = -0.85 Percent)** | | **Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 0.550 Percent)** | | **Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = - 1.55 Percent)** | |
| **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** |
| $3,863.17 | $1,793.01 | $3,783.04 | $1,755.82 | $3,836.46 | $1,780.61 | $3,756.34 | $1,743.43 |

| TABLE 1B. NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX LESS THAN OR EQUAL TO 1)—FY 2019 | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 1.25 Percent)** | | **Hospital Submitted Quality Data and is a NOT a Meaningful EHR User (Update = -0.85 Percent)** | | **Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 0.550 Percent)** | | **Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = - 1.55 Percent)** | |
| **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** |
| $3,506.83 | $2,149.35 | $3,434.09 | $2,104.77 | $3,482.58 | $2,134.49 | $3,409.86 | $2,089.91 |

| TABLE 1C. ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2019 | | | | |
|---|---|---|---|---|
| | Rates if Wage Index Greater Than 1 | | Rates if Wage Index Less Than or Equal to 1 | |
| | **Labor** | **Nonlabor** | **Labor** | **Nonlabor** |
| National[1] | Not Applicable | Not Applicable | $3,506.83 | $2,149.35 |
| [1]For FY 2019, there are no CBSAs in Puerto Rico with a proposed national wage index greater than 1. | | | | |

| TABLE 1D. CAPITAL STANDARD FEDERAL PAYMENT RATE | |
|---|---|
| | **Rate** |
| National | $459.78 |

Note that 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.

Effective January 1, 2016 separate standardized amounts for Puerto Rico no longer apply. The separate labor-related share of 62 percent continues for Puerto Rico hospitals and other hospitals with a wage index of less than 1.0. As all CBSAs in Puerto Rico have a wage index that is less than 1.0, the standardized amounts in Table 1C are the same as those 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 submitted quality data and are meaningful EHR users.

## D. Outlier Payments and Threshold

To qualify for outlier payments for high cost cases, a case must have costs greater than the sum of the prospective payment rate for the MS-DRG, plus IME, DSH, uncompensated care and new

technology add-on payments, plus the "outlier threshold" or "fixed-loss" amount, which is $26,601 in FY 2018. The sum of these components is the outlier "fixed-loss cost threshold" applicable to a case. 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 proposes an outlier fixed-loss cost threshold for FY 2019 equal to the prospective payment rate for the MS-DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $27,545. The process CMS proposes to follow in setting the FY 2019 outlier threshold is described in detail in the proposed rule and summarized below. Noting that commenters on the FY 2016 IPPS/LTCH proposed rule expressed concern about being unable to replicate the calculation of the charge inflation factor, CMS includes specific information on which hospitals were included and excluded from the calculation of charge inflation and once again shows claims data cases and charges grouped by quarter, and posts on its website a table by provider of monthly charges used to compute the charge inflation factor. In addition, CMS says that it continues to work with systems teams and its privacy office to explore expanding the information included in the publicly-available limited data set for future rulemaking, perhaps by providing a supplemental data file.

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 based on the respective federal rates, and it adjusts the respective operating and capital standardized amounts using those percentages.

FY 2019 outlier threshold methodology. CMS proposes to set the target for total outlier payments at 5.1 percent of total operating DRG payments (including outlier payments but proposing to continue to exclude adjustments for value-based purchasing and the readmissions reduction program). To calculate the proposed FY 2019 outlier threshold, 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 of $56,433 ($546,842,933,353/9,690,074) from the second quarter of FY 2016 through the first quarter of FY 2017 (January 1, 2016, through December 31, 2016) to the average covered charge per case of $58,806 ($532,984,507,679/9,063,358) from the second quarter of FY 2017 through the first quarter of FY 2018 (January 1, 2017, through December 31, 2017). This rate-of-change is 4.2 percent (1.04205) or 8.6 percent (1.085868) over 2 years. (See table below, copied from the proposed rule.)

| Quarter | Covered Charges (January 1, 2016, through December 31, 2016) | Cases (January 1, 2016, through December 31, 2016) | Covered Charges (January 1, 2017, through December 31, 2017) | Cases (January 1, 2017, through December 31, 2017) |
|---|---|---|---|---|
| 1 | $140,753,065,878 | 2,506,525 | $149,358,509,178 | 2,551,065 |
| 2 | 135,409,469,345 | 2,414,710 | 140,445,911,726 | 2,397,110 |
| 3 | 132,239,610,957 | 2,356,131 | 135,004,161,478 | 2,293,958 |
| 4 | 138,440,787,173 | 2,412,708 | 108,175,925,297 | 1,821,225 |
| Total | 546,842,933,353 | 9,690,074 | 532,984,507,679 | 9,063,358 |

CMS proposes to use hospital CCRs from the December 2017 update to the Provider-Specific File (PSF) – the most recent data available for the proposed rule – and to apply an adjustment factor to the CCRs to account for cost and charge inflation. The adjustment methodology, used since FY 2014, compares the national average case-weighted operating and capital CCRs from the most recent (December 2017) update of the PSF to the national average case-weighted operating and capital CCRs from the same period of the prior year (December 2016 update of the PSF). The methodology uses total transfer-adjusted cases from FY 2017 to determine the national average case-weighted CCRs for both sides of the comparison.

CMS calculates a December 2016 operating national average case-weighted CCR of 0.266065, a December 2017 operating national average case-weighted CCR of 0.262830. The percentage change between these two figures is -1.22 percent or 0.987842. This figure is the final national operating CCR adjustment factor. The same methodology applied to the capital CCRs produces a December 2016 capital national average case-weighted CCR of 0.023104 and December 2017 capital national average case-weighted CCR of 0.022076. The percentage change between these two figures is -4.5 percent or 0.955517.

For estimating the proposed outlier threshold for FY 2019, CMS proposes to adjust the proposed wage index of eligible hospitals in frontier states. Otherwise, CMS says, the estimate of FY 2019 payments would be too low and the outlier threshold would be too high, resulting in payments less than the projected 5.1 percent of total payments.

Following past practices, CMS also proposes to continue to: 1) include the section 1886(r)(2) uncompensated care payments in determining the outlier threshold and in calculating outlier payments 2) apply a 1-year adjustment factor to the CCRs; and 3) make no adjustments for the possibility that hospitals' CCRs and outlier payments may be reconciled at cost report settlement.

CMS also provides a brief discussion of its proposed policy that would 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. The proposed policy would raise new technology add-on payments or outlier payments relative to using a hospital-specific CCR that will be lower than 1.0**.**

FY 2017 Outlier Payments. CMS' current estimate, using available FY 2017 claims data, is that actual outlier payments for FY 2017 were approximately 5.53 percent of actual total MS-DRG payments. Although actual outlier and other IPPS payments are above estimated payments for FY 2017 when CMS set the outlier threshold, 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 in the proposed rule because FY 2018 claims data 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.

## II. Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights

### A. Background

The FY 2019 proposed 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).

Proposed changes in specific MS-DRGs for FY 2019 are described in section II.F below.

### B. 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 taking into account patient severity of illness in Medicare payment rates for acute care hospitals, the proposed 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 proposed rule refers readers to CMS' implementation of statutory enactments since 2008 that 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 included FY 2010 through FY 2012 IPPS rates that CMS was not authorized to recoup. The proposed 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 large 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 changes 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.

For FY 2019, consistent with section 414 of the MACRA, CMS is proposing to implement a positive 0.5 percentage point adjustment to the standardized amount.

**C. 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 does not propose any changes to the CCR methodology. It calculated the proposed MS-DRG weights for FY 2019 using national averages for the 19 CCRs. Accompanying the proposed rule, CMS posted the version of 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-Proposed-Rule-Home-Page-Items/FY2019-IPPS-Proposed-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.

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

**D. Changes to Specific MS-DRG Classifications**

1. Discussion of Changes to Coding System and Basis for 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 proposes to the MS-DRGs for FY 2019. 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 criterion:

- 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.

CMS invites comment on the MS-DRG classification proposed changes as well as proposals to maintain certain existing MS-DRGs. Highlights of CMS' discussion are summarized below; the reader is referred to the proposed 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.I Commenters recommended that CMS maintain the current logic under the MS-DRGs 001 and 002. The commenters provided examples of common clinical scenarios involving a left ventricular device (LAVD) and included the procedure codes that were reported under the ICD-9 based MS-DRGs in comparison to the procedure codes reported under the ICD-10 MS-DRGs (listed in the proposed rule). Commenters noted that procedures involving the insertion of an implantable heart assist system, such as the insertion of a LAVD, demonstrate clinical similarities and utilize similar resources as other procedures in these MS-DRGs. 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.

CMS agrees with commenters that it should continue to monitor the data for these MS-DRGs. As in the FY 2018 IPPS final rule, CMS notes that it collaborates with the American Hospital Association (AHA) through the Coding Clinic to promote proper coding. CMS recommends that interested parties submit questions pertaining to correct coding for these technologies to the AHA.

CMS provides the results of claims analyses for cases in MS-DRGs 001 and 002 and also examined the cases in MS-DRGs 001 and 002 that reported one of the code combinations or clusters. The findings are shown in 8 tables in the proposed rule. The data show differences in the average length of stay (LOS) and the average costs according to the type of procedure, the type of device, and the approaches that were utilized. Based on these findings, CMS agrees with the commenters' recommendation and is <u>not proposing any modifications to MS-DRGs 001 and 002</u> and will continue to analyze claim data.

<u>MS-DRG 215</u> (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. CMS provides the results of claims analyses for MS-DRG 215, which included 3,428 cases with an average LOS of 8.7 days and average costs of $68,965. The data show a wide variation in the average length of stay and the average costs for cases reporting procedures involving a biventricular short-term external heart assist system versus a short-term external heart assist system. CMS notes there is an even greater range in the average LOS and the average costs when comparing the revision of a short-term external heart assist to the revision of a synthetic substitute in the heart or to the revision of an implantable heart assist system. CMS is aware that the AHA published Coding Clinic advice that clarified coding and reporting for certain external heart assist devices but the current claims data do not yet reflex the updated guidance. In addition, the current claims data do not reflect new procedures codes (02HA0RJ, 02HA3RJ, and 02HA4RJ) that are assigned to MS-DRG 215. CMS agrees with commenters that continued monitoring of the data is necessary and is <u>not proposing any modification to MS-DRG 215</u>.

<u>Extracorporeal Membrane Oxygenation (ECMO)</u>. 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 are lower when ECMO is combined with the insertion of a percutaneous short-term external heart assist system. CMS, however, is unable to determine if the ECMO procedures were performed percutaneously in the absence of a unique code. CMS is proposing not to reassign these cases until there is a way to specifically identify percutaneous ECMO in the claims.

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. CMS' analysis of MS-DRG 268 included a total of 3,798 cases with an average LOS of 9.6 days and an average cost of $49,122. For MS-DRG 269, there were a total of 16,900 cases with an average LOS of 2.4 days and average costs of $30,793. The data show there are differences in the average LOS and average costs for cases in MS-DRGs 268 and 269 according to the type of device and the approaches utilized. CMS is proposing not to make any changes to MS-DRGs 268 and 269 and will continue to analyze the claims data.

*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-OR codes and group to the MS-DRG to which the principal diagnosis is assigned.
CMS analyzed claims data for cases representing patients who received treatment that reported low dose rate (LDR) brachytherapy procedure codes across all MS-DRGs. CMS identified only four cases reporting one of the LDR 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 is not proposing to create a new MS-DRG for procedures involving the CivaSheet® technology.

*c. Laryngectomy*

CMS is proposing 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 is also proposing 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

*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. 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 who 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 (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 believe 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 is proposing to assign cases reporting the use of CAR T-cell therapy (ICD-10-PCS procedure codes XW033C3 and XW043C3) to MS-DRG 016. CMS is proposing to revise the title of MS-DRG 016 to "Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy". CMS discusses an alternative suggestion to create a new MS-DRG for procedures involving the utilization of CAR T-cell therapy. CMS notes that if a new MS- DRG were to be created (consistent with section 1886(d)(5)(K)(ix) of the Act) there may no longer be a need for a new technology add-on payment.

CMS invites comments on the proposed assignment of ICD-10-PCS procedure codes XW033C3 and XW043C3 to MS-DRG. It is also 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 is 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 invites public 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 mentions 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. This alternative is discussed in greater detail in Section IV.A.4.g.(3) in the proposed rule (see below in this summary). Another payment alternative suggested could also take 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.

CMS is also interested in comments about how payment alternatives would affect access to care and how they would affect incentives to encourage lower drug prices.

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 proposes 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 OR 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). They note, however, it would not be appropriate to sequence acute respiratory failure as the principal diagnosis when it is secondary to intracranial hemorrhage or ischemic cerebral infarction. The requestors also stated that for quality reporting the neurologic codes need to be sequenced as the principal diagnosis.

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. The results of the analyses of the first request, including subset analyses, are presented in the proposed rule. Based on the analyses of claims and consultation with its clinical advisors, CMS

believes the findings do not support the creation of two additional MS-DRGs. Based on the findings from the first request, 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 OR 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. The claims data reflected a wide variance with regard to the number of cases and average costs. CMS did similar analysis for cases reporting ≤ 96 hours and also found a wide variance with regard to frequency and average costs. CMS acknowledges it created a new MS-DRGs in FY 2007 for cases of patients with sepsis requiring mechanical ventilation greater than and less than 96 hours but it considered that a specific clinical situation. It believes additional analyses and a broader approach to refining the MS-DRG for cases of patients requiring mechanical ventilation across the MDCs would be needed to avoid instability in the relative weights and disrupting the integrity of the MS-DRG system.

CMS is <u>not proposing to create new MS-DRGs</u> 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 OR procedure. CMS notes that providers are required to assign the principal diagnosis according to the ICD-10-CM Official Guidelines for Coding and Reporting and these assignments are not based on factors used for quality measures.

4. <u>MDC 5 (Diseases and Disorders of the Circulatory System)</u>

*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). CMS examined cases with the ICD-10-CM procedure codes for the insertion of a cardiac rhythm related device (0JH60PZ, 0JH63PZ, 0JH80PZ, and 0JH83PZ) assigned to MS-DRGs 040, 041, and 042 as well as MS-DRGs 907, 908, and 909, and are designated as O.R. procedures. The findings of these analyses are summarized in the proposed rule.

CMS also analyzed claims for cases reporting a procedure code describing (1) the insertion of a pacemaker device only, (2) the insertion of a pacemaker lead only, and (3) both the insertion of a pacemaker device and a pacemaker lead across all the MDCs except MDC 5. This analyses was done to determine the number of cases currently grouping to medical MS-DRGs and the potential impact of these cases moving into the surgical unrelated MS-DRGs 981, 982, and 983. For cases where the insertion of a pacemaker device, the insertion of a pacemaker lead or the insertion of both a pacemaker device and lead were reported on a claim grouping to a medical

MS-DRGs, the average LOS and average costs were generally higher for those case when compared to the average LOS and average costs for all the cases in their assigned MS-DRGs. The analysis showed that if CMS were to restructure the GROUPER logic so that the combination of the insertion of the pacemaker device with the insertion of the lead (complete pacemaker system) are designated as an O.R. procedure across all MDCs, it would expect approximately 2,709 cases to move from the medical MS-DRGs to the surgical unrelated MS-DRGs 981, 982, and 983. CMS' clinical advisors recommended that insertion of a complete pacemaker system should be classified into surgical MS-DRGs because patients receiving these devices demonstrate greater treatment difficulty and utilization of resources when compared to procedures that involve the insertion of only the pacemaker device or only the pacemaker lead. CMS makes the following proposals:

- Creating pairs of procedure code combinations involving the insertion of a pacemaker device with the insertion of a pacemaker lead that act as a procedure code combination pair in the GROUPER logic for designation as O.R. procedures outside of MDC 5 when the codes are reported together.
- Designating 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.

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 proposes 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 notes that procedures 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 solicits 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 also evaluated procedure codes that describe an intracardiac or "leadless" pacemaker; these codes 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 found 1,190 cases reporting a procedure involving an intracardiac pacemaker with an average LOS of 8.6 days and average costs of $38,576. Of these cases, 1,037 cases were in MS-DRGs under MDC 5. CMS found 153 cases that grouped to MS-DRGs outside of MDC 5 grouped to surgical MS-DRGs; another O.R. procedure was also reported on the claim. CMS is soliciting comments on whether these procedure codes should also be considered for classification into all surgical unrelated MS-DRGs outside of MDC 5.

*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 proposed rule) in MS-DRGs 252, 253, and 254. CMS notes 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 show 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 notes 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 do 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 show that the use of a drug-coated balloon alone has a lower average cost ($24,553) than the use or a 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 does 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. As additional claims become available, it will continue to evaluate these procedures.

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 proposes 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. CMS also proposes to 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).
CMS' analysis of claims data indicate that the resources required for cases reporting large bowel reposition procedures are more aligned with the resources required for all cases assigned to MS-DRGs 344, 345, and 346. The clinical advisors agreed. CMS is proposing to maintain the current assignments of the eight specific bowel repositioning procedures.

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. CMS' analysis indicates that the resources for these procedures are more aligned with the resources required for cases assigned to MS-DRGs 329, 330 and 331. The clinical advisors agreed. CMS is proposing to reassign the 12 procedures from MS-DRGs 329, 330, and 331 to MS-DRGs 344, 345, and 346.

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 is not proposing any changes to the MS-DRGs involving spinal fusion procedures for FY 2019. CMS notes that Table 6P.1g associated with this proposed rule lists 99 procedure codes (not 87 codes) describing spinal fusion procedures that have a device value "Z" representing No Device for the 6$^{th}$ character in the code. Because a spinal fusion procedure always requires some type of device, these codes are considered clinically invalid. A total of 213 procedure codes describing fusion of a specific body part with a device value "Z" are being deleted effective October 1, 2018 (see Table 6D – Invalid Procedure Codes).

In response to the commenter's suggestion and findings, CMS provides (in the proposed rule) 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 demonstrate 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 the commenter that until these coding inaccuracies are no longer reflected in the claims data, it would be premature to propose any MS-DRG modifications for spinal fusion procedures.

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.

CMS analyses showed that these cases had an average LOS that was comparable to the average LOS for all cases in MS-DRG 602 and 603. Average costs for this subset were lower than the average costs of all cases in MS-DRG 602 and higher than the average costs for all cases in MS-DRG 603. For MS-DRGS 867, 868, and 869, the average LOS and average costs were lower for all cases in MS-DRG 867, and the average LOS and average costs were higher than all cases in MS-DRG 868 and 869. These findings do not support reassignment of these cases. CMS' clinical advisors agreed. CMS is not proposing to reassign cellulitis cases reported with ICD-10-CM diagnosis code of B95.62 or A49.02 to MS-DRG 867, 868, or 869.

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

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

CMS states it is 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 does not believe there is a justification for creating a new MS-DRG. CMS is not proposing to revise 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).

CMS analysis showed that for MS-DRG 685 all cases were reported with diagnosis code Z49.01. For these 78 cases the average LOS was 4 and the average costs $8,871. CMS' clinical advisors recommended that MS-DRG 685 be deleted. Since dialysis is being performed predominately in outpatient and ambulatory settings, they thought it was not appropriate to maintain a vestigial MS-DRG. CMS is proposing 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).

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 discusses the recommendations it received and provides extensive analyses of possible refinements to the MS-DRGs related to vaginal deliveries. Based on its review, CMS is proposing the deletion of 10 MS-DRGs and the creation of 18 new MS-DRGs. These proposals as 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. CMS refers readers to Tables 6P1h through 6P.1k for the lists of the diagnosis and procedure codes that it is proposing to assign to the GROUPER logic for the proposed new MS-DRGs and the existing MS-DRGs under MDC 14. The interested reader is referred to the proposed rule for more specific details.

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 notes 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 is proposing to reassign diagnosis codes R65.10 and R65.11 to MS-DRG 864 and to revise the title of this MS-DRG to "Fever and Inflammatory Conditions".

CMS discusses the confusion with these codes because although they are displayed in the ICD-10 MS-DRG Definitions Manual under MS-DRGs 870, 871, and 872 they are not acceptable as the principal diagnosis in the Medicare Code Editor (MCE). The GROUPER logic (documented in the MS-DRG Definitions Manual) was not designed to account for coding guidelines or coverage policies and does not routinely prevent data integrity issues. The MCE is designed to identify cases that require further review before classification into an MS-DRG. Data integrity edits address issues such as data validity, coding rules, and coverage policies. CMS notes that prior to assigning the MS-DRG to a claim, the MACs apply a series of data integrity edits using programs such as the MCE.

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 is not proposing to reassign these cases.

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 2018 IPPS Final Rule home page. CMS discusses 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 proposed 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.

Based on the changes proposed for MDC 14 (Pregnancy, Childbirth and the Puerpeium) CMS proposes corresponding changes to the surgical hierarchy for MDC 14.

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

*Proposed Additions and Deletions to the Diagnosis Code Severity Levels.* The following tables identify the proposed additions to the MCC severity list and the proposed additions to the CC severity list for FY 2018:

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

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

CMS invites comments on its proposed severity level designations for the diagnosis codes listed in Tables 6I.1 and 6J.1. CMS notes, 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.
*Principal Diagnosis Is Its Own CC or MCC*. CMS states 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. Specifically, using the claims data from the September 2017 update of the MedPAR file, CMS determined the impact of removing special logic used in the current Version 35 GROUPER to process claims containing a code on the Principal Diagnosis Is Its Own CC or MCC Lists. The methodology used is discussed in the proposed rule and summarized in the tables below (reproduced from the proposed rule). Overall, the number of claims impacted by removal of the special logic (18,596) represents 0.2 percent of the 9.070 million claims analyzed.

| **With Special Logic – 9.070 Million Claims Analyzed** | |
|---|---|
| Number of cases reporting a principal diagnosis from the Principal Diagnosis Is Its Own CC/MCC lists (special logic) | 310,184 |
| Number of cases reporting an additional CC/MCC secondary diagnosis code at or above the level of the designated severity level of the principal diagnosis | 204,749 |
| Number of cases not reporting an additional CC/MCC secondary diagnosis code | 105,435 |

| **Without Special Logic – 105,435 Claims Analyzed** | |
|---|---|
| Number of cases reporting a principal diagnosis from the Principal Diagnosis Is Its Own CC/MCC lists | 310,184 |
| Number of cases resulting in different MS-DRG assignment | 18,596 |

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 proposed rule.

CMS also examined 32 subsets of cases that utilized the special logic and had 100 or more cases. A table in the proposed 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.

As an initial recommendation from this first phase in CMS' comprehensive review of the CC and MCC lists, it proposes 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. CMS is proposing to delete the tables containing the lists of principal diagnosis codes from the ICD-10 MS-DRG Definitions Manual for FY 2019. The following tables are proposed for deletion:

- 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.

The following tables identify the proposed changes to the ICD-10 MS-DRGs Version 35 CC Exclusion List:

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

To identify new, revised and deleted diagnosis and procedure codes for FY 2108, CMS has developed the following tables:

- 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 discusses 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 three requests for changes to severity levels of ICD-10-CM diagnosis codes. CMS proposes 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 is not proposing a change to the severity level for G39.40 (Encephalopathy, unspecified).

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

*Moving Procedure Codes*. 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.

For FY 2019, CMS is not proposing 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.
*Reassignment of Procedures*. CMS proposes 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 proposes 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 proposed 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.

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 is not proposing to add any MS-DRGs to the IPPS policy for replaced devices without cost or with a credit. The list that CMS is proposing to continue 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 |

| 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 | 218 | Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC |
| MDC 05 | 219 | Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC |
| MDC 05 | 220 | Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC |
| MDC 05 | 221 | Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC |
| MDC 05 | 222 | Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC |
| MDC 05 | 223 | Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC |
| MDC 05 | 224 | Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC |
| MDC 05 | 225 | Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC |
| MDC 05 | 226 | Cardiac Defibrillator Implant without Cardiac Catheterization with MCC |
| MDC 05 | 227 | Cardiac Defibrillator Implant without Cardiac Catheterization without MCC |
| MDC 05 | 242 | Permanent Cardiac Pacemaker Implant with MCC |
| MDC 05 | 243 | Permanent Cardiac Pacemaker Implant with CC |
| MDC 05 | 244 | Permanent Cardiac Pacemaker Implant without CC/MCC |
| MDC 05 | 245 | AICD Generator Procedures |
| MDC 05 | 258 | Cardiac Pacemaker Device Replacement with MCC |
| 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 |

| 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 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.

*Percutaneous and Percutaneous Endoscopic Excision of Brain and Cerebral Ventricles.* CMS agrees with a request to move 22 ICD-10-PCS procedure codes (listed in the proposed rule) from the non-O.R. designation. CMS proposes 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).

*Open Extirapation of Subcutaneous Tissue and Fascia.* CMS disagrees with a request to move 23 ICD-10-PCS procedure codes (listed in the proposed rule) from the non-O.R. designation and proposes to maintain these procedure codes as non-O.R. procedures.

*Open Scrotum and Breast Procedures.* CMS agrees 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 proposes 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 proposes to add the breast procedure codes to MS-DRGs 584 and 585 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast).

*Open Parotid Gland and Submaxillary Gland Procedures*. CMS agrees 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 proposes to add these procedures to MS-DRG 139 (Salivary Gland Procedures).

*Removal and Reinsertion of Spacer; Knee Joint and Hip Joint.* CMS agrees 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 agrees with the requestor but it also proposes to reassign these codes

when reported as stand-alone procedures. CMS proposes 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).

*Endoscopic Dilation of Ureter(s) with Intraluminal Device.* CMS agrees with a request to reassign three ICD-10-PCS procedure codes (listed in the proposed rule). CMS proposes 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).

*Thoracoscopic Procedures of Pericardium and Pleura.* CMS agrees 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 adds two related procedure codes. (The nine procedure codes are listed in the proposed rule). CMS proposes to add these procedure codes to the 18 MS-DRGs listed in the proposed rule.

*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 agrees 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 proposes to designation these procedure 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.

*Percutaneous Joint Reposition with Internal Fixation Device.* CMS disagrees with a request to move 22 ICD-10-PCS procedure codes (listed in the proposed rule) from the non-O.R. designation and proposes to maintain these procedure codes as non-O.R. procedures.

*Endoscopic Destruction of Intestine.* CMS agrees with a request to reassign four codes (listed in the proposed rule) and proposes to remove these four codes from the O.R. procedure lists and add them to the non-O.R. procedure list.

*Drainage of Lower Lung Via Natural or Artificial Opening Endoscopic Diagnostic.* CMS agrees 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 proposes to add these five codes to the non-O.R. procedure list.

## E. 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 proposed 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 December 31, 2016, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). The FY 2017 MedPAR file used to calculate the proposed 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 proposed FY 2019 MS-DRG classifications discussed in section II.D.

- 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 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 proposed rule (see unnumbered tables on pp. 343-357 of the display copy). The proposed FY 2019 CCRs are shown in the table below and compared to FY 2016.

| Group | FY 2018 CCR | Proposed FY 2019 CCR |
|---|---|---|
| Routine Days | 0.458 | 0.451 |
| Intensive Days | 0.373 | 0.373 |
| Drugs | 0.194 | 0.196 |
| Supplies & Equipment | 0.297 | 0.299 |
| Implantable Devices | 0.332 | 0.321 |
| Therapy Services | 0.321 | 0.312 |
| Laboratory | 0.120 | 0.116 |
| Operating Room | 0.191 | 0.185 |
| Cardiology | 0.112 | 0.107 |
| Cardiac Catheterization | 0.117 | 0.115 |
| Radiology | 0.153 | 0.149 |
| MRIs | 0.079 | 0.076 |
| CT Scans | 0.038 | 0.037 |

| Group | FY 2018 CCR | Proposed FY 2019 CCR |
|---|---|---|
| Emergency Room | 0.171 | 0.165 |
| Blood and Blood Products | 0.322 | 0.306 |
| Other Services | 0.365 | 0.355 |
| Labor & Delivery | 0.412 | 0.363 |
| Inhalation Therapy | 0.169 | 0.163 |
| Anesthesia | 0.089 | 0.081 |

The proposed cost-based relative weights were normalized by an adjustment factor of 1.760698 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 proposes to compute 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.

## F. 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 proposes 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 proposes 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. Thus, 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 summarizes comments at the end of each discussion of the individual applications in this proposed rule. Comments that are unrelated to the "substantial clinical improvement" criterion are not summarized in this proposed rule. Commenters can resubmit their comments in response to proposals in this proposed rule.

One commenter requested CMS codify in the regulations to explicitly clarify that a new medical service or technology will meet the substantial clinical improvement criterion if it:

- Results in a reduction of the length of a hospital stay;
- Improves patient quality of life;
- Creates long-term clinical efficiencies in treatment;
- Addresses patient-centered objectives as defined by the Secretary; or
- Meets such other criteria as the Secretary may specify.

The commenter acknowledged that these criteria were similar to those defined in the September 2001 New Technology Final Rule (66 FR 46913-46914). The commenter also recommended that final decisions on new technology payment application should explicitly discuss how the service or technology failed to meet these specific criteria. CMS does not believe additional clarity is needed and that the September 2001 New Technology Final Rule provides the criteria it uses and also provides examples of improved clinical outcomes. CMS believes that it already provides detailed explanations when approving or denying an application in the final rule.

Several commenters believe the criteria used by FDA for priority review and break-through therapy should be sufficient for CMS' determination of substantial clinical improvement. A few commenters raised concerns that the threshold for demonstrating substantial clinical improvement was too high and unrealistic to meet, especially for rare diseases, and noted that the FDA often only required single-arm trials with a small number of patients. A commenter recommended that CMS apply a flexible standard for assessing whether a technology represents a substantial clinical improvement over existing, available therapies.

[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.

CMS acknowledges all the comments and believes the criteria explained in the September 2001 New Technology Final Rule are consistent with the statutory requirements and continue to be relevant to determining substantial clinical improvement. CMS states that if a technology has a status designated by the FDA that is similar to the standards and conditions required to demonstrate substantial clinical improvement for the new technology add-on payment, the technology should be able to demonstrate with evidence how it meets this criterion. CMS disagrees that it only considers a limited range of evidence and states it accepts a wide range of data (for example, pee-reviewed articles, study results, or letters from major associations) that demonstrate and support substantial clinical improvement.

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 latter half of the FY.

As discussed below, for FY 2019, CMS proposes to discontinue new technology add-on payments for the EDWARDS INTUITY Elite™ Valve System (INTUITY) and LivaNova Perceval Valve (Perceval), the GORE®EXCLUDER® Iliac Branch Endoprosthesis (IBE), Praxbind® (Idarucizumab), and Vistogard™ (Uridine Triacetate)
CMS proposes to continue new technology add-on payments for Defitelio® (Defibrotide), Ustekinumb (Stelara®) and ZINPLAVA™.

*a. Defitelio® (Defibrotide)*

Defitelio® is used for the treatment of hepatic veno-occlusive disease (VOD) with evidence of multi-organ dysfunction. VOD, also known as sinusoidal obstruction syndrome, is a potentially

life-threatening complication of hematopoietic stem cell transplantation. Cases involving Defitelio® are identified with ICD-10-PCS XW03392 and XW04392.

Because the 3-year anniversary date of the entry of Defitelio® on the US market will occur after in the latter half of FY 2019 (April 4, 2019), CMS proposes to continue the new technology add-on payments for FY 2018. The maximum new technology add-on payment for a case involving Defitelio® will remain at $75,900 for FY 2019. CMS estimates the FY 2019 add-on payments for this technology at approximately $5.161 million.

*b. EDWARDS INTUITY Elite™ Valve System (INTUITY) and LivaNova Perceval Valve (Perceval)*

Two manufacturers, Edwards Lifesciences and LivaNova, submitted applications for new technology add-on payments for INTUITY and Perceval, respectively. Both of these technologies are prosthetic aortic valves inserted during surgical aortic valve replacement (AVR). Cases involving these devices are identified with ICD-10-PCS X2RF032.
Because the 3-year anniversary date of the entry of the INTUITY and Perceval valves on the US market will occur after in the first half of FY 2019 (the Perceval valve became commercially available February 29, 2016), CMS proposes to discontinue the new technology add-on payments for FY 2019.

*c. GORE®EXCLUDER® Iliac Branch Endoprosthesis (IBE)*

The GORE IBE device is used in conjunction with the GORE®EXCLUDER® AAA Endoprosthesis for the treatment of patients requiring repair of common iliac or aortoiliac aneurysms. When deployed the device excludes the common iliac aneurysm from systemic blood flow, while preserving blood flow in the external and internal iliac arteries. Cases involving the Gore IBE device are identified using one of the unique ICD-10-PCS procedure codes listed in the proposed rule.

Because the 3-year anniversary date of the entry of the GORE IBE device on the US market will occur in the first half of FY 2019 (February 28, 2019), CMS proposes to discontinue the new technology add-on payments for FY 2019.

*d. Praxbind® (Idarucizumab)*

Praxbind® is an antidote to reverse the effects of Dabigatran, an oral direct thrombin inhibitor. Praxbind® is a humanized fragment antigen-binding molecule, which specifically binds to deactivate the anticoagulant effect. Cases involving Praxbind® are identified with ICD-10-PCS XW03331 and XW04331.

Because the 3-year anniversary date of the entry of Praxbind® on the US market will occur in the first half of FY 2019 (October 15, 2018), CMS proposes to discontinue the new technology add-on payments for FY 2019.

e. *Ustekinumb (Stelara®)*

IV infusion of Stelara® is indicated for the treatment of adult patients diagnosed with moderately to severely active Crohn's Disease who have: (1) failed or were intolerant to treatment using immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker; or (2) failed or were intolerant to treatment using one or more TNF blockers. Maintenance doses of Stelara® are administered subcutaneously. Cases involving Stelara® are identified with ICD-10-PCS XW033F3.

Because the 3-year anniversary date of the entry of Stelara® on the US market will occur after FY 2019 (September 23, 2016) CMS proposes to continue the new technology add-on payments for FY 2019. The maximum new technology add-on payment for a case involving Stelara® will remain at $2,400 for FY 2019. CMS estimates the FY 2019 add-on payments for this technology at approximately $400,800.

*f. Vistogard™ (Uridine Triacetate)*

Vistogard™ is an antidote to fluorouracil toxicity. The chemotherapeutic agent 5-fluorouracil (5-FU) is used to treat a variety of solid tumors and there is a risk for toxicity in patients receiving 5-FU. Cases involving Vistogard™ are identified using ICD-10-PCS procedure code XW0DX82. Because the 3-year anniversary date of the entry of Vistogard™ on the US market will occur in the first half of FY 2019 (March 2, 2019), CMS proposes to discontinue the new technology add-on payments for FY 2019.

g. Bezlotozumab (ZINPLAVA™)

ZINPLAVA™, is a human monoclonal antibody that neutralizes *Clostridium difficile* (*C-diff*) Toxin B and reduces recurrences of *Clostridium difficile* infection (CDI). ZINPLAVA™ is indicated for use in adult patients receiving antibacterial drug treatment for CDI who are at high risk of CDI recurrence. Cases involving ZINPLAVA™ are identified by ICD-10-PCS procedure codes XW033A3 and XW043A3.
Because the 3-year anniversary date of the entry of ZINPLAVA™ on the US market will occur after FY 2019 (February 10, 2020), CMS proposes to continue the new technology add-on payments for FY 2019. The maximum new technology add-on payment for a case involving ZINPLAVA™ will remain at $1,900 for FY 2019. CMS estimates the FY 2019 add-on payments for this technology at approximately $2.858 million.

6. 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.
The summary below provides a high-level discussion of each new technology assessment; readers are advised to review the proposed rule for more detailed information.

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 (the table is from the proposed 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) Diffuse Large B Cell Lymphoma (DLBCL) not eligible for autologous stem cell transplant (ASCT) | Breakthrough Therapy designation granted by FDA; FDA approval is pending. |
| 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 |

[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.

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.

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.

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™ is not currently approved by the FDA for use in the treatment of patients with relapsed/refractory (R/R) DLBCL that are not eligible for ASCT; the applicant anticipates FDA approval in the second quarter of 2018. CMS notes that at the time each application was submitted, neither technology had received FDA approval for the indication for the requested approval for the new-technology add-on payment.

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, CMS believe 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. In addition, as discussed above (section II.F.2.d.), for FY 2019, CMS proposes that cases reporting these ICD-10-PCS procedure codes would be assigned to MS-DRG 016 (Autologous Bone Marrow Transplant with CC/MCC or T-cell Immunotherapy).

CMS considers these two technologies as substantially similar to each other and it evaluates both technologies as one application. CMS notes that potential cases representing patients eligible for these treatments would group to the same MS-DRGs because the same ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes are used to report either treatment. CMS invites public comment on whether KYMRIAH™ and YESCARTA™ are substantially similar.

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. CMS, however, considers 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 is also concerned that there may be an age overlap between the two different patient populations for the currently approved KYMRIAH™ technology and YESCARTA™. CMS notes 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.

Cost. For the cost criterion, Novartis searched the FY 2016 MEDPAR claims data file to identify potential cases representing patients who may be eligible for treatment using KYMRIAH™. Using the ICD-10-CM diagnosis codes and encounter codes listed in the proposed rule, a total of 22,589 DLBCL potential cases were identified that mapped to 437 MS-DRGs. The applicant chose the top 20 MS-DRGS that accounted for 68 percent of total cases. The applicant conducted an analysis of three scenarios: potential DLBCL cases, potential DLBCL cases with chemotherapy, and potential DLBCL cases without chemotherapy. As part of the analysis, historical charges that would be avoided through the use of KYMRIAH™ were removed. In addition, 50 percent of the chemotherapy charges that would not be required because of KYMRIAH™ treatment were removed. The charges were standardized and the inflation factor of 1.09357 (the 2-year inflation factor in the FY2018 IPPS/LTCH final rule) was applied to update the charges from FY 2016 to FY 2018. The applicant's analysis showed the inflated average case-weighted standardized charge per case for potential DLBCL cases as $63,271; potential cases with chemotherapy as $39,723; and potential cases without chemotherapy as $72,781. The average case-weighted threshold amount for potential DLBCL cases, potential cases with chemotherapy, and potential cases without chemotherapy was $58, 278; $48,190; and $62,355, respectively. Although potential cases with chemotherapy have an inflated average case-weighted standardized charge ($39,723) that is lower that the inflated average case-weighted threshold amount ($48,190), the applicant expects the cost of KYMRIAH™ to be higher than the new technology add-on payment threshold amount for all three cohorts and concluded the cost criterion is met. CMS compared the inflated average case-weighted standardized charge per case for all three cohorts to the average case-weighted threshold amount for MS-DRG 016 ($161,058). Since the applicant expects the cost of KYMRIAH™ to be higher than the new technology add-on payment threshold for MS-DRG 016, CMS expects KYMRIAH™ to meet the cost criterion.

For YESCARTA™, Kite Pharma searched the FY 2016 MEDPAR claims data file to identify potential cases reporting an ICD-10 diagnosis code of C83.38 (DLBCL, lymph nodes of multiple sites). The applicant identified 8 MS-DRGs with 10 or more cases and used these 827 potential cases for its calculation of an average case-weighted unstandardized charge per case and the inflation factor of 1.09357 was applied. The applicant removed 20 percent of radiology charges to account for chemotherapy and the final inflated average case-weighted standardized charge per case was $118,575. The average case-weighted threshold amount was $72,858. Even without considering the cost of its technology, the applicant maintained that the technology meets the cost criterion. CMS again compared the applicant's inflated average case-weighted standardized charge per case to the average case-weighted threshold amount for MS-DRG 016. Since the applicant expects the cost of YESCARTA™ to be higher than the new technology add-on payment threshold amount for MS-DRG 016, CMS expects YESCARTA™ to meet the cost criteria.

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 discusses 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 trials 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 raises 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 notes 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 chemo-refractory DLBCL, there are no curative options. The applicant also provided updated data from ongoing clinical trials 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 is 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 is 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 notes the high rate of CRS.

In addition to comments on whether KYMRIAH™ and YESCARTA™ meet the substantial clinical improvement criterion, **CMS invites comments about the most appropriate mechanism to provide payment to hospitals** for new technologies such as CAR T-cell therapy including the use of new technology add-on payments and:

- Creating a new MS-DRG for procedures involving CAR T-cell therapy as an alternative to CMS' proposed MS-DRG assignment to MS-DRG 016 (discussed in Section II.F.2.d. in the proposed rule).
- Allowing hospitals to utilize a CCR specific to procedures involving the utilization of KYMRIAH™ and YESCARTA™ CAR T-cell therapy drugs as part of the determination of the cost of a case for purposes of calculating outlier payments (discussed in Section IV.A.4.g.(3) in the proposed rule).

CMS also invites comments on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices and alternatives to encourage value-based care.

In response to the New Technology Town Hall meeting, CMS received a public comment from the applicant about YESCARTA™. The applicant supported the use of YESCARTA™ and provided additional supporting data from the SCHOLAR-1 study.

*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. CMS is 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 notes that VYXEOS™ will 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. CMS invites comments on whether VYXEOS™ is substantially similar to existing technology, including whether the mechanism of action differs from current treatment.

Cost. The applicant provided an analysis using the 2016 MedPAR Hospital Limited Data Set to assess the MS-DRGs that are most relevant to patients that may be eligible for VYXEOS™ treatment. The applicant searched for cases indicating a diagnosis of AML or diagnosis codes that indicated the patient received chemotherapy during their hospital stay and excluded cases that had a bone marrow transplant. The analysis identified 5,483 potential cases that mapped to 131 MS-DRGs with 16 MS-DRGs containing more than 10 cases; 4 MS-DRGs contained 4,457 potential cases. The average unstandardized case-weighted charge per case was approximately $185,844. The applicant removed charges for chemotherapy agents. According to the applicant, charges for chemotherapy drugs are grouped with charges for oncology, diagnostic radiology, therapeutic radiology, nuclear medicine, CT scans and other imaging services in the "Radiology

[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.

Charge Amount". Based on analysis of services in the "Radiology Charge Amount", the applicant removed 20 percent of the radiology charge amount to capture the effect of removing chemotherapy pharmacy charges. The applicant applied the 2-year inflation factor of 1.09357. The inflated average case-weighted standardized charge per case of $170,458 exceeded the average case-weighted threshold amount of $82,561 even without the cost of VYXEOS™. The applicant also provided five sensitivity analyses to further demonstrate that the technology met the cost criterion. Based on all the analyses, the applicant maintained that VYXEOS™ meets the cost criterion.

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 summarizes the clinical data results, including published information. CMS discusses 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 is 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).

*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 is 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.

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™. The applicant identified over 350 MS-DRGs containing data for 2,076 cases representing patients hospitalized for CRE infections and used the top five most common MS-DRGs (627 cases) for further analysis. The applicant reported an average case-weighted unstandardized charge per case of $74,815. (CMS notes that instead of using actual charges from the Premier Research Database, the applicant computed the average case-weighted unstandardized charge per case based on the average case-weighted threshold amounts in Table 10 from the FY 2018 IPPS/LTCH PPS final rule.) The applicant estimated the mean antibiotic costs of treating patients with CRE as $1,999 and removed these charges from its calculation. The applicant standardized the charges and applied an inflation factor of 9.357 percent from the FY 2018 IPPS final rule. The applicant stated it does not have sufficient charge data from hospitals and used the wholesale acquisition cost (WAC) price for a treatment duration of 14 days and added this amount to the average charge per case. The applicant calculated the final inflated case-weighted standardized charge per case as $91,304, which exceeds the average case-weighted threshold amount of $74,815 and concludes that VABOMERE™ meets the cost criterion.

CMS notes that because the applicant did not use actual charges form the Premier Research Database, it is not able to determine if the applicant 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 summarizes the clinical data results, including published information. CMS discusses 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 discusses this data and is still concerned that the data provided does not compare other antibiotic treatments of cUTIs used to treat gram-negative uropathogens.

*d. DURAGRAFT® Vascular Conduit Solution*

Somahlution, Inc submitted an application for DURAGRAFT®, a solution used to protect the endothelium of a vein graft following harvesting and prior to grafting to prevent vascular graft disease (VGD) and vein graft failure (VGF) which reduces the clinical complications associated

with graft failure. DURAGRAFT® is used during standard graft handling, flushing and bathing steps of graft harvesting. The applicant has applied for FDA approval and anticipates approval of its premarket application by the second quarter of 2018. The applicant indicated that ICD-10-PCS code XY0VX83 would identify procedures using the DURAGRAFT® technology.

Newness. For the first criterion, the applicant stated there are no other treatment options available with the same mechanism of action as DURAGRAFT®. In addition, the applicant noted there are no other commercial solutions approved for treating arteries or veins intended for bypass surgery. The applicant did not directly address the second and third criteria; whether a product is assigned to the same or a different MS-DRG and whether the use of the technology involves the treatment of the same or similar type of disease and the same or similar population. CMS is concerned that the mechanism of action of DURAGRAFT® may be the same or similar to other vein graft storage solutions such as various saline, blood, and electrolyte solutions. It also states that additional information addressing criteria two and three would be helpful.

Cost. The applicant searched the FY2016 MedPAR file for claims that identified potential cases identified by 15 ICD-10-PCS procedure codes. The applicant identified 98 MS-DRGs with potential cases, approximately 93 percent of potential cases (59,139) mapped to 10 MS-DRGs. The applicant standardized the charges; no charges for any current treatment were removed because the applicant indicated there are no other current treatment options available. The applicant did not provide an inflation factor to project future charges. Using the national average CCR for implantable devices of 0.332 from the FY 2018 IPPS final rule, the applicant added charges for the DURAGRAFT® technology. The final average case-weighted standardized charge per case of $185,575 exceeds the average case-weighted threshold amount and the applicant concluded the technology meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that DURAGRAFT® provides a benefit by protecting vascular grafts in the interval between harvesting to grafting the graft. The applicant stated that because of time, resources and funding, it was not possible for a small company to conduct randomized studies evaluating the clinical outcomes following CABG surgery. The applicant presented information from retrospective studies designed to assess clinical effectiveness and safety based on the use the DURAGRAFT® treatment in two hospitals that had noncommercial access to the product. CMS summarizes the information from the two retrospective studies that demonstrated an association of reduced risk of non-fatal myocardial infarction, repeat revascularization, and major adverse cardiac events (MACE) with DURAGRAFT® treatment. It is concerned however, that the studies are unpublished and have too many variables unaccounted for that could affect vein integrity, such as vein harvest and post-operative care. The applicant also provided information from a multi-center, within patient, randomized, prospective study utilizing multidetector computed tomography (MDCT) on the graft for assessing early anatomic markers of VGD such as graft wall thickening and early stenotic events. According to the applicant, the results indicate no notable differences at 3 months in either safety or efficacy but there are tends towards better safety at 12 months in patients in the DURAGRAFT® treatment group compared to controls. CMS notes that results from this study when it is completed may provide additional helpful information.

At the February 2018 New Technology Town Hall meeting two cardiothoracic surgeons with personal experience with DURAGRAFT® supported the approval of new technology add-on payments for the technology.

*e. 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 severe 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 is concerned that the FDA approved indication is for use in the treatment of adult patients diagnosed with moderate to severe CSA although the applicant's clinical analysis and data results primarily relate to patients diagnosed with CSA and heart failure (HF).

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. The applicant identified 11,949 potential patients eligible for treatment. Using the FY 2015 MedPAR dataset to identify the total mean charges for revenue code 0278, the applicant removed the current treatment options for each DRG. The applicant standardized the charges and applied a 2-year inflation factor of 1.104055 obtained from the FY2018 IPPS final rule. The applicant then added charges for the new technology and calculated a final inflated average case-weighted standardized charge per case of $175,329 and a Table 10 average case-weighted threshold amount of $78,399. The applicant concluded the technology meets the cost criterion. CMS is 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.

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 notes 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 summarizes these studies and discusses their 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 is also concerned that the remedē® System is not directly compared to the CPAP or ASV treatment options, which are the current treatment options for patients with CSA without HF. CMS also is 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.

*f. 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 acknowledges 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.

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

Cost. The applicant provided three analysis of claims data from the FY 2016 MedPAR file: separate analysis for the lumbar and the cervical interbody devices and a combination of the lumbar and cervical analysis. The first analysis search for any of the ICD-10-PCS procedure codes within the code series Lumbar-0SG that are typically assigned to 11 specified MS-DRGs. The applicant calculated the average case-weighted unstandardized charge per case, removed charges related to the predicate technology, standardized the charges, applied an inflation factor of 1.09357 (FY 2018 IPPS final rule) and then added charges related to the Titan Spine nanoLOCK™ lumbar interbody device. This resulted in a final inflated average case-weighted standardized charge per case of $174,688 that exceeds the average case-weighted Table 10 MS-DRG threshold amount of $83,543.

The applicant used the same methodology for the second analysis for the cervical interbody devices. This analysis resulted in a final inflated average case-weighted standardized charge per case of $101,953, which exceeds the average case-weighted threshold amount of $83,543. The third analysis, a combination of the first two analyses, resulted in a final inflated average case-weighted standardized charge per case of $149,915, which exceeded the average case-weighted threshold amount of $104,094. The applicant concluded the technology 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 notes that based on the results of the case series it is unable to determine whether the findings represent a substantial clinical improvement. CMS also has concerns about the case control study and states it is unable to 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.

*g. 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. The proposed indication for Plazomicin is the treatment of adult patient cUTIs, including pyelonephritis and bloodstream infections (BSIs) when the infections are caused by designate susceptible microorganisms. The applicant expects Plazomicin would be reserved for use in the treatment of patients diagnosed with infections with limited or no alternative treatment option and would be used only to treat infections that are proven or strongly

suspected to be caused by susceptible microorganisms. The applicant expects FDA approval by July 1, 2018. The applicant has submitted a request for a unique ICD-10-PCS procedure code. 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 believes 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 is 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. CMS invites public comments on whether Plazomicin's mechanism of action is new.

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. The applicant removed 50 percent of charges associated with other drugs (revenue codes 025x,026x, and 063x) from the MedPAR data because it anticipated that Plazomicin would reduce the charges associated with the use of some of the drugs. The applicant standardized the charges and applied the 2-year inflation factor of 9.357 from the FY 2018 IPPS final rule. No charges for Plazomicin were added to the analysis. The inflated average case-weighted standardized charge per case was $62,511 for the 100 percent scenario and $57,054 for the 75 percent scenario. 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 notes 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 has not been included.

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 is 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 is 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 their results would be to patients in the US. Although the applicant noted that geography is unlikely to affect the results of the study, CMS is concerned because bacterial resistance can vary regionally and it is unknown how quickly resistance to Plazomicin might develop. CMS also notes that Plazomicin is not indicated exclusively for resistant bacteria and it is concerned that the applicant did not provide information demonstrating substantial clinical improvement in treating nonresistant strains.

*h. 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 has 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 is 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 is also concerned that

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

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 discusses 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. For all six scenarios, the applicant removed 50 percent of drug charges for prior technologies or other charges associated with prior technologies from the unstandardized charges. For all analyses' scenarios, the applicant standardized charges using the FY 2015 impact file and then inflated the charges to FY 2019 using an inflation factor of 1.154181 by multiplying the inflation factor of 1.098446 in the FY 2017 IPPS final rule by the inflation factor of 1.057074 in the FY 2018 IPPS final rule. The final average inflated standardized charge per case for all six scenarios exceeded the average case-weighted threshold amount (summarized in a table in the proposed rule). The applicant concluded the technology 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 acknowledges that this is a heterogeneous and difficult patient population to treat and that studies assessing mortality as a primary endpoint are difficult but it is 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 is 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.

*i. GammaTile™*

Isoray Medical, Inc. & GammaTile, LLC submitted an application for GammaTile™, a brachytherapy technology for use in the treatment of patients diagnosed with brain tumors using

cesium-131 radioactive sources embedded in a collagen matrix.[8] GammaTile™ is biocompatible and bioabsorbable and is in the body permanently without the need for future surgical removal. The applicant anticipates FDA clearance for the spring of 2018 for use of GammaTile™ in the salvage treatment of recurrent radiosensitive malignancies of the brain. ICD-10-PCS procedure code 00H004Z identifies procedures involving the use of GammaTile™.

Newness. With respect to the first criterion, the applicant stated that when compared to external beam radiation therapy, GammaTile™ uses a new and unique mechanism of action. According to the applicant, use of cesium-131 and the custom distribution of seeds in a three-dimensional collagen device results in a unique and highly effective delivery of radiation therapy to brain tissue. For the second criterion, patients that may be eligible for treatment with GammaTile™ will be assigned to the same MS-DRGs as other current treatment forms of brachytherapy and external beam radiation therapy. For the third criterion, the applicant stated that GammaTile™ offers a treatment option for a patient population with limited, or no other, available treatment options. CMS is concerned that the mechanism of action for GammaTile™ may be the same or similar to current forms of radiation or brachytherapy.

Cost. The applicant worked with the Barrow Neurological Institute at St Joseph's Hospital and Medical Center to obtain claims from mid-2015 through mid-2016 for craniotomies that did not involve placement of the GammaTile™ technology. The applicant found 460 claims that were assigned to 3 MS-DRGs. The applicant standardized the charges for each case and inflated each case's charges by applying the FY 2017 IPPS final rule outlier charge inflation factor of 1.05074 by the age of each case (that is the factor was applied to 2015 claims 3 times and 2016 claims 2 times). The applicant calculated an estimate for ancillary charges associated with placement of the GammaTile™ device. The applicant concluded that the technology meets the cost criterion because the final inflated average case-weighted standardized charge per case (including the charges for GammaTile™) of $246,310 exceeds the average case-weighted threshold amount of $141,249 for MS-DRG 23.

Substantial Clinical Improvement. The applicant stated that GammaTile™ might provide the only radiation treatment option for patients diagnosed with tumors located close to sensitive vital brain sites and patients diagnosed with recurrent brain tumors that may not be eligible for additional treatment involving the use of external beam radiation therapy. The applicant submitted data from three abstracts, with one associated paper demonstrating feasibility or superior progression-free survival compared to the patient's own historical control rate.

According to the applicant, the data reported support the conclusion that a significant therapeutic effect results from the addition of GammaTile™ radiation therapy to the site of surgical removal. The applicant noted that it is continuing to collect follow-up data on these patients. CMS is concerned that the findings appear to be derived from relatively small case studies with limited clinical efficacy and safety data. CMS notes there is lack of analyses, meta-analyses or statistical tests that indicate seeded brachytherapy procedures represented a statistically significant

[8] Isoray Medical and Gamma Tile previously submitted an application for new technology add-on payments for GammaTile™ in FY 2018.

improvement over alternative treatments. In addition, CMS is concerned with the lack of studies involving the actual manufactured device.

*j. Supersaturated Oxygen ($SSO_2$) Therapy (DownStream® System)*

TherOX, Inc. submitted an application for the DownStream® System, an adjunctive therapy designed to ameliorate progressive myocardial necrosis by minimizing microvascular damage in patients receiving treatment for an acute myocardial infarction (AMI) following a percutaneous intervention (PCI) with coronary artery stent placement. The applicant asserted that the net effect of $SSO_2$ Therapy is to reduce the infarct size and therefore preserve heart muscle. The $SSO_2$ Therapy consists of three main components: the DownStream® System, the Downstream cartridge and the $SSO_2$ delivery catheter. The System and cartridge function together to create an oxygen-enriched saline solution called $SSO_2$ from hospital-supplied oxygen and physiologic saline. Using a small amount of the patient's blood, oxygen enriched hyperoxemic blood is obtained and then delivered to the left main coronary artery via the delivery catheter. The duration of the $SSO_2$ Therapy is 60 minutes and the oxygen partial pressure of the infusion is elevated to approximately 1000mmHg, therefore providing oxygen locally to the myocardium at a hyperbaric level for 1 hour. Coronary angiography is performed as a final step before removing the delivery catheter. The applicant expects to receive pre-market approval from the FDA in the first quarter of 2018. The applicant states that the use of $SSO_2$ Therapy can be identified by the ICD-10-PCS procedure codes 5A0512C and 5A0522C.

Newness. For the first criterion, the applicant stated the $SSO_2$ Therapy increases oxygen levels and re-opens the microcirculatory system within the infarct zone, and once reopened, the blood flow contains additional oxygen to restart the metabolic processes within the stunned myocardium. According to the applicant, currently available treatment options for patients diagnosed with AMI receive treatment for AMI that do not treat hypoxemic damage at the microvascular or microcirculatory level. $SSO_2$ Therapy does not use the same or a similar mechanism of action of any existing treatment for these patients. For the second criterion, CMS believes that potential cases involving the $SSO_2$ Therapy may be assigned to the same MS-DRGs as other similar cases. For the third criterion, the applicant stated that $SSO_2$ Therapy's emphasis is on treating patients diagnosed with AMI at the microvascular level instead of reopening the blocked coronary artery at the macrovascular level as with other treatments, and therefore, treats a different type of disease than currently available treatment options for patients who have been diagnosed with and receive treatment for AMI.

Cost. The applicant searched the FY 2016 MedPAR data for claims reporting 4 ICD-10-CM diagnosis codes for anterior ST-Elevation Myocardial Infarction (STEMI) and identified 11,030 potential cases across 4 MS-DRGs. The applicant standardized the charges but did not remove charges for the current treatment because $SSO_2$ Therapy will be used as an adjunctive treatment option following successful PCI with stent placement. The applicant applied the inflation factor of 1.05074 from the FY 2018 IPPS final rule and added charges related to the new technology. The inflated average case-weighted standardized charge per case was $146,974. Because the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained the technology meets the cost criterion.

Substantial Clinical Improvement. According to the applicant, as an adjunctive treatment, the $SSO_2$ Therapy has demonstrated superiority over PCI with stenting alone in reducing the infarct size for high-risk patients diagnosed with anterior AMI treated within 6 hours of symptom onset. In addition, the treatment has been shown to preserve left ventricular integrity as compared to patients receiving treatment involving PCI with stenting alone, utilizing direct measurements of left ventricular volume over the 30-day post-procedure period. The applicant submitted results from five clinical studies that it believes demonstrate the substantial clinical benefit associated with $SSO_2$ Therapy. CMS summarizes these studies and does not highlight any concerns with these results. The applicant also performed controlled studies in both porcine and canine AMI models to demonstrate the safety, effectiveness, and mechanism of action of the $SSO_2$ Therapy.

In response to the February 2018 New Technology Town Hall meeting CMS received a number of comments supporting the approval of the new technology add-on payments for $SSO_2$ Therapy for the treatment of patients diagnosed with AMI. Commenters highlighted the results from the clinical studies to support the substantial clinical improvement of this therapy.

*k. 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. CMS notes that it appears that the Sentinel® Cerebral Protection System is not substantially similar to other existing technologies.

Cost. The applicant searched the FY 2016 MedPAR data for cases reporting 8 ICD-10-CM procedure codes for TAVR procedures and identified 26,012 potential cases across 2 MS-DRGs (MS-DRGs 266 and 267). The applicant standardized the charges and did not inflate the charges. The applicant added charges for the new technology by taking the cost of the device and dividing the amount by the CCR of 0.332 for implantable devices from the FY 2018 IPPS final rule. The average case-weighted standardized charge per case was $187,707. Because the

average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained the technology 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 discusses its concern that the use of cerebral protection devices may not be associated with a significant reduction in stroke and death. It is 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.

*l. AZEDRA® (Ultratrace® iobenguane Iodine-131) Solution*

Progenics Pharmaceuticals, Inc. submitted an application for AZEDRA®, a drug solution formulated for IV use in the treatment of patients diagnosed with obenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paragangliona. AZEDRA® contains a mall molecule ligand consisting of meta-iodobenzylguanidine (MIBG) and $^{131}$Iodine ($^{131}$I), hereafter referred to as $^{131}$I-MIBG. (Iobenguane Iodine-131 is also known as $^{131}$I-MIBG.) Pheochromocytomas and paragangliomas are rare tumors with an incidence of approximately 2 to 8 people per million per year. There is no curative treatment for these tumors and successful management of patients involves decreasing tumor burden, controlling endocrine activity, and treating debilitating symptoms. Current treatment options include radiation therapy; nonsurgical local ablative therapy; transarterial chemoembolization for liver metastases; and radionuclide therapy using MIBG or somatostatin. According to the applicant, AZEDRA® is a more consistent form of $^{131}$I-MIBG compared to compounded formulations of $^{131}$I-MIBG that are not currently approved by the FDA. The applicant anticipated FDA approval by June 30, 2018. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures involving the administration of AZEDRA®.

Newness. For the first criterion, the applicant stated that while AZEDRA® and low-specific activity conventional I-131 MIBG both target the same sites on the tumor cell surface, the safety and efficacy outcomes are different. The differences are because AZEDRA® is manufactured using the proprietary Ultratrace® technology, which maximizes the molecules that carry the tumoricidal component and minimize the extraneous unlabeled component which could cause cardiovascular side effects. For the second criterion, the applicant noted there are no specific MS-DRGs for the assignment of cases involving the treatment of patients diagnosed with pheochromocytoma and paraganglioma. CMS believes potential cases would be assigned to the

same MS-DRGs as cases representing patients who receive treatment for these tumors and notes that the applicant includes a list of MS-DRGs for potential cases in the cost analysis. For the third criterion, the applicant states that AZEDRA® would be the only FDA-approved drug indicated for use in the treatment of patients with malignant pheochromocytoma and paraganglioma that avidly take up $^{131}$I-MBG and are recurrent and/or unresectable.

Cost. The applicant searched the FY 2015 MedPAR data for cases that may be eligible for AZEDRA® by using a combination of 6 ICD-9-CM diagnosis codes and 5 ICD-9-CM procedure codes. This combination was intended to identify potential patients eligible for treatment and who had received subsequent treatment with a predecessor radiopharmaceutical therapy, such as an off-label use of conventional $^{131}$I MIBG therapy. The applicant identified six MS-DRGs but due to privacy concerns, the MedPAR data did not identify the exact number of cases assigned to these MS-DRGs. Using this information, the applicant determined an inflated average case-weighted standardized charge per case of $103,833. The applicant did not include the price of the drug in its analysis nor did the applicant remove any charges associated with any predecessor radiopharmaceutical therapy use of MIBG agents. The applicant also noted that potential cases that may be eligible for treatment would typically map to other MS-DRGs that were not used in the analysis. Based on an average case-weighted threshold amount of $58,352 the applicant concluded that AZEDRA® meets the cost criterion. CMS acknowledges the difficulties in obtaining cost data for a rare condition but it is concerned that the MS-DRGs identified by the applicant's search of MedPAR do not match the MS-DRGs that the applicant identified as potential cases that may be eligible for therapy.

Substantial Clinical Improvement. The applicant stated that AZEDRA® reduced the use of antihypertensive medications, reduced tumor size, improved blood pressure control, reduced secretion of tumor biomarkers, and demonstrated strong evidence of overall survival rates. The applicant presented information from two open-label, single-arm clinical studies. CMS summarizes these results and acknowledges the challenges with constructing robust clinical studies due to the extremely rare occurrence of patients diagnosed with pheochromocytoma and paraganglioma tumors. CMS raises several issues with the results including lack of comparison of the treatment to other treatment options to decrease the tumor burden, the use of antihypertensive medications as a proxy to assess the long-term effects of hypertension, and the safety profile. It is concerned that it is difficult to make strong efficacy conclusions based on retrospective studies with small, heterogeneous patient cohorts. It notes that only very limited not published data from two, single-arm, noncomparative studies are available to evaluate the safety and effectiveness of AZEDRA® compared to outcomes from historical controls.
In response to the February 2018 New Technology Town Hall meeting, two commenters stated that AZEDRA® demonstrates a substantial clinical improvement over other available therapies.

*m. 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 (LUTS) due to BPH. The device was made available immediately. The applicant applied for approval for a distinct ICD-10-PCS procedure code to identify procedures involving the AQUABEAM System at the March 2018 ICD-10 Maintenance and Coordination Committee meeting.

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 is 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 notes that the use of water to perform tissue removal exists in other areas of surgical treatment. In addition, CMS is 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 is also uncertain that the use of a robotic hand and computer programming are new mechanisms of action.

Cost. The applicant searched the FY 2016 MedPAR data files for potential cases eligible for treatment with the AQUABEAM System by using four ICD-10-PCS procedure codes describing other BPH minimally invasive procedures and identified 133 MS-DRGs. The applicant conducted two analyses, based on 100 percent of claims mapping to the 133 MS-DRGs and 75 percent of claims mapping to 6 MS-DRGs. When there were fewer than 11 cases for individual MS-DRGs, a value of 11 was imputed to ensure patient confidentiality. A total of 8,449 cases were included in the 100 percent analysis and 6,285 cases were included in the 75 percent analysis. The applicant removed 100 percent of total charges associated with the service category "medical/Surgical Supply Charge Amount". The applicant standardized the charges, inflated the charges (using an inflation factor of 1.09357) and then added the charges for the new technology. The final inflated average case-weighted standardized charge per case was $69,588 for the 100 percent sample and $51,022 for the 75 percent sample. The average case-weighted threshold amount was $59,242 for the 100 percent sample, and $48,893 for the 75 percent sample. The applicant concluded the technology 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 discusses several concerns with the interpretation of the results of the meta-analysis, which tested the effects of three separate treatment options. CMS acknowledges 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 provides 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 notes 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 discusses concerns about the comparison between the AQUABEAM System and the TURP procedure, including a finding of improved safety. CMS is interested in information that compares the safety profile of the AQUABEAM System therapy to other treatment modalities.

*n. 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.[9] 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. There is no FDA-approved therapy for the urgent reversal of any Factor Xa inhibitor as a result of serious bleeding disorders. The applicant anticipates receipt of FDA approval for the use of the technology during the first quarter of 2018. The applicant received approval for two ICD-10-PCS procedure codes (XW03372 and XW04372). 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, CMS notes that AndexXa™ is not substantially similar to any existing technologies.

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

Cost. The applicant researched the FY 2015 MedPAR claims data file for cases that may be eligible for treatment using AndexXa™ (see the proposed rule for a table of applicable ICD-9-CM codes). The applicant identified a total of 51,605 cases that mapped to 683 MS-DRGs with an average case-weighted charge per case of $67,197. The applicant also provided an analysis limited to 80 percent of all cases, which mapped to the top 151 MS-DRGs and calculated an average case-weighted charge per case of $69,020. A third analysis was provided that was limited to cases representing 25 percent of all potential cases identified (12,873) that mapped to the top 9 MS-DRGs. This third analysis resulted in an average case-weighted charge of $46,974. For these analysis, the applicant also provided sensitivity based on variables representing two areas of uncertainty: (1) whether to remove 40 or 60 percent of blood and blood administration charges; and (2) whether to remove pharmacy charges based on the ceiling price of factor eight inhibitor bypass activity (FEIBA) or on the pharmacy indicator 5 (PI5) in the MedPAR data file, which correlated to cases utilizing generic coagulation factors. The applicant conducted twelve sensitivity analyses that are discussed in the proposed rule. Charges for AndexXa™ were not added as the price has not been determined. Under each scenario, the applicant stated that the inflated average standardized case-weighted charge per case exceeded the average case-weighted threshold (see the proposed rule for a table summarizing this information).

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 is 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 is 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.

## 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 Proposed 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 notes it lacked the time to include the change in computing the proposed FY 2019 wage index, ratesetting, and Tables 2 and 3 of the proposed rule, but it will do so in the final rule. The new CBSA may impact budget neutrality factors and wage indexes; for example, it may qualify for the rural floor. CMS estimates the area wage index for new CBSA 46300 as follows:

| | Estimated Unadjusted Wage Index for New CBSA 46300 | Estimated Occupational Mix Adjusted Wage Index for New CBSA 46300 |
|---|---|---|
| Proposed National Average Hourly Wage | 42.990625267 | 42.948428861 |
| Estimated CBSA Average Hourly Wage | 35.833564813 | 38.127590025 |
| Estimated Wage Index | 0.8335 | 0.8878 |

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 will continue to do so for FY 2019. For FY 2019, Tables 2 and 3 of the proposed 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 proposed 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). As was done for FY 2018, CMS excluded 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 proposed FY 2019 wage index based on wage data of 3,260 hospitals from Worksheet S-3, Parts II and III of the cost report for cost reporting periods beginning during fiscal year 2015 (referred to as FY 2015 wage data); the data file used to construct the proposed wage index includes FY 2015 data submitted to CMS as of February 6, 2018.

CMS excludes 80 providers due to excessively aberrant data but indicates that if the data could be corrected in time, it intends to include some of those providers in the final wage index for FY 2019. CMS also includes certain aberrant data that it adjusted through imputed estimates under policies established in the FY 2015 IPPS/LTCH PPS final rule (e.g., where a hospital did not have documentable salaries, wages and hours for housekeeping and dietary services).

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 removed 8 hospitals that converted to CAH status after January 22, 2017 through January 26, 2018. For multicampus hospitals, CMS uses the same methodology as it did 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; the table is available from the CMS website: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Proposed-Rule-Home-Page.html. CMS makes a change in the manner in which it designates a subordinate campus in Table 2. In this proposed rule and for future rulemaking, 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 proposed FY 2019 national average hourly wage, unadjusted for occupational mix, is $42.990625267. CMS no longer computes a separate unadjusted wage index for Puerto Rico because section 601 of the Consolidated Appropriations Act, 2016 (Public Law 114–113) provided for 100 percent payment based on the national standardized amount for Puerto Rico hospitals.

CMS proposes to use 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, and it does not propose to change the use of 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 proposes to correct that omission. It clarifies 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.* 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 continues to believe that reporting these costs may not be an appropriate part of a relative measure of wage costs in a particular market area which 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. For these reasons, CMS proposes to exclude other wage-related costs in calculating the wage index for FY 2020 and subsequent fiscal years. **CMS invites comments on the proposal.**

<u>Codification of Certain Policies for Multicampus Hospitals</u>

CMS proposes 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 proposals apply 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.

Generally, CMS proposes that 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. Stated differently, 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) would 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 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 the proposal would not create such a change in circumstance; CMS reminds readers that hospitals must report changes in circumstances to their MACs within 30 days.

CMS believes this proposal is appropriate because (i) remote locations are included in the main campus's cost report and share the same provider number, and (ii) 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).

## 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 a 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 proposes to calculate the occupational mix adjustment factor using the same methodology it has used since the FY 2012 wage index and to apply 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 proposed rule contains the proposed FY 2019 occupational mix adjusted wage index and includes separate wage data for the campuses of 16 multicampus hospitals.

CMS reports a response rate of 94 percent (3078 hospitals responded to the survey) and notes it applies proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data. For FY 2019, the proposed unadjusted national average hourly wage is $42.990625267 and the proposed occupational mix adjusted national average hourly wage is $42.948428861.

## F. Occupational Mix Adjusted Wage Index

The proposed 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 | $41.67064907 |
| National LPN and Surgical Technician | $24.68950438 |
| National Nurse Aide, Orderly, and Attendant | $16.96671421 |
| National Medical Assistant | $18.1339666 |
| *National Nurse Category* | $35.05256013 |

CMS observes that, based on its analysis of the occupational mix data, the national percentage of hospital employees in the nurse category is 42.3%. At the CBSA level, the percentage of hospital employees in the nurse category ranged from 26.6% to 82%. Applying the proposed occupational mix adjustment to wage data, the proposed wage index values for FY 2019 would increase for a larger percentage of urban areas (56.9 percent) than rural areas (48.9 percent) and would decrease for a larger percentage of rural areas (51.1 percent) than urban areas (42.9 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 more CBSAs (56.3%) would decrease due to the application of the 2016 occupational mix survey data; 43.9% of urban areas and 42.6% of rural areas would benefit from 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 proposed wage index for 255 hospitals. CMS calculates a proposed national rural floor budget neutrality adjustment factor of 0.994733. CMS projects that rural hospitals in the aggregate will experience a 0.2% 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 2.2% increase in payments, primarily due to the application of the proposed rural floor in Massachusetts. CMS expects that 35 urban providers in Massachusetts would receive a rural floor wage index value which increases payments overall to Massachusetts by $49 million in FY 2019. Urban Puerto Rico hospitals will receive no increase in IPPS payments.

Proposed 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 proposes to let this program expire effective October 1, 2018. Under the imputed floor program, CMS imputes a “floor” for states with no rural counties; those states are 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. Discontinuing the imputed floor program would mean that only those states with both rural areas and hospitals located in those rural areas (including any hospital reclassified as rural under §412.103) would benefit from the rural floor as provided for under the statute. CMS also notes that it would exclude the imputed floor as a factor in the national budget neutrality adjustment.

Frontier Floor Wage Index. CMS does not propose any changes to the frontier floor wage index policies for FY 2019. Thus, 50 hospitals in Montana, Nevada, North Dakota, South Dakota, and Wyoming would receive the frontier floor value of 1.0000 for FY 2019. This provision is not budget neutral, and CMS estimates an increase of approximately $61 million in IPPS operating payments. Rural and urban hospitals located in the West North Central region would experience an increase in payments of 0.2% and 0.6%, 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). In this proposed rule, 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 directs readers to section VI of the Addendum to the proposed rule for a discussion of the proposed 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 the purposes of calculating the wage index, the hospital is included in the urban wage area to which it is reclassified by the MGCRB.

Reclassifications

CMS notes that 337 hospitals were approved by the MGCRB for wage index reclassifications starting in FY 2019, and because such reclassifications are effective for 3 years, a total of 941 hospitals are in a reclassification status for FY 2019, including those initially approved by the MGCRB for FY 2017 (259 hospitals) and FY 2018 (345 hospitals). 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 would be 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 to require that applications and supporting documentation 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).

Proposed 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 make this documentation, 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.

Beginning with reclassification applications for FY 2021 (which are due September 1, 2019), CMS proposes that a hospital would 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. Thus, a hospital in a single hospital MSA applying for FY 2021 would only have to 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).

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 proposed 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 is not proposing 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 is 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; will instruct MACs to adjust payment for that remote location; and 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.

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.

## J. Out-Migration Adjustment

The "out-migration" adjustment is an adjustment to the hospital wage index based on commuting patterns of hospital employees.[10] CMS proposes to use the same policies, procedures and computation that were used for the FY 2012 out-migration adjustment, and estimates increased

[10] Hospitals located in counties that qualify for the payment adjustment are to receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index.

payments of approximately $36 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 proposed FY 2019 out-migration adjustment, and the number of years the adjustment would be in effect.

## 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 proposes 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 notes 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 would 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 proposed 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 to its MAC requests 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 is the deadline by which hospitals may 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 is 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.

Wage index data PUFs were made available on April 27, 2018 and 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 believes a potential error exists because of these reasons, the hospital is required 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 will be 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 its 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 would change the wage index value for an area, the revised wage index would be 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; nor can the correction be used to revise a prior fiscal year's wage index data. CMS notes that there would also be 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 request for a

wage data revision. A hospital would dispute CMS adjustments under existing deadlines as follows[11]:

- 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.

## 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 that reflects the relative differences in labor costs among geographic areas. The proportion of the standardized amount attributable to wages and wage-related costs is the national labor-related share. The factor that adjusts for the relative differences in labor costs among geographic areas is the wage index. 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.

The Secretary is required to update the labor-related share from time-to-time but no less often than every 3 years. CMS updated the labor-related share in the FY 2018 IPPS rule and began using a national labor-related share of 68.3 percent for FY 2019. If a hospital has a wage index of less than 1.0, its IPPS payments will be higher with a labor-related share of 62 percent. If a hospital a wage index that is higher than 1.0, its IPPS payments will be higher using the national labor-related share.

CMS established a 2014-based IPPS hospital market basket to replace the FY 2010-based IPPS hospital market basket, effective October 1, 2017. Using the 2014-based IPPS market basket, CMS finalized a labor-related share of 68.3 percent for discharges occurring on or after October 1, 2017. CMS is not proposing any changes to the labor-related share for FY 2019 or its application. Therefore, hospitals with a wage index of less than 1.0 will have its IPPS payments determined using a labor-related share of 62 percent and all other hospitals will have their IPPS payments determined using the national average labor-related share of 68.3 percent.

[11] 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.

## N. Request for Public Comments on Wage Index Disparities

1. General Background

The proposed rule indicates there have been numerous studies, analyses, and reports on disparities between the wage index values for individual hospitals and the wage index values among different geographic areas and ways to improve the Medicare wage index. CMS is inviting suggestions for regulatory and policy changes to address these issues including supporting data and specific recommendations. For any suggestions or recommendations presented that involve novel legal questions, CMS welcomes analysis regarding its statutory authority.

CMS discusses the features of the current Medicare wage index system such as use of CBSAs for labor market area definitions and hospital reported wage data. Among its other provisions, CMS notes that the current system relies on hospital wage data submitted by hospitals rather than on data that reflect broader labor market wages such as data from the Bureau of Labor Statistics or data from the American Community Survey. Public comments on prior rulemaking for FYs 2009, 2010, and 2011 argued that the current CBSA labor market definitions and wage data sources used by CMS, in many instances, are not reflective of the true cost of labor for any given hospital or are inappropriate to use for this purpose, or both.[12]

With respect to the labor market definitions, multiple exceptions and adjustments (for example, provider reclassifications under the MGCRB and the rural floor adjustment) have been put into place in attempts to correct perceived inequities. However, many of these exceptions and adjustments may create or further exacerbate distortions in labor market values. The issue of "cliffs," or significant differences in wage index values between proximate hospitals, can often be attributed to one hospital benefiting from such an exception and adjustment when another hospital cannot. With respect to the wage data sources, many stakeholders have argued that the use of hospital reported data results in increasing wage index disparities over time between high wage index areas and low wage index areas. This argument suggests there is circularity in the wage index (being paid based on a higher wage index allows hospitals to pay higher wages and vice versa).

2. Prior Reports, Studies, and Analyses

MedPAC Report to Congress

The Medicare Improvements and Extension Act of 2006 required MedPAC to submit a Report to Congress on the Medicare wage index not later than June 30, 2007 including recommendations for alternatives. The Secretary of Health and Human Services was required to take MedPAC's recommendations into account to make one or more proposals to revise the Medicare wage index in the FY 2009 IPPS proposed rule.

[12] Public comments for proposed rules under file numbers CMS-1390-P, CMS-1406-P, and CMS-1498-P) are available via the Internet on the website at: www.regulations.gov. For responses to public comments, see the FY 2009 IPPS/LTCH PPS final rule (73 FR 48563 through 48567); the FY 2010 IPPS/LTCH PPS final rule (74 FR 43824 through 43826); and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50157 through 50160).

In its June 2007 Report to Congress, "Report to the Congress: Promoting Greater Efficiency in Medicare" (Chapter 6 with Appendix), MedPAC made three broad recommendations regarding the wage index:

1. Congress should repeal the existing hospital wage index statute, including reclassifications and exceptions, and give the Secretary authority to establish a new wage index system.
2. The Secretary should establish a hospital compensation index that—
   - Uses wage data from all employers and industry-specific occupational weights (Bureau of Labor Statistics data);
   - Is adjusted for geographic differences in the ratio of benefits to wages;
   - Is adjusted at the county level and smooths large differences between counties; and
   - Is implemented so that large changes in wage index values are phased in over a transition period.
3. The Secretary should use the hospital compensation index for the home health and skilled nursing facility prospective payment systems and evaluate its use in the other Medicare fee-for-service prospective payment systems.

The full June 2007 MedPAC Report to Congress is available at the MedPAC website: http://medpac.gov/docs/default-source/reports/Jun07_EntireReport.pdf.

During the FY 2009 IPPS rulemaking process, CMS received many public comments regarding MedPAC's recommendations for reforming the wage index (73 FR 48564 through 48566). The public comments varied greatly. There was no consensus among the commenters.

In the FY 2009 IPPS final rule (73 FR 48564 through 48567), CMS summarized an analysis of MedPAC's recommendations done by its contractor, Acumen LLC. Acumen's main findings were that adopting MedPAC's recommendations would:

- Reduce the differentials between wage index values across geographic areas;
- Reduce the difference between the highest wage index hospitals and the lowest wage index hospitals;
- Lower the wage dispersion among both rural hospitals and urban hospitals (whether classified by geography or payment), among hospitals of all sizes, and among all hospitals categorized by teaching status, DSH status, ownership status, and Medicare utilization status;
- Have a differential impact on urban hospitals across geographic regions of the country;
- Decrease the standard deviation among hospitals with most types of reclassifications;
- Lead a substantial number of hospitals to experience a large change in their index values in the transition; and
- Rural counties would experience fewer decreases and more increases in their wage index compared to counties in urban areas.

Acumen Report on Revision of the Medicare Wage Index

In the FY 2010 and FY 2011 IPPS rulemaking (74 FR 43824 through 48325 and 75 FR 50158 through 50159, respectively), CMS discussed a separate report by Acumen on the wage index and methodology entitled "Revision of the Medicare Wage Index" (https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/Medicare_Wage_Index_Commuting_DOC_2011.pdf).

Acumen concluded that MedPAC's recommended methods for revising the wage index represent an improvement over the existing methods, and that the BLS data should be used so that the MedPAC approach can be implemented. Several commenters during the FY 2010 and FY 2011 IPPS rulemakings (74 FR 43824 and 75 FR 50158, respectively) reiterated their concerns regarding the use of the BLS data for computing the Medicare wage index that they had expressed in public comments on the FY 2009 IPPS final rule (73 FR 48564 through 48565). Other commenters expressed support for MedPAC's and Acumen's findings.

Acumen recommended further exploration of labor market area definitions using a wage area framework based on hospital-specific characteristics, such as commuting times from hospitals to population centers, to construct a more accurate hospital wage index. Acumen suggested that such an approach offers the greatest potential for replacing or greatly reducing the need for hospital reclassifications and exceptions. Public comments on this suggestion varied greatly, and there was no consensus among the commenters to Acumen's recommendation.

HHS Report to Congress—Plan to Reform the Medicare Hospital Wage Index

Section 3137(b) of the Affordable Care Act required the Secretary of Health and Human Services to submit a Report to Congress that includes a plan to reform the Medicare wage index taking into account MedPAC's recommendations from its June, 2007 Report to Congress.

The Secretary's Report to Congress described a commuting-based wage index (CBWI). The CBWI would use commuting data to define hospital labor market areas. The CBWI is based on data on the number of hospital workers commuting from home to work to define a hospital's labor market. A CBWI system could use either current hospital cost report data or other alternative sources, such as the BLS Occupational Employment Survey data, to calculate labor market area average wage values.

The April 12, 2012 Report to Congress indicated:

- Because the CBWI accounts for specific differences in hospitals' geographic hiring patterns, it would yield wage index values that more closely correlate to actual labor costs than either the current wage index system (with or without geographic reclassification) or a system that attempts to reduce wage index differences across geographic boundaries, such as MedPAC's proposed wage index based on BLS data for health care industry workers.
- While a CBWI could be constructed with the most recent Census commuting data, were the CBWI to be adopted, a more up-to-date reporting system for collecting commuting data from hospitals would potentially have to be established so that the wage index calculations would accurately reflect the commuting patterns of hospital employees.
- Concerns about a CBWI leading to hospitals altering hiring patterns and distorting labor

markets do not appear to be worse than under the current system and could potentially be mitigated with policy adjustments.
- As current statutory provisions governing the Medicare wage index and exceptions to that wage index were designed for the current MSA-based wage index system, their applicability would need to be reviewed if a CBWI were to be adopted.
- The Medicare statute has traditionally applied payment changes in a budget neutral manner. If a CBWI were to be adopted in a budget neutral manner, payments to some providers would increase while payments to other providers would decrease.

The complete report can be accessed on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Reform.html. Click on the first link under downloads. Again, the public comments varied greatly and there was no consensus (77 FR 53660 through 53663).

Institute of Medicine (IOM) Study on Medicare's Approach to Measuring Geographic Variations in Hospitals' Wage Costs

The Secretary of Health and Human Services commissioned the Institute of Medicine (IOM) to evaluate Medicare's approach for measuring geographic variation in the wage costs faced by hospitals. In the report, IOM's Committee on Geographic Adjustment Factors in Medicare Payment proposed a set of recommendations for modifying the hospital wage index in both the method used in its construction and the data used in its calculation. In constructing the wage index, the IOM recommended altering the current labor market definitions to account for the out-commuting patterns of health care workers who travel to a place of employment in an MSA other than the one in which they live. The IOM also suggested that using out-commuting shares in the smoothing adjustment creates an index based on the wage levels of workers living in that area in which a hospital is located, as opposed to wage levels of workers employed in that area, as in the CBWI model. The IOM's wage index model uses hourly wage data from the BLS Occupational Employment Survey rather than from hospital cost reports. The IOM also recommended measuring hourly wages using data for all health care workers, rather than only hospital workers, and using a fuller set of occupations incorporated in the hospital wage index occupational mix adjustment.

The IOM suggested that BLS data would reduce administrative burdens placed upon hospitals and, by broadening the array of reported occupations from what is currently covered in the hospital cost report, would achieve more accurate labor market definitions and reduce year-to-year volatility. The IOM encouraged CMS to establish an ongoing agreement with the BLS to use occupational survey data specific to health care workers to calculate average hourly wage values. The IOM suggested, for instance, that the 5-year American Community Survey is a potential source of the necessary commuting information. The findings indicated that the IOM hospital wage index method would result in the reduction in wage index "cliffs," and would diminish the need to maintain current wage index exceptions and adjustments. The IOM also recommended that the hospital wage values should be applied to other nonhospital health care providers, shifting to a single measurement of geographic variation to be used in multiple Medicare provider payment systems.

The IOM's Phase I report, published in September 2011, is available at: http://nationalacademies.org/hmd/Reports/2011/Geographic-Adjustment-in-Medicare-Payment-Phase-I-Improving-Accuracy.aspx.

Public comments regarding the IOM Report as part of the FY 2013 IPPS rulemaking (77 FR 53660 through 53663) varied greatly. There was no consensus among the commenters.

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

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

1. Background

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 (SNF) or home with written plan for home health services from a home health agency (HHA) 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 higher 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. Proposed Changes for FY 2019

CMS is proposing to make changes to a number of MS-DRGs effective for FY 2019. Consistent with 42 CFR §412.4(d), CMS evaluated these MS-DRGs using the general post-acute care transfer policy criteria and 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 according to regulations at 42 CFR §412.4(f)(6).

CMS includes an unnumbered chart in this section which provides its findings for proposed new or revised MS-DRGs subject to a review of its post-acute care transfer policy status. Of the 33 new or revised MS-DRGs included on the chart, 10 will be subject to the post-acute transfer policy. The proposed rule indicates that these 10 MS-DRGs are currently subject to the policy (023, 329, 330, 331, 698, 699, 700, 870, 871, and 872).

None of these MS-DRGs are currently subject to the "special payment methodology." However, based on its revised analysis, CMS is proposing to make 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.

CMS' analysis of new or revised MS-DRGs does not take into account the statutory provision that expands the post-acute care policy to hospice discharges. For the FY 2019 final rule, CMS will update its analysis using the most recent available data at that time.

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

Section 53109 of the Bipartisan Budget Act 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. Accordingly, if a discharge is assigned to one of the MS-DRGs subject to the post-acute care transfer policy and the individual is transferred to hospice, CMS is required to make the discharge subject to payment as a transfer case.

CMS is proposing to make 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. It is also proposing that a hospital billing 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) would be subject to the post-acute care transfer policy in accordance with this statutory amendment. Consistent with policy for other qualified discharges, 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.

## 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, subject to the following possible reductions (in the order presented):

1. For hospitals that fail to submit quality information, the FY 2019 inpatient hospital update will be reduced by one quarter of the applicable percentage increase.[13]
2. For a hospital that is not a meaningful electronic health record (EHR) user (and to which no exemption applies), the FY 2019 inpatient hospital update will be reduced by three-

[13] See section 1886(b)(3)(B)(viii) of the Act. This adjustment is calculated before the application of any payment adjustment under sections 1886(b)(3)(B)(ix) [failure to be a meaningful EHR user], 1886(b)(3)(B)(xi) [MFP adjustment], and 1886(b)(3)(B)(xii) [the statutory adjustment] of the Act.

quarters of the market basket update.[14]

3. For all hospitals, the FY 2019 inpatient hospital update is subject to a 0.8 percentage point reduction for changes in economy-wide productivity (i.e., the multifactor productivity (MFP) adjustment)[15] which may result in an applicable percentage increase of less than zero.
4. For all hospitals, the statute calls for a 0.75 percentage point reduction for FY 2019[16] which may result in an applicable percentage increase of less than zero.

CMS proposes to use the 2014-based IPPS operating and capital market baskets for the FY 2019 update, and a revised labor-related share of 68.3 percent (also based on the 2014-based IPPS market basket). CMS bases its proposed FY 2019 market basket update on the IHS Global Insight, Inc. (IGI) fourth quarter 2017 forecast (with historical data through the third quarter of 2017) which it estimates to be 2.8 percent. Using IGI's fourth quarter 2017 forecast, CMS proposes an MFP adjustment of -0.8 percentage points. CMS proposes to use more recent data, if available, to determine the final market basket update and MFP adjustment. If IGI makes changes to the MFP methodology, CMS announces them on its website rather than in annual rulemaking cycles.

One of four different applicable percentage increases may apply to a hospital, depending on whether it submits quality data and/or is a meaningful EHR user, as shown in the following table. In this rule, CMS proposes to revise existing regulations at 42 CFR §412.64(d) to reflect the applicable percentage increase for a hospital that does not submit quality data or is not a meaningful user.

| 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 | 2.8 | 2.8 | 2.8 | 2.8 |
| Adjustment for Failure to Submit Quality Data | 0.0 | 0.0 | -0.7 | -0.7 |
| Adjustment for Failure to be a Meaningful EHR User | 0.0 | -2.1 | 0.0 | -2.1 |
| MFP Adjustment | -0.8 | -0.8 | -0.8 | -0.8 |
| Statutory Adjustment | -0.75 | -0.75 | -0.75 | -0.75 |
| **Applicable Percentage Increase** | **1.25** | **-0.85** | **0.55** | **-1.55** |

[14] See section 1886(b)(3)(B)(ix) of the Act. This adjustment is calculated before the application of any payment adjustment under sections 1886(b)(3)(B)(viii) [failure to submit quality information], 1886(b)(3)(B)(xi) [MFP adjustment], and 1886(b)(3)(B)(xii) [the statutory adjustment] of the Act.
[15] See section 1886(b)(3)(B)(xi) of the Act.
[16] See section 1886(b)(3)(B)(xii)(V) of the Act.

For updates to the hospital-specific rate for SCHs and MDHs, CMS proposes the same four possible applicable percentage increases shown in the table above. CMS notes that because there is no longer a Puerto Rico-specific standardized amount there is no longer a need to separately update the Puerto Rico-specific standardized amount. However, Puerto Rico hospitals are not subject to the quality data requirements, and the penalty for hospitals that are not meaningful EHR users will not apply in Puerto Rico until FY 2022.

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

CMS proposes revised criteria for purposes of determining rural referral center (RRC) status, including updated minimum national and regional case mix index (CMI) values and updated minimum national and regional numbers of discharges. These factors are among those used to determine whether a hospital qualifies for RRC status.

To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2018, CMS proposes that a rural hospital with fewer than 275 beds available for use must, among other things:

- Have a CMI value for FY 2017 that is at least—
  - 1.66185 (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 as the number of discharges for its cost reporting period that began during FY 2016 at least—
  - 5,000 (3,000 for an osteopathic hospital), or
  - The median number of discharges for urban hospitals in the census region in which the hospital is located.

CMS notes that the median number of discharges for urban hospitals in each census region is greater than the national standard of 5,000; thus 5,000 discharges would be the minimum criteria for all hospitals (other than for osteopathic hospitals which is set at 3,000 discharges).

The proposed median regional CMIs and median regional numbers of discharges are listed in the proposed rule and will be revised in the final rule to the extent necessary to reflect the updated FY 2017 MedPAR file containing data from additional bills received through March 2018. A hospital seeking to qualify as an RRC should get its hospital-specific CMI value (not transfer-adjusted) from its 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. However, 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 enactments in effect from FYs 2011 to 2017 changed the criteria to 15 miles from another IPPS hospital and fewer than 1,600 Medicare discharges. The statute also required 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 Bipartisan Budget Act 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 reflective of the new discharge criteria. For FY 2023 and subsequent years, the qualifying criteria will revert to those initially established (25 miles from another IPPS hospital and fewer than 800 total discharges (Medicare and non-Medicare)).

To implement section 50204, CMS published a separate notice to address the FY 2018 implementation of the low-volume hospital provision. CMS is using the FY 2019 IPPS proposed rule to implement the low-volume hospital provisions affecting FYs 2019 to 2022. We are describing CMS' implementation of both in this summary.

2. FY 2018

In its notice implementing section 50204 for FY 2018, CMS indicates that it is using a process similar to those used previously for hospitals to qualify for the low-volume hospital adjustment.

*Discharge Data and Payment Adjustment.* CMS is updating the discharge data source used to identify qualifying low-volume hospitals and calculate the payment adjustment for FY 2018. For FYs 2011 through 2017, a hospital's Medicare discharges from the most recently available MedPAR data, as determined by CMS, were used to determine if the hospital met the discharge criterion to receive the low-volume payment adjustment for a year.

For FY 2018, qualifying low-volume hospitals and the payment adjustment will be determined using Medicare discharge data from the March 2017 update of the FY 2016 MedPAR file, as these data were the most recent data available at the time of the development of the FY 2018 payment rates and factors established in the FY 2018 IPPS/ LTCH PPS final rule. Table 1 lists

IPPS hospitals with fewer than 1,600 Medicare discharges from the March 2017 update of the FY 2016 MedPAR files and their FY 2018 low-volume payment adjustment (if eligible).

Table 1 can only be found 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?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending. In the downloads section on this page, click on "CMS-1677-N Table 1.

Note: The link in CMS' Federal Register notice takes you to a different web page that does not include Table 1 although does include the sub-links where Table 1 is located. Table 1 only shows whether the hospital meets the discharge criterion, not the distance criterion.

*Distance Criterion.* Eligibility for the low-volume hospital payment adjustment for FY 2018 is also dependent upon meeting (in the case of a hospital that did not qualify for the low-volume hospital payment adjustment in FY 2017) or continuing to meet (in the case of a hospital that did qualify for the low-volume hospital payment adjustment in FY 2017) being located more than 15 road miles from any other IPPS hospital.

**In order to receive a low-volume hospital payment adjustment for FY 2018 retroactive to October 1, 2017, a hospital must notify and provide documentation to its MAC that it meets the mileage criterion by not later than May 29, 2018.** For hospitals that met the low-volume hospital criteria in FY 2017, the written verification could be a brief letter to the MAC stating that the hospital continues to meet the low-volume hospital distance criterion as documented in a prior low-volume hospital status request. For hospitals that newly qualify for the low-volume adjustment, the written request must include documentation that the distance criteria have been met. The use of a Web-based mapping tool is acceptable documentation.

The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance (in road miles, as defined in the regulations at 42 CFR §412.101(a)) from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. The MAC may follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the low-volume mileage criterion. In addition, the MAC will refer to the hospital's Medicare discharge data (Table 1) to determine whether or not the hospital meets the discharge criterion, and the amount of the FY 2018 payment adjustment, once it is determined that the mileage criterion has been met.

For written requests or written verification for low-volume hospital status for FY 2018 received after May 29, 2018, if the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital adjustment in determining payments for the hospital's FY 2018 discharges prospectively effective within 30 days of the date of the MAC's low-volume hospital status determination.

CMS intends to make conforming changes to the regulation text at 42 CFR §412.101 to reflect the amendments made by section 50204 of the Bipartisan Budget Act of 2018.

3. FY 2019 – FY 2022

*Distance Criterion*. As previously indicated, section 50204 of the Bipartisan Budget Act of 2018 specified that, for FYs 2019 through 2022, a hospital can qualify for the low-volume adjustment by being more than 15 road miles from another IPPS hospital. The term "road miles" means "miles" as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414). 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 to determine whether or not the hospital meets the applicable mileage criterion.

**In accordance with previously established process, 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 the federal fiscal year that begins one month later on October 1, 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.

Under this process, 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 criterion (which remains unchanged for FY 2019) and it also meets the applicable discharge criterion as modified for FY 2019 (3,800 or fewer total discharges). In this case, a 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 (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) in order to receive the payment adjustment in that fiscal year. Low-volume hospital status is not based on a "one-time" qualification.

*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 during each of the fiscal years. For FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under 42 CFR §412.101(b)(2)(i) and proposed new 42 CFR §412.101(b)(2)(iii), the most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. CMS uses cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data was used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital should refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare)

in order to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

*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 an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. The term "discharge" for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

To implement this requirement, CMS is proposing a 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 is proposing that qualifying hospitals with 500 or fewer total discharges would receive a low-volume hospital payment adjustment of 25 percent applied to each Medicare discharge. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment would be calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. That proportion is calculated by multiplying the discharges in excess of 500 by a fraction that is equal to the maximum available add-on payment (25 percent) divided by a number represented by the range of discharges for which this policy applies (3,800 minus 500, or 3,300). The following formula depicts the calculation:

> Low-Volume Hospital Payment Adjustment = 0.25 – [0.25/3300] x (number of total discharges - 500) = (95/330) x (number of total discharges/13,200).

To reflect these changes for FYs 2019 through 2022, CMS is proposing to revise §412.101(b)(2) by adding paragraph (iii) to specify that a hospital must have fewer than 3,800 total discharges, which includes Medicare and non-Medicare discharges, during the fiscal year, based on its most recently submitted cost report, and be located more than 15 road miles from the nearest IPPS hospital.

CMS is proposing to add paragraph (3) to §412.101(c) to specify that:

- For low-volume hospitals with 500 or fewer total discharges during the fiscal year, the low-volume hospital payment adjustment is an additional 25 percent for each Medicare discharge.
- For low-volume hospitals with total discharges during the fiscal year of more than 500 and fewer than 3,800, the adjustment for each Medicare discharge is an additional percent calculated using the formula [(95/330) - (number of total discharges/13,200)].

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

| Fiscal Year | Distance Criteria | Discharge Criteria | Payment Methodology |
|---|---|---|---|

| | | | |
|---|---|---|---|
| 2005 - 2010 | 25 miles | 200 Total Discharges[17] | 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[18], for discharges occurring in FY 2019, CMS would 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. CMS is also making a technical change to 42 CFR §412.105(f)(1)(vii) that relates to an adjustment to a hospital's full-time equivalent cap for a new medical residency program. Rather than reference §413.79(e)(1) through (e)(4), §412.105(f)(1)(vii) will now just reference §413.79(e) to be inclusive of paragraph (5) of §413.79(e). The change corrects an error and is not intended to change the underlying regulation.

## F. Disproportionate Share and Uncompensated Care

1. General Discussion

This section of the proposed rule describes the additional Medicare payments to IPPS hospitals that serve a significantly disproportionate number of low-income patients under section 1886(d)(5)(F) of the Act. CMS notes that references to "days" in the DSH formula apply only to hospital acute care inpatient days.

2 & 3. Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

Section 3133 of the ACA added a new section 1886(r) to the Act changing the methodology for computing the Medicare DSH payment adjustment. Beginning with FY 2014 discharges, hospitals that qualify for Medicare DSH payments receive two separately calculated payments. The first payment equals 25 percent of the amount they would have received under the statutory formula for Medicare DSH payments prior to the ACA amendments. CMS refers to this payment as the "empirically justified Medicare DSH payment."

The second payment is equal to the Secretary's estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments and reduced to reflect changes in the percentage of

[17] While the Medicare statute established that a hospital would qualify 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.
[18] 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.

individuals who are uninsured. This is used to make additional payments to each hospital that qualifies for "empirically justified Medicare DSH payments". As the statute requires these payments to be distributed to hospitals based on each hospital's share of national uncompensated care costs, these additional payments are referred to as "uncompensated care payments." The statute precludes administrative or judicial review of the Secretary's estimates of the factors used to determine these payments or the data period used to distribute them.

Eligibility for empirically justified Medicare DSH payments is unchanged by the ACA provision. Also, the new DSH policies established by the ACA only affects DSH payment under the operating IPPS. The ACA does not revise or replace the capital IPPS DSH payment under the regulations at 42 CFR Part 412, Subpart M.

For FY 2019, CMS proposes to continue the following policies unchanged from the FY 2018 final rule.

The ACA DSH provisions would apply to:

- hospitals in Puerto Rico;
- sole community hospitals if they are paid based on the federal rate and not the hospital-specific rate;
- IPPS hospitals that elect to participate in the BPCI Advanced model starting October 1, 2018; and
- IPPS hospitals participating in the CJR model.

The ACA DSH provisions would not apply to:

- sole community hospitals paid based on the hospital-specific rate (because add-on payments, such as outliers, DSH, and IME, do not apply to these hospitals);
- hospitals participating in the Rural Community Hospital Demonstration (because these hospitals also do not receive DSH payments); or
- hospitals in Maryland, which are not paid under Section 1886(d) of the Act because the state entered into an agreement with CMS that Maryland hospitals will be paid under the Maryland All-Payer Model.

MDHs paid under the IPPS federal rate are eligible to receive Medicare DSH payments if their disproportionate patient percentage is at least 15 percent. CMS applies the same process to determine eligibility for Medicare DSH and the uncompensated care payment as it does for all other IPPS hospitals. MDHs are paid based on the IPPS Federal rate or, if the hospital's hospital-specific rate is higher than the IPPS Federal Rate, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate. Section 50205 of the Bipartisan Budget Act of 2018 (enacted on February 9, 2018) extended the MDH program for discharges on or after October 1, 2017 through September 30, 2022.

CMS makes interim DSH payments equal to 25 percent of what the DSH payment would have been absent the ACA changes. Final eligibility for Medicare DSH payments and the final amount

of the payments for eligible hospitals is determined at cost report settlement, as occurred prior to the ACA changes.

4. Uncompensated Care Payments

In the sections below, the data sources and methodologies for computing each of these factors and CMS' proposed policies for FY 2019 is discussed.

The statute provides that the uncompensated care portion of the DSH payment amount for each DSH hospital is the product of three factors:

- equals 75 percent of the aggregate DSH payments that would be made under section 1886(d)(5)(F) without application of the DSH changes made by the ACA;
- Factor 2 reduces the amount based on the ratio of the percentage of the population who are insured in the most recent period following implementation of the ACA to the percentage of the population who were insured in a base year prior to ACA implementation; and
- Factor 3 is determined by a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in that fiscal year, expressed as a percentage.

a. Proposed FY 2019 Factor 1

Factor 1 is the difference between CMS' estimates of: (1) the amount that would have been paid in Medicare DSH payments for FY 2019 in the absence of the ACA payment provision and (2) the amount of empirically justified Medicare DSH payments that are estimated to be made for FY 2019 taking into account the requirement to reduce Medicare DSH payments by 75 percent.

Prior to each fiscal year, CMS develops final estimates of both the aggregate amount of Medicare DSH payments that would be made in the absence of section 1886(r)(1) and the aggregate amount of empirically justified Medicare DSH payments to hospitals under section 1886(r)(1). These amounts are estimated based on the most recent data available and are not adjusted based on actual data.

CMS uses the most recently available projections of Medicare DSH payments for a year, as calculated by CMS' Office of the Actuary (OACT), to determine Factor 1. CMS used the OACT's December 2017 Medicare DSH estimates, which were based on the December 2017 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.

The December 2017 OACT estimate for Medicare DSH payments for FY 2019, before application of the ACA reduction, is $16.295 billion. Based on this, the estimate for empirically justified Medicare DSH payments for FY 2019 after the ACA reduction is proposed to be about $4.074 billion (25 percent of the total amount estimated). Thus, **CMS proposes that FY 2019 Factor 1, which is the difference between these two estimates, would be about $12.221 billion ($16.295**

**billion minus $4.074 billion).** The proposed Factor 1 for 2019 is about $556 million more than the final Factor 1 for FY 2018.

OACT's estimates for FY 2019 began with a baseline of $13.232 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 | Total | Estimated DSH Payment (in billions) |
|---|---|---|---|---|---|---|
| 2016 | 1.009 | 0.9864 | 1.031 | 1.046 | 1.073333 | $14.202 |
| 2017 | 1.0015 | 0.9925 | 1.004 | 1.0657 | 1.063531 | $15.105 |
| 2018 | 1.018088 | 0.9921 | 1.005 | 1.02745 | 1.04296 | $15.754 |
| 2019 | 1.0175 | 1.011 | 1.005 | 1.0005 | 1.034353 | $16.295 |

- The discharge factor represents the increase in the number of Medicare FFS inpatient hospital discharges (based on Medicare claims data adjusted by a completion factor).
- The case-mix column shows the increase in case-mix for IPPS hospitals.
- 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.

Finally, 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 | 2.8 | -0.75 | -0.8 | 0.5 | 1.75 |

b. Proposed FY 2019 Factor 2

Factor 2 is based on the percent change in the uninsured, since implementation of the ACA.

For FYs 2014 through 2017, the statute required Factor 2 to equal the percent change in the number of individuals under the age of 65 who are uninsured from 2013 until the most recent period for which data are available minus 0.1 percentage points for fiscal year 2014 and minus 0.2 percentage points for each of fiscal years 2015, 2016, and 2017. 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. At the time, CBO estimated that 18 percent of the under 65 population would be uninsured in FY 2013. CMS consistently used CBO estimates of the rate of uninsured in the under 65 population for the most recent year estimate. For FY 2017, CBO estimated 10 percent of the under 65 population is uninsured.

For FY 2018 and subsequent years, the statute requires Factor 2 to equal the percent change in the number of individuals under the age of 65 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. The statute provides greater flexibility in the choice of the data sources to be used in the estimate of the change in the percent of the uninsured for FY 2018 and subsequent years. This data source can be based on data from the Census Bureau or other sources the Secretary determines appropriate and certified by the Chief Actuary of CMS. In 2018, CMS finalized its proposal to use uninsured estimates from the National Health Expenditure Accounts (NHEA) in place of CBO data as the source of change in the uninsured population used in Factor 2.[19] CMS chose this data source for a variety of factors including that the data are available on an annual basis, from a reliable source (based on data from the Census Bureau), and best account for the full U.S. population as well as public and private insurance coverage.

As in past years, CMS proposes to continue to apply the weighted average approach used in fiscal years in order to estimate the rate of uninsurance for FY 2019 (to ensure that the estimated rate of uninsurance that hospitals experienced reflects their experience during the fiscal years instead of only one of the calendar years that the fiscal year spans).

For FY 2019, CMS proposes to use NHEA data and 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 the proposed Factor 2 for FY 2019 as follows:

- 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)

[19]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

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.

Thus, **CMS calculated Factor 2 for the FY 2019 proposed rule to be 0.6751, or 67.51 percent, and the proposed uncompensated care amount for FY 2019 to be $12.221 billion "times" 0.6751 = $8.250 billion**, which is about $1.5 billion more than the FY 2018 uncompensated care payment total of about $6.767 billion; the percentage increase is 21.9 percent.[20]

c. Proposed FY 2019 Factor 3

(1) Background & (2) Methodology Used to Calculate Factor 3 in Prior Fiscal Years
Factor 3 equals the proportion of hospitals' aggregate uncompensated care attributable to each IPPS hospital (including Puerto Rico hospitals). The product of Factors 1 and 2 determines the total pool available for uncompensated care payments. This result multiplied by Factor 3 determines the amount of the uncompensated care payment that each eligible hospital will receive.

For Factor 3, the statute requires the Secretary to determine: (1) the definition of uncompensated care; (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the amount for each hospital estimated to receive DSH payments. 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 for treating the uninsured.

In FYs 2014-2017, CMS determined Factor 3 based on the utilization of insured low-income patients defined as inpatient days of Medicaid patients plus inpatient days of Medicare SSI patients as defined in 42 CFR 412.106(b)(4) and 412.106(b)(2)(i), respectively. In these years, CMS believed that it was premature to propose the use of Worksheet S-10 data for purposes of determining Factor 3 because of concerns regarding variations in the data reported on the Worksheet S-10 and the completeness of these data. In addition, CMS notes its rationale that hospitals were also not on notice that Worksheet S-10 would be used for purposes of computing uncompensated care payments prior to FY 2014.

CMS stated in the FY 2017 IPPS/LTCH PPS proposed rule that many of these concerns in 2018 would no longer be relevant as hospitals were "on notice" as of FY 2014 that Worksheet S-10 could eventually become the data source for CMS to calculate uncompensated care payments. MedPAC has also commented (as part of the 2016 final rule) that based on its analysis the Worksheet S-10 data was already better than using Medicare SSI and Medicaid days as a proxy for uncompensated care costs. In addition, CMS noted that it also had 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. The purpose of this analysis was to determine the extent to which the uncompensated care costs reported from these data sources were correlated, their stability over time, and level of

[20] For FY 2018, CMS determined Factor 2 to be 0.5801 and the amount available for uncompensated care payments for FY 2018 is approximately $6.767 billion.

convergence.[21] Key findings indicate that the amounts for Factor 3 derived using the IRS Form 990 and Worksheet S-10 data are highly correlated – the correlation coefficient has increased over time, from 0.71 in 2010 to 0.80 in 2012, suggesting some convergence in the data sources over time. CMS believed that this strong correlation indicates that Worksheet S-10 data would be a statistically valid source to use as part of the calculation of the uncompensated care payments in FY 2018.

In 2017, CMS proposed a methodology and timeline for incorporating Worksheet S-10 data in the calculation of Factor 3 beginning in FY 2018 and invited public comments on the proposal. After consideration of comments on the FY 2017 IPPS proposed rule, however, CMS decided not to finalize its proposal to begin incorporating Worksheet S-10 data into the calculation of Factor 3.

In 2018, CMS stated its belief that a "tipping point" has been reached with respect to the use of Worksheet S-10 data and it could no longer conclude that alternative data available for FY 2014 would be a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured than the data on uncompensated care costs reported on the Worksheet S-10. CMS updated its analysis comparing the correlation in Factor 3s derived from using Worksheet S-10 and IRS Form 990 data using more recent data and found that this correlation continues to increase over time from 0.80 in 2011 to 0.85 in 2013.[22] Moreover, CMS was encouraged by the fact that approximately one-quarter of hospitals that receive uncompensated care payments took advantage of the opportunity to submit amended FY 2014 cost reports containing revised or completed Worksheet S-10.

In the FY 2018 IPPS/LTCH PPS final rule, CMS finalized an approach to incorporate Worksheet S-10 data from FY 2014 into the calculation of Factor 3 of the uncompensated care payment for FY 2018. CMS continued to believe that for cost reporting periods prior to FY 2014, it would be appropriate to use low-income insured days as a proxy. Thus, for the time period consisting of three cost reporting years, FY 2012-FY 2014, CMS used Worksheet S-10 data for the FY 2014 cost reporting period and low-income insured days proxy data for the two earlier cost reporting periods. In addition, CMS finalized the following policies:

- Aberrant Data. Uncompensated care costs in excess of 50 percent of a hospital's total operating expenses will be considered aberrant. If the hospital's FY 2014 uncompensated costs exceed 50 percent of its total operating expenses, CMS applied the ratio of the hospital's uncompensated care costs to total operating expenses in FY 2015 to its FY 2014 total operating expenses to determine the hospital's FY 2014 uncompensated care costs. Three hospitals were affected by this adjustment using FY 2014 cost report data.
- S-10 Data Exclusions Due to concerns about the quality of uncompensated care data reported by Puerto Rico hospitals and Indian Health Service and Tribal hospitals, CMS concluded that

[21] This analysis was performed by Dobson DaVanzo & Associates, LLC, under contract to CMS.

[22]Dobson DaVanzo & Associates, LLC, under contract to CMS, updated their report. The report is entitled Improvements to Medicare Disproportionate Share Hospital (DSH) Payments Benchmarking S-10 Data Using IRS Form 990 Data: An Update. The report is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2018-NPRM-Update-of-Benchmarking-S-10-Data.pdf

S-10 data should not be used to determine Factor 3. Likewise, CMS also determined that S-10 data should not be used for All-Inclusive Rate Providers, whose CCRs were determined to be potentially erroneous. Thus, CMS finalized that the best proxy for the costs of Puerto Rico, Indian Health Service and Tribal hospitals, and All-Inclusive Rate Providers for treating the uninsured is the low-income insured data for FY 2012 and FY 2013.

- Proxy for SSI days. In 2017 and 2018, CMS continued to use a proxy for SSI days consisting of 14 percent of a hospital's Medicaid days.

(3) Proposed Methodology for Calculating Factor 3 for FY 2019

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

CMS made additional changes to certain definitions and instructions for data reported on Worksheet S-10. On September 29, 2017, CMS issued Transmittal 11, which, among other things, clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, nonreimbursed Medicare bad debt, and charity care.[23] 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 (referred to as Financial Assistance Policy or FAP) 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.[24]

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. These were to be submitted to the MAC no later than January 2, 2018. CMS incorporated these updated data into the proposed rule. CMS analyzed these data to determine if the Worksheet S-10 data changed on these cost reports as a result of the opportunity for revisions. CMS found that Worksheet data for both FY 2014 and 2015 had changed 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.

Time Period and Data Source

CMS proposed to advance the time period of the data used in the calculation of Factor 3 forward by 1 year to use data from FYs 2013-2015 cost reports to determine Factor 3 for FY 2019. It would continue to use the methodology finalized in FY 2017 and to compute Factor 3 using an average of data from three cost reporting periods instead of one cost reporting period. CMS would use Worksheet S-10 data for FYs 2014 and 2015 cost reporting periods and the low-income insured days for the FY 2013 cost reporting period. CMS continues to believe it would not be appropriate to use Worksheet S-10 data for periods prior to FY 2014. Specifically, for FY 2019, in addition to

[23] Transmittal 11 is available for download on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf

[24] Specifically, the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and nonreimbursed 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.

the Worksheet S-10 data for FY 2014 and FY 2015, CMS proposes to use Medicaid days from FY 2013 cost reports and FY 2016 SSI ratios. By 2020, the calculation of Factor 3 would be solely determined by data from Worksheet S-10 if CMS decided to continue this approach. For purposes of the proposed rule, CMS used the most recent available HCRIS extract (updated through February 15, 2018) and expects to be able to use the March 2018 update of the HCRIS file for the final rule.

Definition of Uncompensated Care

With respect to the definition of "uncompensated care", CMS again proposes that "uncompensated care" would be defined as the amount on line 30 of Worksheet S-10, which is the cost of charity care (line 23) and the cost of non-Medicare bad debt and nonreimbursable Medicare bad debt (line 29). CMS notes that a common theme of almost all the definitions that it explored is that they include both "charity care" and "bad debt".

Technical Considerations in Calculation of Factor 3

With respect to technical considerations related to the calculation of Factor 3, CMS proposes to annualize Medicaid days data and uncompensated care cost data reported on the Worksheet S-10 if a hospital's cost report does not equal 12 months of data. As in FY 2018, CMS proposes to not annualize SSI days because CMS does not obtain these data from hospital cost reports in HCRIS rather from the latest posted SSI ratios (which are aggregated at the hospital level and do not include information necessary to annualize). Moreover, CMS proposes to continue to apply a scaling factor to the Factor 3 values of all DSH eligible hospitals such that the total uncompensated care payments are consistent with the available amounts for the applicable fiscal year.

CMS proposes, however, to discontinue its policy finalized in the 2017 IPPS/LTCH PPS final rule concerning multiple cost reports beginning in the same fiscal year. Instead, CMS would determine if annualization was needed by combining the data across the multiple cost repots before determining the difference between the start and end date. Based on its experience, CMS proposes to use data from a cost report that is equivalent to 12 months or if no such cost report exists, the cost report that is closest to 12 months and annualize the data. In rare instances where a hospital has no cost report beginning in a fiscal year, CMS proposes to use data from the cost report that spans both fiscal years in the Factor 3 calculation (a hospital, for example, may have had a cost reporting period begin at the end of FY 2012 and cover the duration of FY 2013).

CMS proposes to continue to apply statistical trims to anomalous hospital CCRs using the methodology adopted in FY 2018. Under this policy, CMS would assign 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.

Similar to the FY 2018 process, CMS proposes the following steps for trimming CCRs in FY 2019.

| Methodology for Trimming CCRs | |
|---|---|
| Step 1 | Remove Maryland hospitals. In addition, CMS would remove all-inclusive rate providers, and providers that did not report a CCR on Worksheet S-10, Line 1, and assign them the statewide average CCR in step 5 below. |
| Step 2 | For each fiscal year (2014 and 2015), CMS would calculate a CCR ceiling by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year.<br><br>Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR. Based on the information currently available to CMS, this trim would remove 5 hospitals that have a CCR above the calculated ceiling of 1.031 for FY 2014 and 9 hospitals that have a CCR above the calculated ceiling for 0.93 for FY 2015. |
| Step 3 | Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for FY 2014 and FY 2015 for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total inpatient discharges and outpatient visits from Worksheet S-3, Part I, Line 14, Column 14. |
| Step 4 | Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR "ceiling"). The statewide average CCR would therefore be applied to 14 hospitals. |

Aberrant Data

CMS notes that it has instructed the MACs to review situations where a hospital has an extremely high ratio of uncompensated care costs to total operating costs. For program integrity reasons, CMS states that it does not intend to make the MAC's review protocols public. In situations where a hospital cannot justify its reported uncompensated care amount, CMS believes it would be appropriate to utilize data from another fiscal year to address the potentially aberrant Worksheet S-10 data for FY 2014 or FY 2015.

CMS proposes in cases where a hospital's uncompensated care costs for FY 2014 are an extremely high ratio of its total operating costs and the hospital cannot justify the amount, CMS would use the ratio of uncompensated care costs to total operating expenses calculated from the 2015 cost report and apply that ratio to the hospital's FY 2014 cost report to determine an adjusted amount for Factor 3 for FY 2019. Similarly, CMS proposes to use 2016 cost report data to determine an adjusted amount of uncompensated care costs for FY 2015 in such situations. CMS notes that it has tentatively included the data for hospitals that have a high ratio of uncompensated care costs to total operating expenses when calculating Factor 3 for the proposed rule, but that its calculation for the final rule will be contingent on the results of the ongoing MAC reviews of these hospitals.

CMS also notes other situations that may reflect aberrant data and warrant further review. This includes situations where there were extremely large increases or decreases in a hospital's uncompensated care costs when it resubmitted its FY 2014 Worksheet S-10 or FY 2015 Worksheet S-10 data, or when the data it had previously submitted were reprocessed by the MAC. CMS strongly hints (even though it doesn't make its protocols public) that it might be appropriate to review hospitals with increases or decreases in uncompensated care costs in the

top 1 percent of such changes. In such situations where the increase or decrease cannot be justified by the hospital, CMS proposes to use the same approach as discussed above. Specifically, CMS proposes to determine the ratio of the uncompensated care costs to total operating expenses from the hospital's cost report for the subsequent fiscal year and apply that ratio to the total operating expenses from the hospital's resubmitted cost report with the large increase or decrease in uncompensated care payments to determine an adjusted amount of uncompensated care costs for the applicable fiscal year. CMS notes that in the event review necessitate supplemental data edits, these would be incorporated in the final rule for purpose of correcting aberrant data.

Indian Health Service and Tribal Hospitals, Subsection (d) Puerto Rico hospitals, and All-Inclusive Rate Providers

For Indian Health Service and Tribal hospitals, subsection (d) Puerto Rico hospitals, and All-Inclusive Rate Providers, CMS proposes to continue the policy it first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S–10 data when determining Factor 3. CMS believes each of these policies warrants further review and will reexamine as part of its FY 2020 rulemaking.

Steps to Compute Factor 3 for FY 2019

For FY 2019, CMS proposes to compute Factor 3 for each hospital by —

Step 1: Calculating Factor 3 using the low-income insured days proxy based on FY 2013 cost report data and the FY 2016 SSI ratio (or, for Puerto Rico hospitals, 14 percent of the hospital's FY 2013 Medicaid days);

Step 2: Calculating Factor 3 based on the FY 2014 Worksheet S–10 data;

Step 3: Calculating Factor 3 based on the FY 2015 Worksheet S–10 data; and

Step 4: Averaging the Factor 3 values from Steps 1, 2, and 3; that is, adding the Factor 3 values from FY 2013, FY 2014, and FY 2015 for each hospital, and dividing that amount by the number of cost reporting periods with data to compute an average Factor 3 (or for Puerto Rico hospitals, Indian Health Service and Tribal hospitals, and All-Inclusive Rate Providers using the Factor 3 value from Step 1).

CMS explains that 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 also proposes to amend the regulations at §412.106(g)(1)(iii)(C) by adding a new paragraph (5) to reflect this proposed methodology for computing Factor 3 for FY 2019.

Other Issues

With respect to new hospitals that do not have data for any of the three cost reporting periods used in the Factor 3 calculation, CMS proposes to continue to apply the new hospital policy finalized in the FY 2014 IPPS/LTCH PPS final rule that such a hospital would not receive either interim empirically justified Medicare DSH payments or interim uncompensated care payments. If the hospital is later determined to be eligible to receive empirically justified Medicare DSH payments based on its FY 2019 cost report, the hospital would receive an uncompensated care payment using uncompensated care costs reported on Worksheet S-10 of the hospital's FY 2019 cost report.

In the case of hospital mergers, CMS proposes to continue its policies that were finalized in the FY 2015 IPPS/LTCH PPS final rule to address specific issues regarding the process and data to be employed in determining Factor 3. CMS publishes a table on the CMS Web site, in conjunction with the issuance of each fiscal year's proposed and final IPPS rules, containing a list of the mergers known to CMS and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of each year's proposed rule to review the tables and notify CMS in writing of any inaccuracies.[25]

CMS proposes to continue these other policies and procedures in FY 2019 unchanged from the FY 2018 rule.

- Tables published on the CMS website for the FY 2019 proposed rule and forthcoming final rule list Factor 3 levels for all hospitals that CMS projects will receive empirically justified DSH payments in FY 2019 and thus would receive interim uncompensated care payments during the fiscal year. The table also includes Factor 3 levels for the remaining IPPS hospitals that have the potential of receiving a DSH payment in the event that they receive an empirically justified DSH payment for FY 2019 as determined at cost report settlement. Hospitals have 60 days from the date of the proposed rule's public display to review the tables and notify CMS in writing of a change in a hospital's subsection (d) hospital status, such as if a hospital has closed or converted to a CAH. The 60-day period will end June 25th. After the publication of the final rule, hospitals will have until August 31, 2018 to review and submit comments on the accuracy of the tables.[26]

- CMS will continue to make interim uncompensated care payments in FY 2019 on a per-discharge basis. The estimated per-discharge amount, which is fixed for a particular hospital and does not vary by case mix, is based on the amount of the uncompensated care payment that CMS calculates for a 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 not include reconciliation of the values of Factors 1, 2, or 3 established in the final rule. Reconciliation will only include adjustments for changes in

[25] Comments on the list of mergers can be submitted to the CMS inbox at Section3133DSH@cms.hhs.gov.
[26] Comments on the accuracy of the table and supplemental data files can be submitted to the CMS inbox at Section3133DSH@cms.hhs.gov

whether the hospital is actually 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. Similarly, for a hospital that does not receive interim payments for its empirically justified DSH payments and therefore no uncompensated care payments but at cost report settlement is determined to be eligible for DSH payments, the MAC will calculate the uncompensated care payment for the hospital based on the Factor 3 value determined prospectively and published with the final rule.

5. Impact Analysis

The regulatory impact analysis presented in Appendix A of the proposed rule includes a discussion of the estimated effects of the proposed changes to Medicare DSH and uncompensated care payments for FY 2019. CMS' analysis includes 2,485 hospitals that are projected to be eligible for DSH in FY 2019.[27] The impact analysis includes a table of the proposed changes to Factors 1, 2, and 3 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent.

Changes in projected FY 2019 DSH and uncompensated care payments compared to FY 2018 are primarily driven by increases in Factor 1 and Factor 2. Factor 1 increased from $11.665 billion to $12.221 billion, while Factor 2 -- the percent change in percent of individuals who are uninsured – increased from 58.01 percent to 67.51 percent. As a result, the total amount of uncompensated care payments is estimated at $8.250 billion, 21.9 percent increase from FY 2018 uncompensated care payments (about $6.767 billion). Thus, a percent change in DSH payments of less than 21.9 percent indicates that hospitals within that category are projected to experience a smaller increase compared to all hospitals combined, and a percent change of more than 21.9 percent indicates this category of hospitals is doing better than all hospitals combined.

Rural hospitals are projected to receive a larger percentage increase in uncompensated care payments (32.5%) than urban hospitals (21.35%) in FY 2019 compared to FY 2018. Urban hospitals in the Pacific region (California, Oregon, and Washington) are the most negatively affected, with these hospitals projected to receive a 2.3 percent increase. In contrast, urban hospitals in the West South Central region (Arkansas, Louisiana, Oklahoma, and Texas) are projected to receive a 42.28 percent increase. Nonteaching hospitals are projected to receive a larger than average payment increase of 24.9 percent. Government and proprietary hospitals are projected to receive larger than average increases (34.93 percent and 23.98 percent) compared with voluntary hospitals.

## G. Sole Community Hospitals and Medicare Dependent Small Rural Hospitals

1. Implementation of Bipartisan Budget Act of 2018 Provisions on Medicare-Dependent, Small Rural Hospitals (MDHs)

[27] CMS inadvertently included hospitals participating in the Rural Community Hospital Demonstration Program in its current impact analysis but will exclude these in the final rule. There are currently about 30 hospitals participating in this program.

*Background*

To qualify as a Medicare-Dependent, Small Rural Hospital (MDH), a hospital (i) must be located in a rural area; (ii) must not have more than 100 beds; (iii) must not be a sole community hospital; and (iv) must have a "high percentage of Medicare discharges." A high percentage of Medicare discharges means that at least 60 percent of the hospital's inpatient days or discharges must be attributable to inpatients who are entitled to Part A; this is determined using either (i) the cost reporting period beginning in FY 1987 or (ii) two of the three most recently audited cost reporting periods for which settled cost reports are available. CMS counts days and discharges for Medicare Advantage (MA) enrollees toward the 60 percent utilization requirement. 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. The MDH program expired October 1, 2017. Additionally, hospitals in all-urban states (Delaware, Rhode Island and New Jersey) are unable to qualify for MDH status because the states lack rural areas.

*Bipartisan Budget Act of 2018*

Extension. Section 50205 of Bipartisan Budget Act of 2018 extended the MDH program, effective from October 1, 2017 through September 30, 2022 (i.e., through the end of FY 2022). CMS will amend its regulations to reflect this extension.

All-urban states. Additionally, 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 §§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.

*Implementation for Fiscal Year 2018*

CMS includes the instructions for the implementation of the section 50205 amendments in a notice (CMS-1677-N) that will be published in the Federal Register separately from the FY 2019 IPPS/LTCH proposed rule. Generally, a hospital with MDH classification status before September 30, 2017 will have that status reinstated effective October 1, 2017. The hospital does not need to reapply for MDH classification. However, CMS notes that in two situations, the effective date of MDH status may not be retroactive to October 1, 2017:

- MDHs that classified as sole community hospitals (SCHs) on or after October 1, 2017; and
- MDHs that requested a cancellation of their rural classification under §412.103(b).

1. MDHs that Classified as SCHs on or after October 1, 2017. The Act does not allow a hospital to be both an SCH and an MDH. Therefore, in anticipation of the September 30, 2017 expiration of the MDH program, CMS allowed MDHs that applied for reclassification as SCHs by August 31, 2017 to have such status become effective on October 1, 2017. MDHs that applied after the August 31, 2017 deadline were subject to the usual effective date for SCH classification – that is, 30 days after the date of CMS' written notification of approval. To be reclassified as an MDH, these hospitals must first cancel their SCH status and then reapply and be approved for MDH status.

2. MDHs that Requested a Cancellation of Their Rural Classification Under §412.103(b). A hospital must be classified as a rural hospital to be considered for MDH status. To qualify for MDH status, some MDHs reclassified from an urban to a rural hospital designation under the regulations at §412.103(b). With the September 30, 2017 expiration of the MDH provision, some of these providers may have requested a cancellation of their rural classification. To qualify for MDH status, these hospitals must again request to be reclassified as rural and must also reapply for MDH status.

A provider that falls within either of the two situations described above may not have its MDH status automatically reinstated effective October 1, 2017. Thus, if a provider reclassified to SCH status or cancelled its rural status effective October 1, 2017, its MDH status will be applied prospectively based on the date the hospital is notified that it again meets the requirements for MDH status, after the hospital reapplies for MDH status. However, if a provider reclassified to SCH status or cancelled its rural status effective on a date later than October 1, 2017, MDH status will be reinstated effective from October 1, 2017 but will end on the date on which the provider changed its status to an SCH or cancelled its rural status. These hospitals also may reapply for MDH status to be effective again 30 days from the date the hospital is notified of the determination of qualifying again for MDH status.

To reapply, the hospital must submit a written request along with qualifying documentation to its MAC. The MAC will make its determination and notify the hospital within 90 days from the date of receipt of the request for MDH classification and accompanying documentation; MDH status would be effective 30 days after the date of the MAC's written notification to the hospital. The notice includes several examples of how MDH status may be determined for hospitals that were MDHs when the program expired. CMS also reminds readers that MDHs are required to

report to their MACs changes in circumstances that relate to their status as MDHs and that MACs are required to monitor whether a hospital continues to qualify for MDH status.

2. Proposal Regarding Change to 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 CMS' written notification of approval. The regulations do not set a deadline for CMS' Regional Offices to approve an application for SCH status. The effective date for urban to rural reclassification under section 1886(d)(8)(E) of the Act and 42 CFR §412.103 is the date on which CMS receives the reclassification application (i.e., the filing date). An urban hospital may reclassify as rural under §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 proposes to revise the effective date for SCH classification status (and for the associated payment adjustment) to the date CMS 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. This would include rural reclassification for geographically urban hospitals. CMS would also make the effective date change for hospitals not reclassifying as rural under §412.103 (e.g., for geographically rural hospitals seeking SCH status).

CMS proposes parallel changes for the effective date of MDH status determinations. Thus, for applications received on or after October 1, 2018, a determination of MDH status would be effective as of the date CMS receives the complete application in lieu of the current policy of 30 days after the MAC provides written notification to the hospital. CMS notes that a hospital in an all-urban state applying for MDH status must submit its application for a determination that it meets the MDH criteria no later than its MDH application for the application to be considered complete.

## H. Hospital Readmissions Reduction Program:

1. Background

The Hospital Readmissions Reduction Program 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,[28] 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 proposes to retain 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 would be collected for FYs 19, 20 and 21 are proposed, and certain definitions pertaining to the dual-eligible stratification would be codified in the regulatory text. The proposed 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 proposes (as summarized in section VIII.A below) to remove the readmission measures from the IQR Program so as not to duplicate measures with the HRRP.

*Applicable Periods for FYs 2019, 2020 and 2021.* CMS proposes 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) would be based on claims data from the 3-year periods shown in the following table. The FY 2018 period is also shown in the table for reference. The applicable March update to the MedPAR file would be used. For example, for FY 2019, CMS would 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 |
| ***Proposed:*** | |
| FY 2019 | July 1, 2014-June 30, 2017 |

[28] 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.

| | |
|---|---|
| FY 2020 | July 1, 2015-June 30, 2018 |
| FY 2021 | July 1, 2016-June 30, 2019 |

*Codification of Definitions*. CMS proposes to codify 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 proposed to the previously finalized dual-eligible peer group methodology that begins in FY 2019. As adopted in the 2018 IPPS/LTCH final rule, a beneficiary 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)[29] 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)[30] that is the same across all hospitals and all conditions.

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

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

[29] 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.

[30] 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.

Quality Forum (NQF)[31] on its 2-year trial period of risk adjustment for social risk factors, and notes that NQF has launched a follow-up 3-year initiative[32] 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.

5. Impact Analysis

CMS estimates that 2,610 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 proposed rule shows the distribution of HRRP penalties as a percent of payments by type of hospital. The 2,610 hospitals expected to be penalized represent 85 percent of the 3,064 hospitals that could potentially be penalized. Across all hospitals, penalties are shown to represent 0.7 percent of FY 2016 base operating DRG payments. The proportion of hospitals that are penalized ranges from 71 percent of hospitals with fewer than 50 beds (aggregate penalty of 0.6 percent) to 96 percent of hospitals with 100 or more medical residents (aggregate penalty of 0.5 percent). The estimates were calculated using data from the FY 2018 HRRP applicable period (July 1, 2013 – June 30, 2016).

## I. Hospital Value-Based Purchasing Program:

Substantial changes are proposed to the Hospital Value-Based Purchasing (VBP) Program, including changes to the criteria for removal of measures, removal of 10 measures and one domain, and reweighting of the remaining domains. Performance standards for FYs 21-24 are also proposed.

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

[31] 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
[32] See http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=86357.

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.)

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 December 2017 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 16 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 reflect the most recently available performance scores that hospitals have been given the opportunity to review and correct. This table will be updated as Table 16A in the final rule to reflect changes based on 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 proposes to modify the regulatory text to provide that although a measure must be selected for the Hospital VBP Program from the Hospital Inpatient Quality Reporting (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, proposed changes to the Hospital IQR Program are discussed, including removal of measures that are proposed to continue in the Hospital VBP Program.)

CMS also proposes to adopt for the Hospital VBP Program the list of seven factors used for considering removal of measures from the Hospital IQR Program and to add 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; 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 proposed eighth removal factor would be that the costs associated with a measure outweigh the benefit of its continued use in the program. CMS notes that there are different types of costs associated with measures. These include the direct cost of information collection and submission of quality measures to CMS; the provider and clinician cost associated with complying with quality program requirements; the provider and clinical cost associated with participating in multiple quality programs and tracking similar or duplicative measures across programs; the CMS cost associated with program oversight of the measure; and the provider/clinician cost associated with compliance with other federal or state regulations (if applicable). CMS 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.

CMS also proposes that, if it believes a measure in the Hospital VBP Program poses "specific patient safety concerns" it could 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, such as use of the QualityNet website. Removal would be confirmed in the next IPPS rulemaking. Other measure removals that do not involve specific patient safety concerns would continue to be proposed through the rulemaking process.

3. Proposed Removal of Ten Hospital VBP Program Measures

Elsewhere in the proposed rule, CMS discusses the Meaningful Measures Initiative[33], 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 part 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 proposed 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

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

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

Specifically, CMS believes that the Hospital VBP Program should focus on measurement priorities that are not covered by the HRRP or the HAC Reduction Program. This includes measures related to clinical outcomes, patient and caregiver experience, and healthcare costs.

Consistent with that approach, ten measures are proposed for removal from the Hospital VBP Program. The table below shows the measures proposed for removal, the effective dates, the removal factor justifying the proposal, and whether the measure is proposed for retention in another Medicare hospital quality reporting or pay-for-performance program. All ten measures would be retained in either the HAC Reduction Program or the IQR Program and would continue to be reported on *Hospital Compare*. CMS notes that if the proposal to create an eighth removal factor based on whether the costs associated with a measure outweigh the benefit of its continued use in the program is not finalized, none of the measures proposed for removal based on that factor would be removed in the final rule.

| Measure (NQF #) | Proposed removal begins | Proposed end of data collection | Removal factor | Retained in another program? |
|---|---|---|---|---|
| Elective Delivery (0469) | FY 21 | 12/31/18 | 8- costs | IQR |
| NHSN CAUTI (0138) | FY 21 | 12/31/18 | 8- costs | HAC |
| NHSN CLASBI (0139) | FY 21 | 12/31/18 | 8- costs | HAC |
| NHSN MRSA (0716) | FY 21 | 12/31/18 | 8- costs | *HAC |
| NHSN CDI (1717) | FY 21 | 12/31/18 | 8- costs | HAC |
| Colon/Abdominal Hysterectomy Surgical Site Infection (0753) | FY 21 | 12/31/18 | 8- costs | HAC |
| Patient safety composite (0531) | FY 23* | n/a | 8- costs | HAC |
| 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 |

*This measure is currently scheduled to be added to the VBP Program in FY 23. Technically, removal would be effective with the FY 2019 IPPS/LTCH final rule. A previous version of this measure, AHRQ PSI 90 was removed from the VBP Program effective with FY 2019.

** These measures have been finalized for the VBP but not yet implemented; the removal date reflects when they are scheduled to be added to the program. Technically, CMS proposes their removal to be effective with promulgation of the FY 2019 IPPS/LTCH final rule.

With respect to the elective delivery measure, CMS says that performance on this measure has been such 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. However, it offers the newly proposed cost factor 8 as the reason for removal, citing the costs of duplication with the IQR Program, where the measure is proposed for retention.

The six patient safety measures, including five measures reported through the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) are proposed for removal because these measures are also used in the HAC Reduction Program and will continue to be reported on *Hospital Compare*. The three payment episode measures, all of which were previously finalized for future adoption in the Hospital VBP Program and have not yet been implemented, would 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 would be retained as an efficiency measure in the Hospital VBP Program. (Section VIII.A of this summary discusses CMS' proposal to remove the MSPB measure from the IQR Program to avoid duplication with the Hospital VBP Program.)

Under the proposed rule, the total number of VBP Program measures for FY 2021 would be reduced from 15 to 7 measures. Beginning in 2022 there would be eight measures, as the COP mortality measure is scheduled for addition to the VBP Program in FY 2022.

| **Summary Table VBP-1: Measures and Domains for selected payment years** | | | | | | |
|---|---|---|---|---|---|---|
| **Measure** | | **2018** | **2019/ 2020** | **2021** | **2022** | **2023** |
| **Clinical Care – *Proposed to be 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 *Proposed for removal* |
| Central Line Associated Blood Stream Infection (CLABSI) | | X | X | *Proposed for removal* | | |
| Catheter Associated Urinary Tract Infection (CAUTI) | | X | X | *Proposed for removal* | | |
| Surgical Site Infection:<br>Colon<br>Abdominal hysterectomy | | X | X | *Proposed for removal* | | |
| Methicillin-Resistant Staphylococcus Aureus (MRSA) Bacteremia | | X | X | *Proposed for removal* | | |

| **Summary Table VBP-1: Measures and Domains for selected payment years** | | | | | | |
|---|---|---|---|---|---|---|
| **Measure** | | **2018** | **2019/ 2020** | **2021** | **2022** | **2023** |
| Clostridium Difficile infection (CDI) | | X | X | *Proposed for removal* | | |
| Perinatal Care: elective delivery < 39 completed weeks gestation (moved from Clinical Care – Process) | | X | X | *Proposed for removal* | | |
| **Patient and Caregiver Centered Experience of Care/Care Coordination** ***(Person and Community Engagement)*** | | | | | | |
| **Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)** | | | | | | |
| **8 Dimensions:**<br>• Communication with Nurses<br>• Communication with Doctors<br>• Responsiveness of Hospital Staff<br>• Pain Management (before 2018)*<br>• Communication About Medicines<br>• Cleanliness and Quietness of Hospital Environment<br>• Discharge Information<br>• Overall Rating of Hospital<br>• 3-Item Care Transition measure (beginning 2018) | | X | X | X | X | X |
| **Efficiency and Cost Reduction** | | | | | | |
| Medicare Spending per Beneficiary | | X | X | X | X | X |
| AMI payment per 30-day episode | | | | X *Proposed for removal* | | |
| HF payment per 30-day episode | | | | X *Proposed for removal* | | |
| Pneumonia (PN) payment per 30-day episode | | | | | X *Proposed for removal* | |
| *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.

3. Changes to VBP Program Domains and Weighting

CMS proposes to remove the Safety domain from the VBP Program scoring beginning with the FY 2021 payment determination, and to change the name of the Clinical Care Domain to "Clinical Outcomes" beginning with FY 2020.

Removal of the safety domain is proposed because all the current measures in that domain are proposed for removal from the VBP Program beginning with FY 2021 payment; no new measures are proposed for this domain. CMS notes that the HAC Reduction program is the part of the quality payment framework focused on the safety aspect of care quality, and in keeping with its goal of streamlining and eliminating duplication of measures across programs, this domain should be removed from the VBP Program. CMS references comments from stakeholders objecting in particular to the duplication of safety measures between the HAC Reduction and VBP Programs. CMS believes that hospitals will continue to have incentive to perform well on these measures even if they are only included in one program and says that it will monitor the effects of this change as performance data on the safety measures will be publicly reported on *Hospital Compare.*

Removal of the Safety domain would require reweighting of the remaining three domains. CMS proposes to weight 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. It believes this aligns with a desired emphasis on outcomes and also notes that this domain will have five measures in FY 21 and six beginning in FY 22, so they would contribute 10 percent and 8.33 percent each toward the TPS in those years, respectively. By contrast, the Efficiency/Cost Reduction domain would have only one measure (weighted at 25 percent of the TPS) and the eight HCAHPS dimensions would continue to contribute 3.125 percent each to the TPS.

CMS notes that the current policy under which a hospital receives a TPS if it has scores on at least three domains would not be changed under the proposed rule. As a result, a hospital without a score on any one of the proposed remaining three domains, e.g., Clinical Outcomes, would not receive a TPS.

CMS also discusses a June 2017 report from the Government Accountability Office which raised concerns about lower-quality hospitals receiving VBP bonuses. That report pointed out that some hospitals below the median on the quality measures were able to receive a bonus because of high performance on the MSPB measure. CMS believes that its proposed domain weighting will address this concern, noting that analysis of 2018 program data found that 200 hospitals with composite quality scores below the median would no longer receive a positive VBP payment adjustment driven by high performance on the efficiency measure. In all, CMS estimates that the

percentage of hospitals receiving positive payment adjustments that have quality scores below the median would be reduced from 21 percent of hospitals receiving a VBP adjustment to 11 percent.

Furthermore, CMS says that its analysis found that some hospital groups which have usually received lower TPSs on average (large, urban, teaching and safety net hospitals) would move closer to the average TPS under the proposed weighting. This is because these groups have typically had lower performance on the Efficiency and Patient Community Engagement domains and higher performance on the Clinical Outcomes measures, which would receive greater weight under the proposal. The converse would also be true, that small, rural, nonteaching hospitals which tended to have higher TPSs would have these scores reduced toward the average TPS.

The effect of these shifts in scores would decrease the slope of the linear exchange function and decrease the percentage of hospitals receiving a positive VBP adjustment. CMS believes this is because larger hospitals with a higher level of MS-DRG payments would have higher scores and therefore, to keep the program budget neutral, positive adjustments would have to be reduced.

CMS discusses alternative weighting schemes it considered and welcomes comment on these. One alternative would weight each of the three remaining domains at 1/3 of the TPS; CMS says that this approach would not address the concerns raised by GAO regarding positive payment adjustments for hospitals with low quality measures scores. Another alternative considered would retain the Safety domain with one or more measures, which would not address the duplication of measures across Medicare's hospital quality programs.

The proposed rule includes two tables which are reproduced below. The first shows estimated TPSs and unweighted domain scores by certain hospital groupings under current (FY 2018) scoring, the proposed 3 domain re-weighting, and the 3-domain equal weighting alternative. The second table displays aggregate information on the current, proposed and alternative weightings. The proposed rule's impact analysis (discussed in section IV.I.7 below) provides additional information on the estimated effects of the proposed changes in domains and weighting.

| Comparison of Estimated Average TPSs and Unweighted Domain Scores* | | | | | | |
|---|---|---|---|---|---|---|
| Hospital Characteristic | Actual FY 2018 Average Clinical Care Domain Score | Actual FY 2018 Average Person and Community Engagement Domain Score | Actual FY 2018 Average Efficiency and Cost Reduction Domain Score | Actual FY 2018 Average TPS (4 domains) + | Proposed Increased Weighting of Clinical Care Domain: Estimated Average TPS | Alternative Weighting: Estimated Average TPS |
| All Hospitals** | 43.2 | 33.5 | 18.8 | 37.4 | 34.6 | 31.8 |
| Bed Size | | | | | | |
| 1-99 | 33.4 | 46.0 | 35.7 | 44.6 | 37.2 | 38.4 |
| 100-199 | 42.2 | 34.5 | 21.0 | 39.2 | 35.0 | 32.6 |
| 200-299 | 44.5 | 27.9 | 12.9 | 34.4 | 32.4 | 28.4 |
| 300-399 | 48.2 | 27.3 | 10.0 | 33.3 | 33.4 | 28.5 |

| Comparison of Estimated Average TPSs and Unweighted Domain Scores* | | | | | | |
|---|---|---|---|---|---|---|
| Hospital Characteristic | Actual FY 2018 Average Clinical Care Domain Score | Actual FY 2018 Average Person and Community Engagement Domain Score | Actual FY 2018 Average Efficiency and Cost Reduction Domain Score | Actual FY 2018 Average TPS (4 domains) + | Proposed Increased Weighting of Clinical Care Domain: Estimated Average TPS | Alternative Weighting: Estimated Average TPS |
| 400+ | 50.9 | 26.9 | 7.6 | 31.9 | 34.1 | 28.5 |
| Geographic Location | | | | | | |
| Urban | 46.8 | 30.7 | 13.7 | 35.7 | 34.5 | 30.4 |
| Rural | 33.7 | 40.5 | 31.7 | 41.9 | 34.9 | 35.3 |
| Safety Net Status*** | | | | | | |
| Non-Safety Net | 42.7 | 35.4 | 19.0 | 37.9 | 34.9 | 32.4 |
| Safety Net | 45.1 | 25.7 | 18.1 | 35.6 | 33.5 | 29.6 |
| Teaching Status | | | | | | |
| Non-Teaching | 39.9 | 36.7 | 22.9 | 39.4 | 34.9 | 33.2 |
| Teaching | 48.7 | 27.9 | 11.8 | 34.1 | 34.3 | 29.5 |

*Analysis based on FY 2018 Hospital VBP Program data.
** Only eligible hospitals are included in this analysis. Excluded hospitals (for example, hospitals not meeting the minimum domains required for calculation, hospitals receiving three or more immediate jeopardy citations in the FY 2018 performance period, hospitals subject to payment reductions under the Hospital IQR Program in FY 2018, and hospitals located in the state of Maryland) were removed.
+ Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.
*** For purposes of this analysis, 'safety net' status is defined as those hospitals with top 10 percentile of DSH patient percentage from the FY 2018 IPPS/LTCH PPS final rule impact file.

| Summary of Estimated Impacts on Average TPS and Payment Adjustments Using FY 2018 Program Data | Actual (4 domains)+ | Proposed Increased Weight for Clinical Outcomes (3 domains) | Equal Weighting Alternative (3 domains) |
|---|---|---|---|
| Total number of hospitals with a payment adjustment | 2,808 | 2,701 | 2,701 |
| Number of hospitals receiving a positive payment adjustment (percent) | 1,597 (57%) | 1,209 (45%) | 1,337 (50%) |
| Average positive payment adjustment percentage | 0.60% | 0.58% | 0.70% |
| Estimated average positive payment adjustment | $128,161 | $233,620 | $204,038 |
| Number of hospitals receiving a negative payment adjustment (percent) | 1,211 (43%) | 1,492 (55%) | 1,364 (50%) |
| Average negative payment adjustment percentage | -0.41% | -0.60% | -0.57% |
| Estimated average negative payment adjustment | $169,011 | $189,307 | $200,000 |
| Number of hospitals receiving a positive payment adjustment with a composite quality score* below the median (percent) | 341 (21%) | 134 (11%) | 266 (20%) |

| Summary of Estimated Impacts on Average TPS and Payment Adjustments Using FY 2018 Program Data | Actual (4 domains)+ | Proposed Increased Weight for Clinical Outcomes (3 domains) | Equal Weighting Alternative (3 domains) |
|---|---|---|---|
| Average TPS | 37.4 | 34.6 | 31.8 |
| Lowest TPS receiving a positive payment adjustment | 34.6 | 35.9 | 30.9 |
| Slope of the linear exchange function | 2.8908851882 | 2.7849297316 | 3.2405954322 |
| + Based on current policies, which includes the Safety domain, and proportionate reweighting for hospitals with sufficient data on only three domains.<br>* "Composite quality score" is defined as a hospital's TPS minus the hospital's weighted Efficiency and Cost Reduction domain score. | | | |

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 proposed. 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.

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 proposed to those policies. The proposed rule includes tables that display the baseline and performance periods for each fiscal year beginning with 2019 through 2024.

6. Performance Standards

The proposed rule includes a series of tables that display the previously adopted numeric performance standards for certain VBP Program measures for FYs 2020-2023, proposed standards for the HCAHPS dimensions for FY 2021, and proposed standards for the Clinical Outcomes domain measures for FY 2024.

7. Impact Analysis for FY 2019

The Impact Analysis section of the proposed rule includes a table and discussion of the estimated impact of the VBP Program for FY 2019 by type of hospital. However, these calculations rely on the FY 2018 hospital performance scores to estimate the effects of the 2019 VBP Program. Nonetheless, the table shows a range of effects. Rural hospitals as a group are shown as receiving the largest positive VBP adjustment (+0.465%) while rural hospitals with 200 or more beds (-0.125%) urban hospitals with 300-499 beds (-0.185%), hospitals in the East South Central and

Middle Atlantic regions (-0.101%) and teaching hospitals (-0.032%) are shown with the largest negative adjustments.

The rule also includes a table showing the effects of the proposed and alternative domain weighting approaches for 2021. This is also based on 2018 hospital performance scores. The proposed domain weighting is shown as leading to an average VBP adjustment that is negative; the largest positive effects are shown for hospitals with fewer than 100 beds, and New England hospitals. The largest negative effects shown are for DSH hospitals, urban hospitals with 300-499 beds and rural hospitals with 100 or more beds.

Results from both of these tables on selected hospital groups are combined and summarized in the following table.

| Average VBP Payment Adjustment for Selected Hospital Categories from Proposed Rule Impact Analysis Tables on VBP Program for 2019 and Two Alternative Domain Weightings for 2021 | | | | | |
|---|---|---|---|---|---|
| Category | Number In Analysis* | 2019 VBP | Number In Analysis* | Proposed Domain Weighting | Alternative Domain Weighting |
| All Hospitals | 2,808 | 0.163% | 2,701 | -0.071% | 0.059% |
| Urban | 2140 | 0.068% | 2,050 | -0.081% | -0.023% |
| Rural | 668 | 0.465% | 651 | -0.040% | -0.318% |
| Nonteaching | 1,763 | 0.278% | 1,702 | -0.040% | -0.318% |
| Teaching | 1,045 | -0.032% | 999 | -0.097% | -0.098% |
| DSH 0-25 | 1,082 | 0.254% | 1,031 | 0.021% | 0.182% |
| DSH 25-50 | 1,381 | 0.126% | 1,359 | -0.127% | 0.012% |
| DSH 50-65 | 196 | 0.005% | 185 | -0.184% | -0.156% |
| DSH 65+ | 149 | 0.046% | 126 | 0.058% | -0.119% |
| *The proposed rule does not explain the differences in the number of hospitals in the two analyses, both of which are based on FY 2018 hospital VBP performance. A possible explanation is that the elimination of the safety domain reduced the number of hospitals with a VBP Total Performance Score. | | | | | |

## J. Hospital-Acquired Condition Reduction Program

CMS proposes to modify the weighting of measures in scoring hospital performance for the HAC Reduction Program. While the current six HAC Reduction Program measures would be retained for FY 2019, elsewhere in this rule these measures are proposed for removal from the VBP and the IQR programs. Because the HAC Reduction Program would be the only hospital quality program where these six measures are used, CMS proposes to adopt for this 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 in this rule 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. After review, CMS has determined that the existing six HAC Reduction Program measures are appropriate for this program and should be retained. To avoid duplication, elsewhere in this rule CMS proposes to remove these measures from the Hospital VBP and IQR programs.

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% | * | * |
| **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):<br>◦ SSI Following Colon Surgery<br>◦ SSI Following Abdominal Hysterectomy | | X | X | X | X | X |

| Summary Table: HAC Reduction Program Measures, Performance Periods, and Domain Weights | | | | | | |
|---|---|---|---|---|---|---|
| | **FY 2015** | **FY 2016** | **FY 2017** | **FY 2018** | **FY 2019** | **FY 2020** |
| 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 proposes to change the weighting of HAC Reduction Program measures and offers two alternatives. See text discussion. | | | | | | |
| Note: PSI-90 is a composite of eight PSI 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.

4. HAC Reduction Program Data Collection

CMS proposes to adopt IQR Program data collection processes for the HAC Reduction Program. The program would begin receiving NHSN measure data beginning with January 1, 2019 infection events. This timing corresponds with HAC Reduction Program annual performance periods and the proposed removal of these measures from the IQR Program beginning with 2019 calendar year reporting. Quarterly reporting requirements, deadlines, and data submission through the NSHN would 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 would be continued. Hospitals would receive the same quarterly updates on NSHN measures via the QualityNet secure portal. No changes are proposed to the process for submission, review and correction of claims data or data used for the chart-abstracted NSHN 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.

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 proposal, the five chart-abstracted NHSN measures would be subject to validation under the HAC Reduction Program beginning with Q3 2019 discharges for FY 2022 payment.

All subsection (d) hospitals would 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 would 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 would 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 would 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 abstractor using a standard protocol. However, under the IQR Program the NSHN measures are combined with clinical process of care measures in determining whether the hospital passes or fails validation. For the HAC Reduction Program, CMS proposes that beginning in FY 2022, CMS would score the NSHN measures the same way, compute a confidence interval for the NHSN measures, and a hospital would pass validation if the upper bound of the confidence interval is 75 percent or higher.

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

One difference from the IQR Program data validation is in how the proposed rule would apply the penalty for failing validation. 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 proposes that a hospital that fails validation would 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 the proposed approach is fairer to hospitals and would lessen the likelihood of receiving a HAC Reduction Program penalty due to data validation failure. The proposal 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.

CMS proposes that the HAC Reduction Program data validation period would include 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 proposed validation period aligns with the current NSHN measure validation quarters. HAC Reduction Program Validation would begin with the July 2019 (Q3) infection event data. A table in the proposed rule sets out key dates for FY 2022 and 2023 validation. CMS notes that the data validation templates would be due before the HAC Reduction Program data submission deadlines, and it expects that providers would be familiar with the validation process because it would function in the same way as the IQR Program validation.

Finally, CMS proposes that if in the final rule the NSHN measures are removed from the IQR Program, the HAC Reduction Program would adopt the Data Accuracy and Completeness Acknowledgement (DACA) requirements. Between April 1 and May 15$^{th}$ each year hospitals would 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 signing would begin in 2020 for 2019 data.

6. Public Reporting

CMS intends to continue making 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. Quarterly NSHN data would continue to be made available on *Hospital Compare* in the same form and manner it is displayed there now as part of the IQR Program.

7. Changes to HAC Reduction Program Scoring

CMS proposes to change the weighting of the HAC Reduction Program domains in calculating the Total HAC Score beginning with 2020. 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. This is illustrated in the table that follows. Additionally, a few hospitals (36 in 2018, or 1 percent of all hospitals) have no Domain 1 score (i.e., no score on the PSI 90 measure) and in that case the weight of the Domain 2 measures

varies greatly (from 20 to 100 percent) based on how many Domain 2 measures the hospital reports.

| Weight Applied To Each Measure By Number Of Domain 2 Measures With Measure Scores For Hospitals With A Domain 1 Score In FY 2018 (N=3,147) | | | |
|---|---|---|---|
| **Number of Domain 2 measures with measure scores** | **Number (percent) of hospitals in FY 2018[a]** | **Weight applied to:** | |
| | | **CMS PSI 90** | **Each Domain 2 measure** |
| 0 | 188 (5.9%) | 100.0 | N/A |
| 1 | 288 (9.1%) | 15.0 | 85.0 |
| 2 | 218 (6.9%) | 15.0 | 42.5 |
| 3 | 196 (6.2%) | 15.0 | 28.3 |
| 4 | 251 (7.9%) | 15.0 | 21.3 |
| 5 | 2,006 (63.0%) | 15.0 | 17.0 |
| Note that 36 hospitals did not receive a Domain 1 score for FY 2018. | | | |

CMS discusses two alternative approaches to re-weighting the domain scores. The proposed approach would eliminate the domains and weight each of the six measures equally in calculating the Total HAC Score. Under this "equal measure weights" approach, each measure would receive a weight of 16.7 percent if the hospital had a score on each of the six measures, increasing to 50 percent each if two measures were scored and 100 percent if only one measure was scored. CMS believes this approach would address concerns about the disproportionate weight assigned to Domain 2 measures when a hospital only has scores for one or two such measures.

Comments are also sought 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. The following summary table combines information from two tables in the proposed rule that show how the weights would work under each alternative.

| Measure/Domain Weights Under Two HAC Reduction Program Alternatives | | | | | |
|---|---|---|---|---|---|
| | **Equal Measure Weights (CMS Preferred Approach)** | | **Variable Domain Weights* (Alternative Approach)** | | |
| **Number of NHSN/Domain 2 measures scored** | **PSI 90** | **Each NSHN measure** | **Domain 1 (PSI 90)** | **Domain 2** | **Each Domain 2 measure** |
| 0 | 100.0 | n/a | 100.0 | n/a | n/a |
| 1 | 50.0 | 50.0 | 40.0 | 60.0 | 60.0 |
| 2 | 33.3 | 33.3 | 30.0 | 70.0 | 35.0 |
| 3 | 25.0 | 25.0 | 20.0 | 80.0 | 26.7 |
| 4 | 20.0 | 20.0 | 15.0 | 85.0 | 21.3 |
| 5 | 16.7 | 16.7 | 15.0 | 85.0 | 17.0 |
| Any number | n/a | 100 Equally divided | n/a | 100.0 | 100 Equally divided |
| *Domain weights would vary by hospital. | | | | | |

The proposed rule includes the following table that illustrates the impact of the potential change in weighting on the percentage of hospitals in the worst performing quartile (i.e., hospitals penalized). Both approaches would benefit hospitals with 100 or fewer beds while more major teaching and large urban hospitals would be penalized. 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." Furthermore, CMS points out that the original program design (for 2015) provide for roughly the same weight for each measure when a hospital had a score for all the measures.

**Estimated Impact of Scoring Approaches on Percentage of Hospitals in Worst-Performing Quartile by Hospital Group**

| Hospital Group[a] | Equal Measure Weights | Variable Domain Weights |
|---|---|---|
| Teaching hospitals: 100 or more residents (N=248) | 2.4% | 1.6% |
| Safety-net[b] (N=644) | 0.6% | 0.8% |
| Urban hospitals: 400 or more beds (N=360) | 2.2% | 1.1% |
| Hospitals with 100 or fewer beds (N=1,169) | -1.8% | -0.9% |
| Hospitals with a measure score for: | | |
| Zero Domain 2 measures (N=188) | 0.0% | 0.0% |
| One Domain 2 measure (N=269) | -4.2% | -1.9% |
| Two Domain 2 measures (N=225) | -0.8% | -0.4% |
| Three Domain 2 measures (N=198) | -2.5% | -2.5% |
| Four Domain 2 measures (N=253) | -0.4% | 0.4% |
| Five Domain 2 measures (N=2,022) | 1.0% | 0.5% |

[a] The number of hospitals in the given hospital group for FY 2018 is specified in parenthesis in this column (for example, N=248).
[b] Hospitals are considered safety-net hospitals if they are in the top quintile for DSH percent.

8. Performance Period for FY 2021

CMS proposes that the HAC Reduction Program "applicable period", or performance period, for FY 2021 would 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 welcomes suggestions for additional HAC Reduction Program measures, specifically comments on the potential for the program's future adoption of eCQMs. CMS believes that eCQMs allow for the improved measurement of processes, observations, treatments and outcomes, and reduce burden on clinicians.

10. Impact Analysis

The impact analysis section of the proposed rule includes a table that shows the estimated distribution of hospitals in the worst performing quartile of Total HAC scores for FY 2019 by hospital characteristic. This analysis reflects the current domain weighting scheme and not the proposed or alternative approaches discussed above for implementation in 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 18 percent for rural hospitals with 100 or more beds to 47 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 costs (DGME). 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. Proposed 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 proposed rule indicates that CMS has received questions about whether an affiliated group consisting solely of new urban teaching hospitals is permissible. CMS does not believe a Medicare GME affiliation agreement consisting solely of new urban teaching hospitals is permissible under 42 CFR §413.79(e)(1)(iv). However, the proposed rule indicates that CMS does not wish to preclude affiliations that clearly are designed to facilitate additional training at a new teaching hospital. CMS believes that allowing two (or more) new urban teaching hospitals to form a Medicare GME affiliated group will enable these hospitals to provide residents training at their facilities with both the required and more varied training experiences necessary to complete their residency training programs. Furthermore, CMS indicates the proposed change would facilitate increased training within local, smaller-sized communities because generally new urban teaching hospitals are smaller-sized, community-based hospitals compared with existing urban teaching hospitals, which are generally large academic medical centers.

Accordingly, CMS is proposing to revise the regulation 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. Because Medicare GME affiliation agreements can only be entered into at the start of an academic year (that is, July 1), CMS is proposing the change would be effective beginning with affiliation agreements entered into for the July 1, 2019 through June 30, 2020 residency training year. If adopted, the proposed change would apply 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. Notice of Closure of Two Teaching Hospitals 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. In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule (75 FR 72212), CMS established regulations (42 CFR §413.79(o)) and an application process for qualifying hospitals to apply to CMS to receive DGME and IME FTE resident cap slots from the hospital that closed. CMS made modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434). It made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134).

*Notice of Closure of Affinity Medical Center, Located in Massillon, OH—Round 11*

CMS is notifying the public of the closure of Affinity Medical Center, located in Massillon, OH. The proposed rule describes this closure as "Round 11" and includes the following information about Affinity Medical Center:

**Round 11 Available Resident Cap FTEs**

| CCN | Provider Name | City and State | CBSA Code | Terminating Date | IME Resident Cap | DGME Resident Cap |
|---|---|---|---|---|---|---|
| 360151 | Affinity Medical Center | Massillon, OH | 15940 | February 11, 2018 | 22.36 | 22.48 |

*Notice of Closure of Baylor Scott & White Medical Center—Garland, Located in Garland, TX—Round 12*

CMS is notifying the public of the closure of Baylor Scott & White Medical Center--Garland, located in Garland, TX. The proposed rule describes this closure as "Round 12" and includes the following information about Baylor Scott & White Medical Center—Garland:

**Round 12 Available Resident Cap FTEs**

| CCN | Provider Name | City and State | CBSA Code | Terminating Date | IME Resident Cap | DGME Resident Cap |
|---|---|---|---|---|---|---|
| 450280 | Baylor Scott & White Medical Center Garland | Garland, TX | 19124 | February 28, 2018 | 12.52 | 13.53 |

*Application Process for Available Resident Slots*

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notification to the public of a hospital closure (77 FR 53436). Therefore, **hospitals that wish to apply for and receive slots from the above hospitals' must submit applications (Section 5506 Application Form posted on Direct Graduate Medical Education (DGME) directly to the CMS Central Office no later than July 23, 2018. The mailing address for the CMS Central Office is included on the application form. Applications must be received by the CMS Central Office by the July 23, 2018 deadline date. It is not sufficient for applications to be postmarked by this 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 policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

An applying hospital may apply for either or both of the above two hospitals FTE resident cap slots. However, two separate applications must be submitted if the hospital wishes to apply for available resident FTE cap slots from both hospitals. After applying, 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 [11 or 12] due to the closure of [Affinity Medical Center or Baylor Scott & White Medical Center Garland]. 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 CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, CMS reviews all applications received by the deadline and will notify applicants of its determinations 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) bringing the total participation of previously participating and newly participating hospitals to 30 for 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 multiplied that figure by a 3-percent annual volume adjustment for each fiscal year (Step 1); and
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 multiplied that figure by a 3-percent annual volume adjustment for each fiscal year (Step 2).

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 comprise 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 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 (ii) to 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 will incorporate those costs in the budget neutrality offset amount in a future IPPS final rule, and it will 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.

Because CMS did not announce the selection of newly participating hospitals by June 2017, there was no budget neutrality offset adjustment for the demonstration in the FY 2018 IPPS/LTCH PPS final rule. Similarly, CMS was unable to verify which previously participating hospitals would continue participating during the 21st Century Cures Act extension by the date of the publication of the final rule; thus, it did not include an estimate of the demonstration costs for those hospitals for purposes of the budget neutrality adjustment in the final rule.

*c. FY 2019*

For FY 2019, the budget neutrality methodology will be similar to the FY 2018 budget neutrality methodology with the addition of several components. For previously participating hospitals, CMS will use available finalized cost reports for the actual costs of the demonstration for FYs 2015, 2016 and 2017. Additionally, the estimated costs of the demonstration will be included using the FY 2018 methodology. 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 will 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. CMS also notes that it is evaluating whether the 3 percent annual volume adjustment is appropriate in light of empirical trends specific to participating hospitals; thus, it is possible that the estimated budget neutrality offset amount may change in the final rule.

CMS proposes to include the difference between actual and estimated costs for the demonstration for FYs 2011, 2012 and, if cost report data are available, 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 reverted to its general procedure to reconcile estimated and actual demonstration costs. Thus, as finalized cost reports become available, CMS determines the difference between actual and estimated costs of the demonstration for the fiscal year involved.

CMS proposes to adjust the budget neutrality offset amount by the combined difference between actual and estimated costs of the demonstration as indicated on finalized cost reports for FYs 2011 and 2012. CMS notes that if the cost reports for FY 2013 are available in time to calculate the difference between estimated and actual costs of the demonstration for FY 2013 in time for the final rule, CMS would incorporate that amount into the offset amount. For FYs 2011 and 2012, actual costs of the demonstration were less than estimated costs by $29,971,829 and $8,500,373, respectively.

4. Total Proposed Budget Neutrality Offset Amount for FY 2019

CMS proposes to apply $73,191,887 as the total budget neutrality offset amount for FY 2019 calculated as the sum of Steps 1 and 2 less the sum of Steps 3 and 4 as follows:

Step 1. $33,254,247 (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. $78,409,842 (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).

CMS reiterates that if the cost reports for FY 2013 are available in time to calculate the difference between estimated and actual costs of the demonstration for FY 2013 in time for the final rule, CMS will incorporate that amount into the offset amount.

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. Proposed Revisions Regarding Admission Order Documentation Requirements

The proposed rule 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 otherwise medically reasonable necessary inpatient stay, even if such denials occur infrequently.

CMS proposes to revise the regulations at 42 CFR §412.3(a) to remove the language stating 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. This proposal does not change the requirement that an individual is considered an inpatient if formally admitted as an inpatient under an order for inpatient admission.

## 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. CMS proposes a national capital Federal rate of $459.78 for FY 2019.

*Update Factor:*

For FY 2019, CMS proposes to increase the national capital Federal rate by 1.2 percent based on the capital input price index (CIPI) of 1.2 percent and other factors shown in Table 1 below. Real across DRG case mix change and project 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**

| **PROPOSED CMS FY 2019 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE** | |
|---|---|
| Capital Input Price Index (FY 2014-based CPI) | 1.2 |
| 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* | 1.2 |
| Effect of FY 2017 Reclassification and Recalibration | 0.0 |
| Forecast Error Correction | 0.0 |
| *Total Proposed Update* | 1.2 |

*Other Adjustments:*

The proposed FY 2019 budget neutrality adjustment factor which is applied to the capital Federal rate for changes in the MS-DRG classifications and relative weights and changes in the geographic adjustment factors (GAFs) is 0.9997; this adjustment in FY 2018 was 0.9987.

The proposed 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 capital federal rate. The proposed FY 2019 outlier adjustment of 0.9494 would yield a net change in the outlier adjustment to the 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 proposed FY 2019 capital federal rate by 0.12 percent.

*Final Calculation:*

The proposed rule includes the following chart to show how each of the proposed factors and adjustments affects the computation of the proposed for 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 Proposed FY 2019 Capital Federal Rate**

| | FY 2018 | Proposed FY 2019 | Proposed Change | Percent Change |
|---|---|---|---|---|
| Update Factor* | 1.0130 | 1.0120 | 1.0120 | 1.20 |
| GAF/DRG Adjustment Factor* | 0.9987 | 0.9997 | 0.9997 | -0.03 |
| Outlier Adjustment Factor** | 0.9483 | 0.9494 | 1.0012 | 0.12 |
| Capital Federal Rate | $453.95 | $459.78 | 1.0128 | 1.28 |

* The proposed update factor and the proposed GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rates. Thus, for example, the incremental change from FY 2018 to FY 2019 resulting from the application of the proposed 0.9997 GAF/DRG budget neutrality adjustment factor for FY 2018 is a net change of 0.9997 (or -0.03 percent).

** The proposed 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 proposed 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 proposes a national capital Federal rate for FY 2019 equal to $459.78, representing a 1.28 percent increase over the FY 2018 rate of $453.95.

As noted with respect analogous to operating payments in section I.C above, effective January 1, 2016, separate capital rates for hospitals located in Puerto Rico no longer apply. Puerto Rico hospitals will receive the national capital Federal rate.

Exception Payments. The proposed rule would continue exception payment if the 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 2017 fourth quarter forecast, CMS proposes to set 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.

CMS proposes to use the percentage increase in the 2014-based IPPS operating market basket to update the target amounts and proposes to use more recent data for the final rule if they become available.

### B. Changes to Regulations Governing Satellite Facilities

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.

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 changes CMS adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38292 through 38294) effective October 1, 2017, apply only to HwHs, not satellites. However, in the FY 2018 IPPS/LTCH PPS final rule, CMS indicated that it would consider only requiring satellites to comply with the separateness and control requirements when co-located within an IPPS hospital.

CMS indicates that its policies on satellite facilities have been premised on many of the same concerns that formed the basis for its HwH policies. That is, the separateness and control policies for satellite facilities at 42 CFR §412.22(h) were aimed at mitigating concern that the co-location of a satellite facility and a host hospital raised a potential for inappropriate patient

shifting that CMS believed could be guided more by attempts to maximize Medicare reimbursements than by patient welfare (71 FR 48107). The rules were adopted to address policy concerns regarding inappropriate patient shifting and hospitals acting as de facto units not authorized by statute.

For HwHs, the FY 2018 IPPS/LTCH PPS final rule indicated that concerns motivating separateness and control requirements are sufficiently moderated in situations where IPPS-excluded hospitals are co-located with each other, in large part due to changes that have been made to the way most types of IPPS-excluded hospitals are paid under Medicare. The rule indicates that there are significant similarities between the definition of a satellite facility and an HwH. CMS believes that there is no compelling policy rationale for treating satellite facilities and HwHs differently on the issue of separateness and control. (The rule notes that the separateness and control requirements for satellite facilities are similar but not the same as those for HwHs.)

Therefore, CMS is proposing effective October 1, 2018, that a satellite facility that is part of an IPPS-excluded hospital that provides inpatient services in a building also used by an IPPS-excluded hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS-excluded hospital, is not required to meet the separateness and control requirements in order to be excluded from the IPPS. A satellite facility that is part of an IPPS-excluded hospital which is located in a building also used by an IPPS hospital, or in one or more entire buildings located on the same campus as buildings used by an IPPS hospital, is still required to meet the separateness and control requirements to be excluded from the IPPS.

As described in further detail in section VI.C., CMS is proposing that, for cost reporting periods beginning on or after October 1, 2019, an IPPS-excluded hospital would no longer be precluded from having an excluded psychiatric and/or rehabilitation unit. Consistent with proposed changes to the regulations governing satellite facilities discussed earlier, CMS is proposing to specify that an IPPS-excluded satellite facility of 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) would not have to comply with the separateness and control requirements so long as the satellite of the excluded unit is not co-located with an IPPS hospital.

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.

The proposed rule further indicates that the proposal 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. These regulations were codified in the FY 1994 IPPS final rule (58 FR 46318). 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 proposing to revise 42 CFR §412.25(a)(1)(ii) to specify that the requirement that an excluded psychiatric or rehabilitation unit cannot be part of an IPPS-excluded hospital is only effective through cost reporting periods beginning on or before September 30, 2019. Under this proposal, effective with cost reporting periods beginning on or after October 1, 2019, an IPPS-excluded hospital would be permitted to have an excluded psychiatric and/or rehabilitation unit. In addition, CMS is proposing to revise 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 proposed 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 proposed 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 proposing that these regulatory changes would be 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 proposed changes.

## D. Critical Access Hospitals (CAHs)

1. The Frontier Community Health Integration Project (FCHIP) Demonstration[34]

The FCHIP Demonstration is designed to develop and test new models of care by CAHs located in frontier areas of certain States (i.e., Alaska, Montana, Nevada, North Dakota, and Wyoming). The FCHIP is a 3-year demonstration which limits participation to no more than four States; provides broad waiver authority; and requires budget neutrality. CMS will permit enhanced reimbursement under the FCHIP for telemedicine, nursing facility, ambulance, and home health services. CMS selected ten CAHs in Montana, Nevada, and North Dakota to participate in the demonstration beginning August 1, 2016.

CMS intends for the demonstration to maintain budget neutrality on its own terms; reduced transfers and admissions to other health care providers may offset any increase in payments under the waivers. However, due to the small size of the demonstration, CMS is concerned that the estimated savings will not offset the increased costs and adopted a contingency budget neutrality plan in prior rulemaking. Specifically, CMS would recoup any additional expenditures attributable to the FCHIP through a reduction in payments to CAHs nationwide—not just those participating in the FCHIP demonstration. CMS would perform a final budget neutrality estimate based on the entire demonstration period (August 1, 2016 through July 31, 2019) and would recoup any costs over 3 cost reporting periods, beginning with CY 2020.

CMS estimates the payment recoupment would not exceed 0.03 percent of CAHs' total Medicare reimbursement within a fiscal year. 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

Significant changes to the LTCH PPS, as mandated by Section 1206 of Pathway for SGR Reform Act (Pub.L.113-67), were implemented starting in FY 2016, establishing a dual-rate payment structure. For FY 2019, CMS again applies the term “LTCH PPS standard federal payment rate case” when the criteria for site neutral payment rate exclusion are met and applies the term “site neutral payment rate case” 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 remain the same for FY 2019:

- Case cannot have a principal diagnosis relating to a psychiatric diagnosis or rehabilitation (the DRG criterion).
- 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).

[34] The FCHIP Demonstration was authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110-275).

- 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).

To qualify for exclusion from the site neutral payment rate, the case must meet the DRG criterion and either the ICU or ventilator criterion.

CMS proposes updates for LTCHs using a process that is generally consistent with prior regulatory policy and that cross-links to relevant IPPS provisions. Section 51005 of the BBA 2018 extends the transitional blended payment rate for site neutral payment cases for an additional 2 years. The FY 2019 IPPS proposed rule makes conforming changes to the regulations to implement these provisions (discussed in further detail on section VII. C. below).

| **Summary of Proposed Changes to LTCH PPS Rates for FY 2019*** | |
|---|---|
| **Standard Federal Rate, FY 2018** | $41,415.11 |
| **Proposed Rule Update factors** | |
| Update as required by Section 1886(m)(3)(C) of the Act | +1.15% |
| Penalty for hospitals not reporting quality data | -2.0% |
| **Net update, LTCHs reporting quality data** | +1.15% (1.0115) |
| **Net update LTCHs not reporting quality data** | -0.85% (0.9915) |
| **Proposed Rule Adjustments** | |
| Proposed average wage index budget neutrality adjustment | 0.999713 |
| Proposed budget neutrality adjustment to eliminate the 25-percent threshold policy | 0.990535 |
| **Proposed Standard Federal Rate, FY 2019** | |
| LTCHs reporting quality data ($41,415.11∗1.0115∗0.999713*0.990535) | $41,482.98 |
| LTCHs not reporting quality data ($41,415.11*0.9915*0.999713*0.990535) | $40,662.75 |
| **Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases** | |
| LTCH PPS standard federal payment rate cases | $30,639 |
| Site neutral payment rate cases (same as the IPPS fixed-loss amount) | $27,545 |
| **Impact of Proposed Policy Changes on LTCH Payments in 2019** | |
| Total estimated impact | -0.1% ($5 million) |
| LTCH standard federal payment rate cases (64% of LTCH cases) | +0.2% (+$6 million) |
| Site neutral payment rate cases (36% of LTCH cases)** | -1.1% (-$11 million) |
| *More detail is available in Table IV, "Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for Standard Payment Rate Cases for FY 2019" (see page 1,828 in display copy). Table IV does not include the impact of site neutral payment rate cases.<br>** 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

Similar to FY 2018, 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. Thereby, the MS-LTC-DRG relative weights are not used to determine the site neutral payment rate and site neutral payment case data are not used to develop the relative weights.

2. Patient Classification into MS-LTC-DRGs

CMS proposes to continue to apply the same MS-DRG classification system used for the IPPS payments to the LTCH PPS in the form of MS-LTC-DRGs. Other MS-DRG system updates also would be incorporated into the MS-LTC-DRG system for FY 2019 since the two systems share an identical base. Proposed MS-DRG changes are described elsewhere in this summary and details can be found in sections II.F. of the preamble.

3. Development of the MS-LTC-DRG Relative Weights

In developing the FY 2019 relative weights, CMS proposes 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.

Relative Weights Source Data

FY 2019 proposed relative weights are derived from the December 2017 update of the FY 2017 MedPAR file. These data are filtered to identify LTCH cases meeting the established site neutral payment exclusion criteria. The filtered 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 proposed relative weights.

Hospital-Specific Relative-Value Methodology (HSRV)

CMS proposes to continue to use its HSRV methodology in FY 2019, unchanged from FY 2018, to mitigate relative weight distortions due to nonrandom case distribution across MS-LTC-DRGs and charge variation across providers. The HSRV methodology scales each LTCH's average relative charge value by its case mix.

Volume-related adjustments

CMS proposes to continue to account for low-volume MS-LTC-DRG cases as follows:

- If an MS-LTC-DRG has at least 25 cases, it is assigned its own relative weight. (In the proposed rule, CMS indicated there are 142 such MS-LTC-DRGs.)
- If an MS-LTC-DRG has 1-24 cases, it is assigned to one of five quintiles based on average charges (CMS finds that there are 271 such MS-LTC-DRGs). CMS then determines a proposed relative weight and average length of stay for each quintile; each quintile's weight and length of stay are then assigned to each MS-LTC-DRG within that quintile. (See Table 13A at the Table link provided below for these low-volume MS-LTC-DRGs.)

- If an MS-LTC-DRG has zero cases after data trims are applied (CMS finds that there are 347 such MS-LTC-DRGs), it is cross-walked to another proposed MS-LTC-DRG based on clinical similarities in resource use intensity and relative costliness in order to assign an appropriate proposed relative weight. If the MS-LTC-DRG that is similar is a low-volume DRG that has been assigned to one of the five quintiles noted above, then the zero volume MS-LTC-DRG would be assigned to that same quintile. This total excludes the 8 transplant, 2 "error" and 15 "psychiatric or rehabilitation" MS-LTC-DRGs. (See Table 13B at the Table link provided below for these zero-volume MS-LTC-DRGs.)

CMS will assign a 0.0 relative weight for eight transplant MS-LTC-DRGs since no LTCH has been certified by Medicare for transplantation coverage. CMS also will assign a 0.0 relative weight for the 2 "error" MS-LTC-DRGs (998 and 999) which cannot be properly assigned to a MS-LTC-DRG group. CMS will not calculate a weight for the 15 "psychiatric and rehabilitation" proposed MS-LTC-DRGs because these MS-LTC-DRGs would never include any LTCH cases meeting the site neutral payment rate exclusion criteria. To determine a transitional payment for FY 2019, CMS is using the FY 2015 relative weights for these MS-LTC-DRGs (as was done for FYs 2016- 2018).

Treatment of Severity Levels, Monotonicity Adjustments

Each MS-LTC-DRG contains one, two or three severity levels; resource utilization and relative weights typically increase with higher severity. When relative weights decrease as severity increases in a DRG ("nonmonotonic"), CMS proposes to continue for FY 2019 its approach of combining severity levels within the nonmonotonic MS-LTC-DRG for purposes of computing a relative weight to assure that monotonicity is maintained.

4. Selected Steps for Determining the MS-LTC-DRG Relative Weights

CMS is continuing to calculate the relative weights by first removing cases with a length of stay of 7 days or less (Step 1) and then removing statistical outliers (Step 2). The effect of Short Stay Outlier (SSO) cases (those with a length of stay of five-sixths or less of the average for that MS-LTC-DRG) is adjusted for by counting an SSO as a fraction of a discharge based on the ratio of the length of stay of the SSO case to the average length of stay for the MS-LTC-DRG for non-SSO cases (Step 3).

CMS is applying its existing two-step methodology to achieve budget neutrality for the FY 2019 MS-LTC-DRG and relative weights update (Step 7). First, a normalization adjustment is applied to the recalculated relative weights to ensure that the recalibration does not change the average case mix index (1.27598 proposed for FY 2019). Second, a budget neutrality factor is applied to each normalized relative weight (0.992183 proposed for FY 2019).

Extensive discussion of the entire 7-step process to determine MS-LTC-DRG relative weights is provided in the proposed rule (pages 1,110 to 1,124 of the display copy).

## C. Application of the Site Neutral Payment Rates

The transitional site neutral blended payment rate is comprised of 50 percent of the IPPS comparable amount and 50 percent of the LTCH PPS standard Federal payment rate. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49610 through 49612), CMS indicated that the blended rate would apply for discharges occurring in cost reporting periods beginning during FYs 2016 and 2017. In addition, CMS indicated that the site neutral payment rate and the LTCH PPS standard Federal rate would include any applicable adjustments, such as high cost outlier payments, as applicable.

Section 51005 of the BBA 2018 extended the transitional blended payment rate for site neutral payment rate cases for 2 years. CMS is proposing to extend the transitional blended payment rate for site neutral payment rate cases 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 proposing to implement 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).

As proposed, CMS is applying the extension to the transitional blended payment amount on the basis of cost reporting periods but the reduction in the IPPS comparable amount on the basis of a federal fiscal year. Thus, 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.

There is no discussion of this issue. It would appear that CMS has concluded that the BBA 2018 requires the reduction of IPPS comparable amount on the basis of a federal fiscal year because BBA 2018 specifies the reduction will occur for "for each of fiscal years 2018 through 2026" rather than concluding that the reduction should occur on the basis of cost reporting periods as is specified in the law for determining the transitional blended payment rates.

## D. LTCH PPS Payment Rates and Other Changes

1. Overview LTCH PPS Payment Rate Adjustments

Only LTCH discharges meeting the site neutral payment rate exclusion criteria are paid based upon the LTCH PPS standard federal payment rate. The LTCH PPS uses a single payment rate to cover both operating and capital-related costs, so that the LTCH market basket includes both operating and capital cost categories.

As in FY 2018, site neutral payment rate cases are proposed to be paid in FY 2018 at a rate that is based on the lower of the IPPS comparable per diem amount rate or 100 percent of the estimated cost of the cases.

2. Proposed Annual Update for LTCHs

The proposed annual update to the LTCH PPS standard federal payment rate is equal to 1.1 percent. The update is equal to the 2013-based LTCH market basket of 2.7 percent less 0.8 percentage points (PP) 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 proposed LTCH update for FY 2019 is:

| Factor | Full Update (PP=Percentage Points | Reduced Update for Not Submitting Quality Data |
|---|---|---|
| LTCH Market Basket | 2.7% | 2.7% |
| Multifactor Productivity | -0.8 PP | -0.8 PP |
| Statutory Factor | -0.75 PP | -0.75 PP |
| Quality Data Adjustment | 0.0 | -2.0 PP |
| Total | 1.15% | -0.85% |

3. Area Wage Levels and Wage-Index

CMS sets out a proposed labor-related share of 66.2 percent for FY 2019 based on the most recent IGI's fourth quarter 2017 forecast of the 2013-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (62.0%) and capital costs (4.2%). Operating costs include the following cost categories: wages and salaries; employee benefits; professional fees; labor-related; administrative and facilities support services; installation, maintenance, and repair services; and all other labor-related services.

CMS proposes to compute the wage index in a manner that is consistent with prior years. Further, CMS proposes an area wage level budget neutrality adjustment, computed as in prior years, of 0.999713.

3. Proposed LTCH Standard Federal Payment Rate Calculation

CMS proposes the following LTCH PPS standard federal payment rates for FY 2019:

- FY 2019 payment rate = $41,415.11 (FY 2018 payment rate) * 1.0115 (statutory update factor) * 0.999713 (area wage budget neutrality factor) * 0.990535 (25% threshold budget neutrality factor) = $41,482.98

- For LTCHs not reporting data to the LTCH QRP: FY 2019 payment rate = $41,415.11 (FY 2018 payment rate) * 0.9915 (statutory update factor less quality adjustment) * 0.999713 (area wage budget neutrality factor) * 0.990535 (25% threshold budget neutrality factor) = $40,662.75

4. Cost-of-Living (COLA) Adjustment

CMS proposes to continue updating the COLA factors for Alaska and Hawaii as it has done since FY 2014. To account for higher living costs in Alaska and Hawaii, a COLA is provided to LTCHs in those states. 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

| **Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii Under the LTCH PPS for FY 2019** | **Proposed 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 |

5. 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 the CMS to set the outlier threshold such that estimated outlier payments equal 99.6875 percent of the 8 percent estimated aggregate payments for standard federal payment rate cases (that is, 7.975 percent). Consistent with the statute, CMS proposes an HCO threshold of $30,639 which CMS estimates will result in 7.9795 of LTCH standard federal payment rate cases being paid as outliers. The HCO payment continues to equal 80 percent of the estimated care cost and the outlier threshold (adjusted standard rate payment plus fixed-loss amount). If an HCO case is also an SSO case, the HCO payment will equal 80 percent of the estimated case cost and the outlier threshold (SSO payment plus fixed-loss amount).

The proposed FY 2019 fixed-loss amount of $30,629 that applies to LTCH standard federal payment rate cases is significantly higher than the FY 2018 fixed-loss amount of $27,381. CMS states that the current FY 2018 HCO threshold of $27,381 results in estimated HCO payments for LTCH PPS standard Federal payment rate that exceed the 7.975 percent target by 0.01 percentage points. CMS believes this increase is largely attributable to an increase in the Medicare allowable charges on the claims data in addition to updates to CCRs from the December 2016 update of the PSF to the March 2017 update of the provider-specific file. Consistent with historical practice, CMS will use the most recent available LTCH claims data and CCR data for the final rule.

Consistent with its practice since FY 2016, CMS continues to believe that the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount. For FY 2019, CMS proposes a fixed-loss amount for site neutral payment rate cases of $27,545.

CMS also proposes for FY 2019 a budget neutrality factor of 0.949 for site neutral payment rate cases. Consistent with the policy adopted in FY 2018, CMS proposes that the HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount. CMS estimates that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments.

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

CMS proposes to continue its policy that the calculations of the "IPPS comparable amount" (42 CFR §412.529) and the "IPPS equivalent amount" (§412.534 and §412.536) continue to 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 patient discharges from an LTCH when the number of such patients originating from any single referring hospital is in excess of the applicable threshold for a given cost reporting period (such threshold is generally set at 25-percent, with exceptions for rural and urban single or MSA-dominant hospitals). If an LTCH exceeds the applicable threshold during a cost reporting period, payment for the discharge that puts the LTCH over its threshold and all discharges subsequent to that discharge in the cost reporting period from the referring hospital are 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 does 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 proposing to eliminate the 25-percent threshold policy. Independent of this goal, 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. The 25-percent threshold policy would have reduced LTCH PPS payments for certain discharges. Therefore, if finalized, the proposal to eliminate the 25-percent threshold policy would be expected to result in an increase in aggregate LTCH PPS payments.

As a result, if CMS finalizes its proposal to eliminate the 25-percent threshold policy, it is proposing to make a one-time, permanent adjustment to the proposed FY 2019 LTCH PPS standard Federal rate to make the policy budget neutral. CMS cites section 123 of the BBRA, as amended by section 307(b) of the BIPA as its authority to make this adjustment. The adjustment would be set such that CMS' projection of aggregate LTCH payments in FY 2019 will be the same both with and without the 25-percent threshold policy applied.

CMS is proposing to apply this one-time adjustment only to the LTCH PPS standard Federal payment rate (or such portion of a blended payment) because payments made under the site neutral payment rate would be unaffected by the 25-percent threshold policy. CMS provides a detailed explanation of the steps it used to determine the budget neutrality adjustment on pages 1,148-1,151 of the display copy of the proposed rule. Based on the FY 2017 LTCH claims data used for this proposed rule, CMS estimates that elimination of the 25-percent threshold policy would increase aggregate LTCH PPS payments by approximately $36 million which results in CMS proposing a budget neutrality factor of 0.990535 (-0.95 percent).

CMS also considered delaying application of the 25-percent policy for one additional year rather than eliminating it permanently. If CMS adopted that policy, it would also have proposed to apply a budget neutrality factor of 0.990535 for the one-year delay.

**CMS invites comments on permanently eliminating the 25-percent threshold policy in a budget neutral manner, or, in the alternative, the adoption of an additional 1-year delay on the implementation of the policy with a budget neutrality adjustment. In addition, CMS invites inviting comments on whether the 25-percent threshold policy should be retained in FY 2019 and subsequent years.**

## 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 result in a decrease of 0.1 percent or $5 million in aggregate payments (from $4.515 billion to $4.510 billion). This estimated decrease in payments reflects the projected increase in payments to LTCH PPS standard federal payment rate cases of approximately $6 million and the projected decrease in payments to site neutral payment rate cases of approximately $11 million. CMS modeling assumes that approximately 64 percent of LTCH cases would meet the criteria for exclusion from the site neutral payment rate (that is, those cases would be paid the LTCH PPS standard federal payment rate) and approximately 36 percent of LTCH cases would be paid the site neutral payment rate (calculated using FY 2017 LTCH claims data). The increase in LTCH PPS standard federal payment rates cases results from the 1.15 percent update and the -0.9 percent one-time permanent budget neutrality adjustment for the proposed elimination of the 25-percent threshold policy.

CMS was unable to model the impact of LTCH PPS payment changes for site neutral payment rate cases as it did for standard federal payment rate cases. Thus, Table IV "Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for Standard Payment Rate Cases for FY 2019" in the proposed 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 $6 million or 0.2 percent. CMS reports that regional differences in impacts are largely due to update to the wage index.

| **Summary of Impact of Proposed Changes to LTCH PPS for Standard Federal Payment Rate Cases for FY 2018*** | | |
|---|---|---|
| **LTCH Classification** | **Number of LTCHs** | **Estimated percent change in payments per discharge** |
| **All LTCH providers** | 409 | +0.2% |
| **By Location:** | | |
| **Rural** | 21 | 0.0% |
| **Urban** | 388 | +0.2% |
| **By Ownership Type:** | | |
| **Voluntary** | 77 | +0.3% |
| **Proprietary** | 319 | +0.1% |
| **Government** | 13 | +0.4% |
| **By Region** | | |
| **New England** | 12 | -0.5% |
| **Middle Atlantic** | 24 | +0.7% |
| **South Atlantic** | 66 | +0.2% |
| **East North Central** | 68 | -0.2% |
| **East South Central** | 36 | +0.2% |
| **West North Central** | 28 | -0.2% |
| **West South Central** | 120 | 0.0% |
| **Mountain** | 29 | -0.1% |
| **Pacific** | 26 | +1.1% |
| *More detail is available in Table IV, "Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for Standard Federal Payment Rate Cases, For FY 2019," | | |

(see page 1,828 of display copy).

2. Tables

The complete set of tables providing detail on the proposed 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-P.html?DLPage=1&DLEntries=10&DLSort=3&DLSortDir=descending

The information at that link provides:

- Table 11: MS-LTC-DRGs, relative weights, geometric average length of stay, SSO threshold, and IPPS comparable threshold for FY 2019
- Table 12A: LTCH PPS Wage Index for Urban Areas for FY 2019
- Table 12B: LTCH PPS Wage Index for Rural Areas for FY 2019
- Table 8C: LTCH PPS statewide Average Cost-to-Charge Ratios for FY 2019
- Table 13A: Composition of low-volume quintiles for MS-LTC-DRGs for FY 2019
- Table 13B: No volume MS-LTC-DRG crosswalk for FY 2019
- LTCH PPS FY 2019 Proposed Impact File

## VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the proposed rule, substantial changes are proposed 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 proposed 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 proposes to remove 39 measures from the Hospital IQR Program for the FYs 2020 through 2023 payment determinations; 19 of these measures would continue to be used in either the HRRP, the Hospital VBP Program or the HAC Reduction Program and hospital-specific performance would still be reported on *Hospital Compare*. In discussing its decision to propose removal of 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 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 proposes 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 proposed rule, the measure set for FY 2020 would include 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 would be 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 measure sets beginning with FY 2018 and the proposed changes. No new measures are 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 proposes an eighth new factor. This proposal 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 proposed eighth removal factor would be 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.

CMS proposes no change to its policy for retaining measures adopted for the Hospital IQR Program until they are proposed for removal, suspension or replacement.

3. Proposed Removal of 39 Hospital IQR Program Measures

CMS proposes to remove a total of 39 measures from the Hospital IQR Program; 19 beginning with the FY 2020 payment determination, 10 with FY 2021; 9 with FY 2022 and 1 beginning with FY 2023. The following table summarizes the measures proposed for removal, the effective date, the removal factor cited and whether the measure would continue in one of the three pay-for-performance programs. CMS notes that to the extent the addition of proposed removal factor 8 is not finalized, the measures proposed for removal based on that factor would be retained in the final rule.

| 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 | HAC |
| NHSN CDI NQF #1717 | FY 21 | 8- costs | HAC |
| NHSN CAUTI NQF #0138 | FY 21 | 8- costs | HAC |
| NHSN CLABSI NQF# 0139 | FY 21 | 8- costs | HAC |
| NHSN MRSA NQF #0176 | FY 21 | 8- costs | HAC |
| Colon/abdominal hysterectomy SSI NQF #0753 | FY 21 | 8- costs | 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 |
| 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 would be retained in the Hospital IQR Program
(5) Two related eCQMs addressing venous thromboembolism (VTE) would be retained (VTE-1 and VTE-2)
(6) The chart-abstracted version of this measure would be retained in the Hospital IQR Program.

CMS discusses the proposed removal of each measure. In many cases the measures are removed from the Hospital IQR Program because they duplicate measures in one of the three pay-for-performance programs. In addition to what is shown in the table, those discussions reveal the following information:

- *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. They have 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 would end 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 would end May 15, 2018.
- *NSHN measures.* CMS discusses the burden on providers of monitoring three different feedback reports on these four NHSN measures and PSI 90 based on three different reporting periods. These four measures are proposed for removal beginning with the FY 2021 payment determination because by the time the FY 2019 IPPS/LTCH final rule is published hospitals would already have submitted data for the first three quarters of CY 2018 for the FY 2020 payment determination. By contrast, the claims-based nature of PSI 90 allows for earlier removal from the Hospital IQR Program.
- *Stroke readmissions.* Unlike the other readmission measures, this measure is not included in the HRRP. CMS proposes to remove it based on proposed new factor 8 and believes that this measure overlaps with the Hospital IQR Program's measure of Hospital Wide All-Cause Unplanned Readmissions. Stroke readmissions are captured in that measure's neurology cohort. CMS further notes the costs it bears in maintaining specifications and tools to analyze and publicly report performance data. CMS acknowledges that condition-specific readmission measures may provide hospitals with actionable feedback but says that hospitals would continue to have motivation to reduce stroke readmissions in order to improve performance on the hospital-wide all-conditions readmissions measure.
- *Mortality measures*. The staggered proposed removal dates for the five mortality measures reflect when the measures have previously been finalized for addition to the VBP Program. The removal dates would therefore avoid 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 would be removed from the IQR Program beginning with the FY 2023 payment determination. CMS says it 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 proposed for removal 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 balancing the costs of the measures to the benefit 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 payment measures proposed for removal 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 this reporting this measure is another reason for its proposed removal. CMS notes that the Influenza Vaccination Coverage Among Healthcare Personnel will be retained in the IQR Program. The proposed beginning with the FY 2021 payment determination reflects the fact that by the time the FY 2019 IPPS/LTCH final rule is published hospitals would already have submitted data for the first three quarters of CY 2018 for the FY 2020 payment determination.
- *ED throughput (ED-1 and ED-2) chart-abstracted measures.* CMS discusses the burden of information collection for these measures and points out that hospitals would 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 would be removed for the FY 2021 payment because data collection for the 2020 payment determination is already underway during 2018. The ED-2 measure would be retained 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). This measure would be removed beginning with FY 2021 because data collection for FY 2020 will be largely complete by the time the final rule is published.
- *eCQMs*. CMS proposes to remove 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 proposed for the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, now to be named the Medicare and Medicaid Promoting Interoperability Programs. Removal for FY 2022 payment (CY 2020 reporting) is proposed rather than an earlier date because stakeholders have previously emphasized the time needed for vendors and hospitals to make eCQM changes. CMS believes that waiting until the 2020 reporting year to make changes will

assist hospitals that have already expended resources in preparation for the 2019 reporting year.

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    - 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) would be 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. Retaining the chart-abstracted version would provide for public reporting of a maternal and child health measure.
    - As discussed below, CMS proposes to extend current requirements for eCQMs into the 2019 reporting/2021 payment years. That is, hospitals would submit one self-selected quarter of data on four selected eCQMs.

4. Possible Future Hospital IQR Program Measures

CMS seeks 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 are sought on adoption of eCQMs.

*Hospital-Wide Mortality.* CMS seeks 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 proposed rule describes these measure 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.

In addition to general comments on the possible future inclusion of one or both of the hospital-wide mortality measures in the Hospital IQR Program, CMS seeks comments on specific issues: 1) feedback about the service-line division structure of the measures; 2) input on the measure testing approach, particularly on validity testing that would be meaningful, and 3) how the measure results might be presented to the public. With respect to the latter CMS seeks ways to present supplemental hospital performance information to create a more meaningful measure, and ways to report more information about hospitals in the "no different from national average" group.

*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.

*General Adoption of eCQMs*. CMS discusses stakeholder concerns regarding the implementation of eCQMs in the Hospital IQR Program, the Medicare and Medicaid Promoting Interoperability Programs among others. Particular concerns relate to the costs of implementing these measures. Sources of costs CMS references are those associated with rapidly shifting timelines and lack of alignment across programs, lack of transparency from developers, the variation in eCQM offerings among IT products, incorporating new measure specifications. Challenges to extracting data from the EHR and integrating with other applications are also identified as a source of costs. CMS specifically seeks feedback on the following questions:

1. What aspects of the use of eCQMs are most costly to hospitals and health IT vendors?
2. What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM costs?
3. What are the most significant barriers to the availability and use of new eCQMs today?
4. What specifically would stakeholders like to see us do to reduce costs and maximize the benefits of eCQMs?
5. How could we encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?
6. How could we encourage hospitals and health IT vendors to engage in testing new eCQMs?
7. Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?
8. What ways could we incentivize or reward innovative uses of health IT that could reduce costs for hospitals?
9. What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?

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 in hospital confidential feedback report, 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 will convene 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.

6. Form, Manner and Timing of Data Submission

CMS reviews procedural and data submission requirements for the Hospital IQR Program; no changes are 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 proposed changes would 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 proposes 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 proposed for both the Hospital IQR Program and the Medicare EHR Incentive Program (now Promoting Interoperability Program) requirements. (See section VIII.D below.)

*Certification Requirements for 2019 Reporting (FY 2021 payment).* Under this proposed rule, hospitals would be required to use the 2015 Edition only 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.

While no changes are proposed to the data submission requirements for the structural measures, CMS notes that under this proposed rule these measures would be removed, and no structural measure reporting would 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; data on these measures would be reported through the HAC Reduction Program as described in section IV.J above.

7. Data Validation

No changes are proposed to the data validation process, but CMS notes that under the proposed rule there would be fewer IQR Program measures requiring validation. By the FY 2022 payment determination, only two chart abstracted measures would remain, and by FY 2023 only one would remain. CMS would 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 would 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 proposed rule, CMS estimates that for FY 2019, 54 hospitals would fail to meet the requirements of the Hospital IQR Program and be subject to a payment reduction estimated to be 0.7 percentage points (one quarter of the proposed rule market basket update). Some 43 of these hospitals would also fail to meet the requirements of the Medicare EHR Incentive Payment Program and therefore be subject to a combined 2.8 percentage point reduction for FY 2019 (0.7 percentage points and another 2.1 percentage points, or three-quarters of the market basket update for failure to comply with the EHR Incentive Payment Program).

In the Collection of Information requirements section of the proposed rule, CMS estimates the potential reduced burden on hospitals associated with the proposed 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, proposed removal of ED–2 would result 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 would occur because these measures would no longer be subject to data validation; no specific estimates are provided for that. CMS does estimate the savings from eliminating the NSHN measures from the Hospital IQR Program but notes that this burden would not be eliminated entirely, only shifted to the HAC Reduction Program.

Under the proposed rule the eCQM reporting requirement for the 2019 reporting period/FY 2021 payment determination would be unchanged from 2018/2020 payment. CMS estimates this burden associated with eCQM reporting requirements at 40 minutes per hospital per year (10 minutes per record x 4 eCQMs x 1 quarter.

| **Summary Table: IQR Program Measures by Payment Determination Year<br>X= Mandatory Measure *Proposed Changes in Italics*** | | | | |
|---|---|---|---|---|
| | **2018** | **2019** | **2020** | **2021+** |
| **Chart-Abstracted Process of Care Measures** | | | | |
| STK-4 Thrombolytic therapy for acute ischemic stroke | X | Removed | | |
| VTE-5 VTE discharge instructions | X | Removed | | |
| VTE-6 Incidence of potentially preventable VTE | X | X | X | *Remove* |
| **Severe sepsis and septic shock: management bundle (NQF #500)** | **X** | **X** | **X** | **X** |
| ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital (NQF #0495) | X | X | X | *Remove* |
| ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status (NQF #0497) | X | X | X | *Remove FY 22* |
| IMM-2 Immunization for influenza (NQF #1659) | X | X | X | *Remove* |
| **PC-01 Elective delivery < 39 weeks gestation (NQF#0469)** | **X** | **X** | **X** | **X** |
| **Electronic Clinical Quality Measures** | | | | |
| AMI-2 Aspirin prescribed at discharge for AMI<br>AMI-7a Fibrinolytic (thrombolytic) agent received within 30 minutes of hospital arrival<br>AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) (NQF #0163)<br>AMI-10 Statin at discharge<br>PN-6 Appropriate initial antibiotic selection<br>STK-2 Antithrombotic therapy for ischemic stroke (NQF #0435)<br>STK-3 Anticoagulation therapy for Afib/flutter (NQF #0436)<br>STK-4 Thrombolytic therapy for acute ischemic stroke<br>STK-5 Antithrombotic therapy by end of hospital day 2 (NQF #0438)<br>STK-6 Discharged on statin (NQF #0439)<br>STK-8 Stroke education<br>STK-10 Assessed for rehabilitation services (NQF #0441)<br>VTE-1 VTE prophylaxis (NQF #0371)<br>VTE-2 ICU VTE prophylaxis (NQF #0372)<br>VTE-3 VTE patients with anticoagulation overlap therapy | Must report at least 4 of 28 eCQMs | For FY 2019-2021 must report 4 of 15 eCQMs<br><br>The 15 eCQMs:<br>AMI-8a<br>CAC-3<br>ED-1<br>ED-2<br>EHDI-1a<br>PC-01<br>PC-05<br>STK-02<br>STK-03<br>STK-05<br>STK-06<br>STK-08<br>STK-10 | ***For FY 2022 payment, (2020 reporting) report 4 of the following 8 eCQMs (others would be removed)<br>ED-2<br>PC-05<br>STK-02<br>STK-03<br>STK-05<br>STK-06*** |

| **Summary Table: IQR Program Measures by Payment Determination Year<br>X= Mandatory Measure *Proposed Changes in Italics*** | | | | |
|---|---|---|---|---|
| | **2018** | **2019** | **2020** | **2021+** |
| VTE-4 VTE patients receiving un-fractionated Heparin with doses/labs monitored by protocol<br>VTE-5 VTE discharge instructions<br>VTE-6 Incidence of potentially preventable VTE<br>SCIP INF-1 Prophylactic antibiotic received within 1 hour prior to surgical incision<br>SCIP-INF-2 Prophylactic antibiotic selection for surgical patients<br>SCIP–INF-9 Postoperative urinary catheter removal on postoperative day 1 or 2 with day of surgery being day zero<br>ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital (NQF#0495)<br>ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status (NQF #0497)<br>PC-01 Elective delivery < 39 completed weeks gestation (NQF #0469)<br>PC-05 Exclusive breast milk feeding (NQF #0480)<br>Healthy term newborn<br>EDHI-1a Hearing screening prior to hospital discharge<br>CAC- 3 Children's asthma care – 3 | | VTE-1<br>VTE-2 | | ***VTE-1***<br>***VTE-2*** |
| **Healthcare-Associated Infection Measures** | | | | |
| Central Line Associated Bloodstream Infection (CLABSI) | X | X | X | *Remove* |
| Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy | X | X | X | *Remove* |
| Catheter-Associated Urinary Tract Infection (CAUTI) | X | X | X | *Remove* |
| MRSA Bacteremia | X | X | X | *Remove* |
| Clostridium Difficile (C. Diff) | X | X | X | *Remove* |
| **Healthcare Personnel Influenza Vaccination** | **X** | **X** | **X** | **X** |
| **Claims-Based Measures** | | | | |
| **Mortality** | | | | |
| AMI 30-day mortality rate | X | X | *Remove* | |
| Heart Failure (HF) 30-day mortality rate | X | X | *Remove* | |
| Pneumonia 30-day mortality rate | X | X | X | *Remove* |
| **Stroke 30-day mortality rate** | **X** | **X** | X | **X** |
| COPD 30-day mortality rate | X | X | X | *Remove* |
| CABG 30-day mortality rate | X | X | X | *Remove FY22* |
| **Readmission/ Coordination of Care** | | | | |
| AMI 30-day risk standardized readmission | X | X | *Remove* | |
| Heart Failure 30-day risk standardized readmission | X | X | *Remove* | |
| Pneumonia 30-day risk standardized readmission | X | X | *Remove* | |
| TKA/THA 30-day risk standardized readmission | X | X | *Remove* | |
| **Hospital-wide all-cause unplanned readmission** | **X** | **X** | **X** | **X** |
| Stroke 30-day risk standardized readmission | X | X | *Remove* | |
| COPD 30-day risk standardized readmission | X | X | *Remove* | |
| CABG 30-day risk standardized readmission | X | X | *Remove* | |
| Hybrid (claims+EHR) hospital-wide readmission | | | Voluntary | |
| Excess days in acute care after hospitalization for AMI | X | X | X | X |
| Excess days in acute care after hospitalization for HF | X | X | X | X |
| Excess days in acute care after hospitalization for PN | | X | X | X |
| **Patient Safety** | | | | |
| PSI-90 Patient safety composite (NQF #0531) | X | X | *Remove* | |

| Summary Table: IQR Program Measures by Payment Determination Year<br>X= Mandatory Measure *Proposed Changes in Italics* | | | | |
|---|---|---|---|---|
| | **2018** | **2019** | **2020** | **2021+** |
| **PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351)** | **X** | **X** | **X** | **X** |
| THA/TKA complications | X | X | X | *Remove FY 23* |
| **Efficiency/Payment** | X | X | X | |
| Medicare Spending per Beneficiary | X | X | *Remove* | |
| **AMI payment per 30-day episode of care** | **X** | **X** | **X** | **X** |
| **Heart Failure payment per 30-day episode of care** | **X** | **X** | **X** | **X** |
| **Pneumonia payment per 30-day episode of care** | **X** | **X** | **X** | **X** |
| **THA/TKA payment per 30-day episode of care** | **X** | **X** | **X** | **X** |
| Kidney/UTI clinical episode-based payment | | X | *Remove* | |
| Cellulitis clinical episode-based payment | | X | *Remove* | |
| Gastrointestinal hemorrhage clinical episode-based payment | | X | *Remove* | |
| Aortic Aneurysm Procedure clinical episode-based payment | | X | *Remove* | |
| Cholecystectomy/Common Duct Exploration episode-based payment | | X | *Remove* | |
| Spinal Fusion clinical episode-based payment | | X | *Remove* | |
| **Patient Experience of Care** | | | | |
| **HCAHPS survey + 3-item Care Transition Measure** | **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 | *Remove* | |
| Hospital Survey on Patient Safety Culture | X | X | *Remove* | |

## 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. 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. Currently, there are 11 PPS-exempt cancer hospitals.[35] Technical specifications for PCHQR Program measures are available on the QualityNet.org website.

In this rule, CMS discusses its Meaningful Measure Initiative and proposes to adopt the same new cost-related eighth measure removal criterion that it proposes for the Hospital IQR Program (see IV.A above). CMS further proposes to remove the following measures from the PCHQR Program beginning with FY 2021. The four cancer-related measures are proposed for removal because CMS has found that performance on these measures is topped out. The two NHSN

[35] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html

infection measures are proposed for removal under the newly proposed cost removal factor; CMS believes that the burden of reporting outweighs the benefits, especially because the volume of results is too low for public reporting and therefore of no use to beneficiaries.

- 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)
- NHSN CLABSI (NQF #0139)
- NHSN CAUTI (NQF #0138)

CMS proposes to add one new claims-based measure to the program, 30-Day Unplanned Readmissions for Cancer Patients (NQF #3188). The proposed 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.) Data collection for this measure would begin July 1 of the year 3 years prior to the program year to June 30 of the year 2 years prior to the program year. However, the proposed rule identifies the first data collection period as running from October 1, 2018 through September 20, 2019.

Previously adopted deadlines for public reporting of certain PCHQR Program measures are discussed. CMS proposes to defer public reporting of four measures until 2019 because 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 previously adopted and proposed public reporting dates for each measure.

CMS discusses issues regarding accounting for social risk factors in the PCHQR Program. This discussion is like the one summarized with respect to the HRRP in item IV.H.4 above.

Comments are sought 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 are 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.

In the impact analysis section of the proposed rule CMS estimates that the proposed removal of six measures from the PCHQRP would reduce burden for the 11 PPS-exempt cancer hospitals by a total of 27,709 hours.

| **Proposed PCHQR Program Measures for 2021 (*Proposals in Italics)*** | |
|---|---|
| **Measure** | **Public Display** |
| **Safety and Healthcare Associated Infection** | |
| Colon/Abdominal Hysterectomy SSI (NQF #0753) | *2019* |
| NHSN CDI (NQF #1717) | *2019* |
| NSHN MRSA bacteremia (NQF #1716) | *2019* |
| NHSN Influenza vaccination coverage among health care personnel (NQF #0431) | *2019* |
| **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** | |
| 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 Proposed for Removal 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 |
| *NHSN CLABSI (NQF #0139)* | |
| *NHSN CAUTI (NQF #0138)* | |

## 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 proposed 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 reviews the seven factors it currently uses to consider removal of a measure from the LTCH QRP and proposes addition of a new removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. (This proposed new removal factor is identical to the one proposed for the Hospital IQR Program as described above.) The current 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. Under the proposed rule, all the factors would be codified in regulatory text.

Three measures are proposed for removal from the LTCH QRP measure set.

- The NSHN MRSA infection measure would be 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 would be effective beginning with FY 2020 payment determination, and reporting beginning with October 1, 2018 admissions and discharges.
- The NHSN Ventilator-Associated Event (VAE) Outcome measure would be 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 would be effective beginning with FY 2020 payment determination, and reporting beginning with October 1, 2018 admissions and discharges.
- Percent of Residents or Patients Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) would be removed based on proposed 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 would be effective with FY 2021 payment determination and LTCHs would not have to report the associated data elements beginning October 1, 2018.

In the Collection of Information requirements section of the proposed rule, CMS estimates that removal of these measures would 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

CMS seeks 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.

5. Changes to Reconsideration Requirements

Changes to the regulatory text at 42 CFR 412.560(d) regarding reconsiderations would be to provide that instead of notifying an LTCH that it is noncompliant with LTCH QRP requirements through the QIES ASAP system, CMS would 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 would be used to communicate CMS' final decision regarding any reconsideration request.

| LTCH QRP Measures, by Year<br>*Proposals in Italics* | | | |
|---|---|---|---|
| **Measure Title** | **FY 2019** | **FY 2020** | **FY 2021** ***(proposed)*** |
| 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 | *Remove* |
| 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 | *Remove* |
| 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 | *Remove* |
| 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

CMS announces 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 an estimated reduction of 2.1 percentage points in the update factor for FY 2019. In the impact analysis section of this rule, 148 hospitals are estimated to not meet the meaningful use requirements for FY 2019 payment; 43 hospitals are estimated to fail to meet both the meaningful use and Hospital IQR Program requirements and are subject to an estimated total update factor reduction of 2.8 percentage points.

In this proposed rule CMS addresses certification requirements and proposes substantial changes to program policies including reporting periods and the scoring methodology used in determining whether hospitals have met the meaningful use requirements.

1. Certification Requirements Beginning in 2019

CMS proposes 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.) CMS discusses 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 2014 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 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. It has 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.

2. Reporting Periods for 2019 and 2020

CMS proposes that for 2019 and 2020, Medicare and Medicaid Promoting Interoperability Program participants would 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 would replace the current requirement that beginning in 2019 the EHR reporting period would be the full calendar year. CMS believes this proposal would allow providers to test systems and make adjustments to fully implement the 2015 Edition as well as to meet the requirement for use on a API to incorporate patient data. Furthermore, under this proposed rule eligible hospitals and CAHs would 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 proposed change would modify the definition of reporting period in 42 CFR 495.4 with respect to eligible providers (EPs) as well as eligible hospitals and CAHs.

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 proposes 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. It states its goals as reducing burden and increasing flexibility for hospitals while focusing on interoperability and patient access. 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 proposed new scoring system relies on fewer measures and eliminates the threshold-based methodology currently used. It would 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 would defer to the states. States would have the option to use the measures and scoring as proposed in this rule. This is discussed further in section VIII.D.10 below. The proposed new methodology for eligible hospitals and CAHs attesting to CMS beginning with 2019 reporting would be codified in a new subsection 42 CFR 495.24(e). Other conforming changes would be made to regulatory text.

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. CMS emphasizes that if it does not finalize a new scoring methodology, the current Stage 3 methodology would continue, but the new measures proposed in section VIII.D.5 would be added if they are finalized. The following table summarizes the current requirements and shows how the proposed new measures would be incorporated if they are adopted and the current scoring is retained in the final rule.

**Existing Stage 3 Objectives, Measures and Reporting Requirements for the Medicare EHR Incentive Program for Eligible Hospitals and CAHs**
***Proposed New Measures in Italics***

| Objective | Measure (Stage 3 Threshold) | Reporting Requirement |
|---|---|---|
| Protect Patient Health Information | Security Risk Analysis (Yes/No) | Report |
| Electronic Prescribing | e-Prescribing (>25%)<br><br>*Verify Opioid Treatment Agreement (at least one patient)*<br>*Query of Prescription Drug Monitoring Program (at least one patient)* | Report and meet threshold<br><br>*Report but only meet threshold for one* |
| Patient Electronic Access to Health Information | Provide Patient Access (>50%)<br>Patient Specific Education (>10%) | Report and meet thresholds |
| Coordination of Care Through Patient Engagement | View, Download or Transmit (at least one patient)<br>Secure Messaging (>5%)<br>Patient Generated Health Data (>5%) | Report all, but only meet the threshold for two |
| Health Information Exchange | Send a Summary of Care (>10%) Request/Accept Summary of Care (>10%)<br>Clinical Information Reconciliation (>50%) | Report all, but only meet the threshold for two |
| Public Health and Clinical Data Registry Reporting | Immunization Registry Reporting Syndromic Surveillance Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting | Report Yes/No to Three Registries |

The proposed new methodology requires eligible hospitals and CAHs to report on four objectives and six measures. What it refers to as the burdensome pre-defined performance thresholds would be eliminated, and instead points would be awarded for individual measures based on performance or participation. A score of 50 points or more would satisfy the meaningful use requirement; eligible hospitals and CAHs earning a score of less than 50 points would not be considered meaningful users. CMS believes the proposed scoring approach would 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 proposed rule to display the proposed objectives, measures and points for meaningful use scoring for 2019 and 2020.

CMS seeks public comment on other approaches. In particular, it considered an alternative approach under which scoring would occur at the objective level and an eligible hospital or CAH would report on one measure from each objective for a total of four measures. The four objectives would be given weight similar to the proposed methodology, and bonus points would be awarded for additional measures reported beyond the required four. Comments are also sought on other scoring alternatives and on whether additional flexibilities should be provided, such as allowing eligible hospitals and CAHs to select among measures within an objective.

**Proposed 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, Required in 2020:* Verify Opioid Treatment Agreement | 5 points (bonus) | 5 points |
| 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 | 35 points |
| Public Health and Clinical Data Exchange | Syndromic Surveillance Reporting (Required)<br><br><u>Choose one or more additional:</u><br>Immunization Registry Reporting<br>Electronic Case Reporting<br>Public Health Registry Reporting<br>Clinical Data Registry Reporting<br>Electronic Reportable Laboratory Result Reporting | 10 points | 10 points |

CMS chose the smaller set of objectives to reflect HHS priorities. It believes the e-Prescribing and Health Information Exchange objectives reflect core goals of the 2015 Edition for interoperability, while the Provider to Patient Exchange promotes patient awareness and involvement. The Public Health and Clinical Data Exchange objective supports systematic collection, analysis and interpretation of data for use in preventing and controlling disease.

Comments are sought on the proposed weighting of the objectives and measures, and whether a different distribution, such as equal weighting of measures would be more suitable.

*e-Prescribing Objective (1 to 3 measures; 5 to 15 points)*. For 2019 reporting, the e-Prescribing objective would include the existing e-prescribing measure, weighted at 10 points, and two optional new measures (discussed in section VIII.D.5 below) for which five bonus points each could be earned. If an eligible hospital or CAH meets the criteria for exclusion for the e-prescribing measure in 2019, the 10 points for this objective would be redistributed equally between the two measures in the Health Information Exchange objective. The exclusion criteria would be unchanged from current regulations. For 2020, all three measures would be required, with new exclusions available. In a case where the hospital or CAH claims an exclusion for all three measures in this objective, the 15 points would be divided equally among the three measures in the Health Information Exchange objective and the provide patients electronic access to their health information measure. If exclusions apply only to one or both of the new measures, the points would be added to the e-prescribing measure. The addition of the two proposed new measures as required measures at 5 points each beginning in 2020 would be

accompanied by a decrease in the points for the e-prescribing measure (from 10 to 5) and the patient access measure (from 40 to 35).

*Health Information Exchange Objective (2 measures; 40 points).* For this objective CMS proposes two measures worth 20 points each. The heavy weighting of this objective is proposed to emphasize the sharing of health information through interoperable exchange to promote care coordination and better patient outcomes. CMS proposes to change the name of one measure (from Send a Summary of Care to Support Electronic Referral Loops) and to add 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 would be worth 20 points. An exclusion is proposed for 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. In that case, the Support Electronic Referral Loops measure would be worth all 40 points. CMS specifically seeks comments as to whether the points should be redistributed to other measures instead.

*Provider to Patient Exchange Objective (1 measure; 35 to 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, in 2019 the Provide Patients Electronic Access to Their Health Information measure would be worth 40 points to emphasize the importance of patients having control over their own health information.

*Public Health Data Exchange Objective (2 measures; 10 points)*. These measures cannot be scored on performance and would be reported using a yes/no response. An eligible hospital or CAH would be required to meet this objective in order to receive a score and be considered a meaningful user of EHR. All eligible hospitals and CAHs would be required to report the Syndromic Surveillance Reporting measure and to choose one additional measure for reporting from among five other available measures (shown in the table above). 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 would be available for reporting more than two measures. Reporting 'yes' on only one measure for this objective would result in a score of zero for the objective and also for the total Promoting Interoperability score. Previously finalized exclusions for these measures would be continued. If an eligible hospital or CAH claims an exclusion for one or both measures required for this objective, the 10 points would be redistributed to the Provider to Patient Exchange objective, raising that weight to 50 points for 2019 (45 points for 2020).

*Attestation to Stage 3 Objective: Protect Patient Health Information*. CMS says that the Stage 3 objective Protect Patient Health Information and the associated Security Risk Analysis measure would remain part of the program but would not be individually scored. Instead, in order to receive any Promoting Interoperability score, eligible hospitals and CAHs would have to 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 would already be meeting the requirements of this objective and measure as a result of requirements under the Health

Insurance Portability and Accountability Act (HIPAA). CMS seeks comments on whether it should assign points for this measure.

*Assignment of Performance Points.* Performance points would be assigned for each measure as follows. As a requirement for receiving a score, each eligible hospital and CAH would submit complete numerator/denominator and yes/no data for all required measures. The numerator and denominator would translate into a performance rate which would be 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 would be awarded). CMS would 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 would be summed into the total score. The proposed rule includes a table showing a numerical example for the proposed scoring methodology.

CMS acknowledges that the requirement to report on all measures and to report yes on all yes/no measures maintains an "all-or-nothing" element to the meaningful use requirements. However, it believes by requiring fewer measures and providing more flexibility with the performance-based scoring approach, its proposal reduces provider burden. Comments are specifically sought on whether allowing reporting on a subset of optional measures would be appropriate.

*Minimum Score for Meaningful User Designation.* In discussing the proposal to use a 50-point minimum score for determining meaningful use, CMS says that while its vision is for every eligible hospital and CAH to perform at 100 percent for all of the objectives and measures, it seeks to be realistic about what can be achieved and to provide flexibility for hospitals to create their own score using measures that are best suited to their practice. It may propose to adjust the minimum score over time as eligible hospitals and CAHs adjust to the new focus and scoring methodology. Comments are sought on whether a higher or lower minimum score would be better suited for the first year of this new scoring methodology.

In review, in order to be considered a meaningful user beginning with the 2019 reporting year under the proposed new scoring methodology, an eligible hospital or CAH would have to 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 would result in a total score of zero

CMS also seeks public comment on the feasibility of the proposed new scoring methodology for 2019, and how the program should evolve in future years with respect to scoring methodology and related program aspects.

4. Measures for Eligible Hospitals and CAHs under the Medicare Promoting Interoperability Program

In constructing the proposed scoring methodology described immediately above, CMS proposes to reduce the number of measures required for a hospital or CAH attesting to meaningful use under the Medicare Promoting Interoperability Program. CMS believes that the proposed smaller number of required measures would focus the program on interoperability and patient access.

The changes would add three new measures and remove six existing measures; these changes are detailed below. One of the new measures would combine the functionality and goals of two of the measures that would be removed. For 2019, that new measure would be required, with exclusions, while the other two new measures would be optional until 2020. Some of the other remaining objectives and measures would be 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 would be removed from all the retained Stage 3 measures with exceptions. The measures with exclusion criteria are those associated with the e-Prescribing objective, the Public Health and Clinical Data Exchange objective, and the three proposed new measures (of which two are e-prescribing measures). The exclusion criteria related to broadband availability would be 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.

CMS reiterates that the proposed changes to measures would only apply with respect to the Medicare Promoting Interoperability Program and would not apply to Medicaid-only eligible hospitals that submit an attestation to their state Medicaid agency for the Medicaid Promoting Interoperability Program. CMS does not believe an exclusion based on the number of transitions or referrals received or new patient encounters is warranted for any of the measures associated with the Health Information Exchange objective.

The proposed rule includes the following table which summarizes the proposals for retaining, modifying, removing and adding measures. CMS states that if the final rule does not adopt a new scoring methodology, the proposed changes in objectives and measures would not be finalized. The current objectives, measures, scoring methodology would be retained and the two new opioid measures would be added.

| **Measure Status** | **Measure** |
|---|---|
| Measures retained from Stage 3 with no modifications<br><br>(The Security Risk Analysis measure is retained as a requirement but is not included in the proposed scoring methodology.) | e-Prescribing<br>Immunization Registry Reporting<br>Syndromic Surveillance Reporting<br>Electronic Case Reporting<br>Public Health Registry Reporting<br>Clinical Data Registry Reporting<br>Electronic Reportable Laboratory Result Reporting |
| Measures retained from Stage 3 with modifications | Send a Summary of Care (Proposed Name: Supporting Electronic Referral Loops by Sending Health Information)<br>Provide Patient Access (Proposed Name: Provide Patients Electronic Access to Their Health Information) |

| Measure Status | Measure |
|---|---|
| Removed measures | Request/Accept Summary of Care Clinical Information Reconciliation Patient-Specific Education<br>Secure Messaging<br>View, Download or Transmit<br>Patient Generated Health Data |
| New measures | Query of Prescription Drug Monitoring Program (PDMP)<br>Verify Opioid Treatment Agreement<br>Support Electronic Referral Loops by Receiving and Incorporating Health Information |

CMS notes that the proposed changes to the Health Information Exchange objective do not affect standards the certification criteria and standards finalized for the 2015 Edition (80 FR 62601-62759). Because of this it believes that the proposed changes could potentially be implemented in time for the 2019 reporting period.

5. Proposed New e-Prescribing Measures

CMS reviews the HHS Opioid Strategy and proposes to add two new measures which it believes align with the HHS objectives 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 proposed new opioid measures summarized briefly here are described in detail in the proposed rule, and the specific requirements are spelled out in proposed new regulatory text at 42 CFR 495.24(e)(5)(iii). CMS proposes that for both measures opioids would be defined as Schedule II controlled substances and that existing policies for the e-prescribing measure would apply, including the requirement that CEHRT be used as the sole means of creating the prescription and transmitting it to the pharmacy.

If the proposed new scoring system is not adopted but the new measures are adopted, eligible hospitals and CAHs would be required in 2019 to report on all three measures associated with the e-Prescribing objective but would only be required to meet the threshold for the existing e-prescribing measure (or claim the exclusion).

The existing exclusion for the e-prescribing measure would also be adapted to the proposed new measures: Any 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. Eligible hospitals and CAHs claiming this exclusion for the existing e-prescribing measure would automatically receive an exclusion for all three measures. If the proposed new scoring system is adopted in the final rule, an additional exclusion would begin in 2020 for those providers that could not report on the new measure in accordance with applicable law.

*Query of PDMP* would assess 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. CMS proposes that the PDMP query would have to be conducted before the electronic transmission of the prescription. The proposed threshold for this measure (should the proposed new scoring methodology not be finalized) would be at least one 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 addition to reaction to the proposed measure, CMS seeks comment on a number of specific issues:

- Under the proposal, multiple opioid prescriptions prescribed on the same day would not require multiple queries of the PDMP, and CMS seeks comment on whether it should further refine the measure to limit queries of the PDMP to once during a hospital stay regardless of whether multiple Schedule II opioids are prescribed.
- CMS acknowledges that PDMP integration into CEHRT is not widespread, and it may require eligible hospitals and CAHs to manually enter data into CEHRT to document the completion of the PDMP query. Further, the measure may not be machine calculable. CMS seeks comment on whether ONC should consider adopting standards and certification criteria to support the query of a PDMP, and what timeline CMS should require for use with this measure.
- Comments are sought on the challenges associated with querying the PDMP with and without CEHRT integration and whether the measure should require certain standards, methods or functionalities to reduce burden.
- Do health care providers and IT developers believe that the NCPDP SCRIPT 2017071 standard for e-prescribing can support eligible hospitals and CAHs seeking to report on this measure? Should HHS encourage use of this standard through separate rulemaking?
- What are perceived and real technological barriers to the implementation of electronic prescribing for controlled substances (EPCS), including two-factor authentication? Could telehealth modalities support established patient provider relationships subsequent to in-person visit(s) and for prescribing purposes?
- Comments are sought on limiting the exclusion criteria to electronic prescription for controlled substances and whether there are circumstances which may justify any additional exclusions for the Query of PDMP measure.

*Verify Opioid Treatment Agreement* would assess the percentage of patients for whom a Schedule II opioid was prescribed during the EHR reporting period 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 would be 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. CMS proposes this six-month look-back element to the measure to identify egregious cases of overuse of opioids and to cover timeframes outside the EHR reporting period. The look-back period would be 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). The proposed threshold for this measure (should the proposed new scoring methodology not be finalized) would be at least one unique patient.

CMS discusses the debate over the value of opioid treatment plans, and seeks specific comment on:

- Challenges associated with opioid treatment agreements and how they could impact the feasibility of the proposed measure, how any challenges might be mitigated, and whether this measure should be included in the Promoting Interoperability Program.
- Burdens in identifying whether a treatment agreement exists and pathways to facilitate the identification and exchange of treatment agreements and opioid abuse treatment planning. CMS cites pilot projects focused on increasing connectivity and data exchange among providers for this purpose.
- CMS is not proposing to define an opioid treatment agreement, define its data elements, content structure or clinical purpose. It seeks comment on what characteristics should be included in an opioid treatment agreement and incorporated into CEHRT?
- What methods or processes could be used to incorporate the treatment agreement into CEHRT?
- Are there specific data elements that are currently standardized that should be incorporated via reconciliation? Could the patient health data capture functionality be used to incorporate a treatment plan that is not a structured document with structured data elements?

CMS also seeks comment on whether it should explore adoption of a measure focused only on the number of Schedule II opioids prescribed and the successful use of electronic prescribing for controlled substances (ECPS) for permissible prescriptions electronically prescribed. Comments are requested on the feasibility of such a measure and whether it would encourage broader adoption of ECPS.

6. Modifications to the Health Information Exchange Objective Measures

CMS proposes a number of changes to the measures associated with this objective, including renaming, combining, and adding measures. The proposed changes are in response to stakeholder concerns regarding implementation of effective health information technology (IT)-supported workflows, complexity and burden associated with manual tracking of workflows to support health IT measures. CMS emphasizes the importance of using health IT to support closing the referral loop to improve care coordination. It believes the proposals will address stakeholder concerns and generally streamline the measures to remove redundancy and reduce complexity and burden. If the proposed new scoring methodology is not finalized, the measures and scoring for this objective would not change.

*Modifications to Send a Summary of Care Measure*. CMS proposes to rename 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 proposed new scoring methodology, the existing 10 percent threshold for this measure would be removed, and the measure would be required for at least one transition of care or referral.

CMS discusses the history of this measure and makes clarifications, including which transitions and referrals are included in the denominator and the ability of providers to constrain the

information transmitted in the summary care record to support transitions of care. Further, CMS proposes that 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 proposed flexibility will support efforts to ensure that the information provided during a care transition is relevant.

*Removal of the Request/Accept Summary of Care Measure and the Clinical Information Reconciliation Measure*. CMS proposes to remove these measures based on stakeholder input and its 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 have 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 proposed new measure would build on and replace the two measures proposed for removal from this objective. The measure would assess 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 would no longer be 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. If the proposed new scoring methodology is adopted, an exclusion would be available for eligible hospitals and CAHs that could not implement the proposed new measure for an EHR reporting period in CY 2019.

Comments are sought on whether this new measure should be adopted or the existing two measures retained, and on the following specific issues regarding this measure:

- Existing policy would be continued to allow the eligible hospital or CAH to count in the numerator cases in which it determines no update or modification is necessary within the patient record based on the electronic clinical information received. CMS seeks comments on methods by which this specific action could potentially be electronically measured by the provider's health IT system.
- Methods and approaches to quantify the reduction in burden for eligible hospitals and CAHs implementing streamlined workflows under the proposed measure.
- The impact on health IT developers in updating, testing, and implementing new measure calculations. Should ONC require developers to recertify their EHR technology as a result of the changes proposed, or should they be able to make the changes and engage in testing without recertification?

Like the current measures associated with the Health Information Exchange objective, both measures proposed for this objective could be calculated to include only actions for patients whose records are maintained using CEHRT rather than for all patient records.

7. Measures for the Provider to Patient Exchange Objective

CMS proposes to change 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 would be removed from this objective, while the Coordination of Care Through Patient Engagement objective and three associated measures are also proposed for removal. If the proposed new scoring methodology is not adopted, none of these changes would be finalized. The one measure remaining in this objective would also be renamed "Provide Patients Electronic Access to Their Health Information" and modified to remove the current 50 percent threshold consistent with the proposed changes in the scoring methodology. The measures would require action for at least one unique patient.

*Removal of the Patient Specific Education Measure*. CMS proposes to remove this measure because 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 would be other resources and materials otherwise available to patients and the measure could increase the burden on providers in seeking additional materials.
*Removal of Patient Generated Health Data Measure*. CMS proposes to remove 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 believes that this measure does not align with the current program emphasis on interoperability, and 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 proposes to remove this measure based on the feedback it received from stakeholders regarding concerns about measures that require patient actions for successful provider attestation.

8. Measures for the Public Health and Clinical Data Registry Reporting Objective

CMS proposes to change the name of this objective to "Public Health and Clinical Data Registry Reporting" and to require eligible hospitals and CAHs to report the Syndromic Surveillance

Reporting measure and one other measure selected from among five other available measures. The value of syndromic surveillance EHR data to the CDC is highlighted, and CMS notes that the EHR Incentive Program has enabled the growth of syndromic surveillance nationally and allowed public health departments to better identify and respond to emerging health threats. Nonetheless, CMS seeks to reduce burden and therefore is proposing that providers report on only two measures for this objective instead of three as currently required. If the proposed new scoring methodology is not adopted, these changes would not be finalized, and the current measures and requirements would continue to apply in 2019 reporting.

Furthermore, CMS states its intention to propose removal of this objective from the Promoting Interoperability Programs no later than the 2022 reporting year, and seeks comments on identifying other appropriate venues in which reporting to public health and clinical data registries could be encouraged, the role that these agencies and registries should have in the Promoting Interoperability Programs, and whether these programs are the best means to promote sharing data with public health entities.

9. Request for Comment on Potential New Health Information Exchange Measures

CMS seeks 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.
"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.

"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.

CMS specifically seeks comments on whether these two potential measures should be combined into a single measure, whether inclusion could be adopted as early as 2019 or should be considered for a later date, and whether the measure(s) should be focused specifically on information exchange with long-term and post-acute care providers, or whether such a narrowing should be at the option of the reporting eligible hospital or CAH. CMS also seeks comments on the impact these measures could have on health IT developers regarding developing, testing and implementing a new measure calculation.

10. Application of Scoring Methodology to the Medicaid Promoting Interoperability Program

As noted earlier, CMS proposes to give states the option to adopt the proposed 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 seeks public comment on whether to modify the objectives and measures for eligible professionals in the Medicaid Promoting Interoperability Program in order to encourage greater interoperability. Comments are also sought on policy options with respect to these providers including the benefits of greater alignment with the Merit Based Incentive Payment System (MIPS).

Under this proposed rule, eligible hospitals and CAHs that participate in both the Medicare and Medicaid Promoting Interoperability Programs would demonstrate meaningful use to CMS and not their state Medicaid agency. If they meet the Medicare definition they would (under current regulations) be deemed to be meaningful users for purposes of Medicaid incentive payments. That proposal is made because under the proposed new scoring methodology there would no longer be a common definition of meaningful between the two programs.

CMS proposes to modify the requirements for state reporting to CMS to no longer require states to report provider level attestation data for program years after 2018.

11. Future Directions

CMS seeks 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 seeks 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.

Comments are sought on the concept of adopting these activities and on the specific activities mentioned in the proposed rule or others that add value for patients and health care providers, are relevant to patient care and clinical workflows, support alignment with existing objectives, promote flexibility, are feasible for implementation, are innovative in the use of health IT and promote interoperability.

Comments are also sought on the following questions:

- What health IT activities should CMS consider recognizing in lieu of reporting on objectives that would most effectively advance priorities for nationwide interoperability and spur innovation? What principles should CMS employ to identify health IT activities?

- Do stakeholders believe that introducing health IT activities in lieu of reporting on measures would decrease burden associated with the Promoting Interoperability Programs?
- If additional measures were added to the program, what measures would be beneficial to add to promote CMS goals of care coordination and interoperability?
- How can the Promoting Interoperability Program for eligible hospitals and CAHs further align with the Quality Payment Program (for example, requirements for eligible clinicians under MIPS and Advanced APMs) to reduce burden for health care providers, especially hospital-based MIPS eligible clinicians?
- What other steps can HHS take to further reduce the administrative burden associated with the Promoting Interoperability Program?

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 proposes to reduce the number of available eCQMs from sixteen to eight. The eCQMs are proposed for removal 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 proposed for removal 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 proposed for removal 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 would perfectly align. Removal for FY 2022 payment (CY 2020 reporting) is proposed rather than an earlier date because stakeholders have previously emphasized the time needed for vendors and hospitals to make eCQM changes. CMS believes that waiting until the

2020 reporting year to make changes will assist hospitals that have already expended resources in preparation for the 2019 reporting year.

*2019 Reporting Period.* For 2019, CMS proposes to continue the policies in place for reporting during 2018. That is, eligible hospitals and CAHs that report eCQMs electronically would report for one self-selected calendar quarter of 2019 data, and the submission deadline would be 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 would also be February 29, 2020. States have the flexibility to determine the method of reporting and submission periods, subject to CMS approval.

Further, for 2019 eligible hospitals and CAHs reporting electronically would continue to report on 4 selected eCQMs from the current list of 16 available measures. Those reporting by attestation would report on all 16 available eCQMs. The form and manner of reporting are explained in subregulatory guidance and documents are available from the eCQI Resource Center webpage at https://ecqi.healthit.gov/. Reporting for 2019 would continue through the QualityNet Portal, and CMS also proposes to continue 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.

*Request for Comment on eCQMs.* CMS discusses stakeholder concern about the burdens of eCQM reporting, and invites comment on the following questions:

- What aspects of the use of eCQMs are most burdensome to hospitals and health IT vendors?
- What program and policy changes, such as improved regulatory alignment, would have the greatest impact on addressing eCQM burden?
- What are the most significant barriers to the availability and use of new eCQMs today?
- What specifically would stakeholders like to see CMS do to reduce burden and maximize the benefits of eCQMs?
- How could CMS encourage hospitals and health IT vendors to engage in improvements to existing eCQMs?
- How could CMS encourage hospitals and health IT vendors to engage in testing new eCQMs?
- Would hospitals and health IT vendors be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would explore less

burdensome ways of approaching quality measurement, such as sharing data with third parties that use machine learning and natural language processing to classify quality of care or other approaches?

- What ways could CMS incentivize or reward innovative uses of health IT that could reduce burden for hospitals?
- What additional resources or tools would hospitals and health IT vendors like to have publicly available to support testing, implementation, and reporting of eCQMs?

13. Participation of Subsection (d) Puerto Rico Hospitals

CMS proposes to codify in regulatory text the program instructions it has issued regarding the participation of subsection (d) Puerto Rico hospitals to 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 would apply beginning with FY 2022 payment, and conforming changes are made to various regulations to reflect this. General deadlines for hardship exception requests would 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 CERHT and for application of the downward payment adjustment for MA organizations with affiliated hospitals that are not meaningful users of CEHRT. CMS proposes changes to 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 discusses the history of federal payments to states for administration of the Medicaid Promoting Interoperability Program payments. It proposes 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 Systems. Further, because state Medicaid Promoting Interoperability Program incentive payments to Medicaid eligible professionals and hospitals may not be made after December 31, 2021, CMS proposes 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 would be extended to September 30, 2023.

## 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. Proposed 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. In this proposed rule, CMS is proposing 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.

2. Intern and Resident Information System (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.

CMS collected the IRIS data from hospitals on a diskette. Because diskettes are no longer used by providers to furnish these data to contractors, in this proposed rule, CMS is proposing to remove the reference in the regulations to a diskette and instead reference "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 is proposing the IRIS data must contain the same total counts of direct GME FTE residents (unweighted and weighted) and of IME FTE residents as the total counts of direct GME FTE and IME FTE residents reported in the hospital's cost report or the cost report will be rejected for lack of supporting documentation.

The rule further notes that CMS is in the process of producing a new Extensible Markup Language (XML)-based IRIS file format that captures FTE resident count data consistent with the manner in which FTEs are reported on the Medicare cost report.

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) described above 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 proposes to 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. This proposal is also consistent with a provider's recordkeeping and cost reporting requirements of 42 CFR §§413.20 and 413.24 and would facilitate the contractor's review and verification of the cost report.

4. Disproportionate Share Hospital (DSH) Payment Adjustment

Medicare DSH payments are based, in part, on the hospital's number of patient days for patients who are eligible for Medicaid, but were not entitled to benefits under Medicare Part A. While hospitals are required to maintain documentation of Medicaid eligible days, there is no

requirement for the hospital to submit a listing of its Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's cost report. Currently, when this information is not submitted by the DSH eligible hospital with the cost report, contractors must request it. An audit may reveal an overstatement of a hospital's Medicaid eligible days. However, an audit of these data may not take place for more than a year after the cost report has been submitted, and tentative program reimbursement payments are often issued to a provider upon the submission of the cost report.

CMS is proposing that, 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 or an addendum to the original listing of the hospital's Medicaid eligible days that corresponds to the Medicaid eligible days claimed in the hospital's amended cost report would be required.

The proposed rule indicates that this new proposed requirement 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.

CMS further states that the proposal would not affect a hospital's ability to submit an amended cost report within 12 months after the hospital's cost report is due that reflects updated information on Medicaid eligible patient days after the hospital receives updated Medicaid eligibility information from the State.

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. (See section IV. F. for more details for how the national uncompensated care pool is established). 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.

Currently there is no requirement for a DSH-eligible hospital to submit supporting documentation with its cost report to substantiate charity care or other discounts in order for cost report submission to be acceptable. When the documentation to support charity care charges and uninsured discounts is not submitted by DSH eligible hospitals with the cost report, contractors must request it. The proposed rule indicates that requiring this supporting information to be

submitted 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.

Effective for cost reporting periods beginning on or after October 1, 2018, CMS is proposing that the provider's cost report would be rejected for lack of supporting documentation if it does not include 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 document with the hospital's cost report. CMS indicates that because the existing burden estimate for a DSH eligible hospital's cost report already reflects the requirement that these hospitals collect, maintain, and submit this data when requested, there is no additional burden associated with its proposal.

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 constitutes the documentary support required of the provider to be reimbursed for home office costs in the provider's cost report 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.

The proposed rule indicates the following CMS concerns:

- 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. The proposed rule further indicates that having this information submitted with the cost report would facilitate the contractor's review and verification of the cost report without needing to request additional data from the provider.

CMS is proposing that, effective for cost reporting periods beginning on or after October 1, 2018, a provider must have a Home Office Cost Statement completed by the home office or chain organization with amounts that correspond to those on the provider's cost report as supporting documentation. Consistent with this proposal, CMS proposes to reject costs reports that do not include this information. CMS indicates that this proposal will result in no additional provider burden because the existing burden estimate for a provider's cost report already reflects the requirement that providers collect, maintain, and submit this data.

## X. Hospital Requirements to Publicly List Standard Charges

The Affordable Care Act established section 2718(e) of the Public Health Service Act. This provision requires each hospital operating within the United States to 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 proposed 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 also seeking public comment on the following:

- Should "standard charges" be defined to mean: average or median rates for the items on the chargemaster; average or median rates for groups of services commonly billed together (such as for an MS-DRG), as determined by the hospital based on its billing patterns; or the average discount off the chargemaster amount across all payers, either for each item on the chargemaster or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of the average contracted rate and the chargemaster? Or is the best measure of a hospital's standard charges its chargemaster?

- What types of information would be most beneficial to patients, how can hospitals best enable patients to use charge and cost information in their decision-making, and how can CMS and providers help third parties create patient-friendly interfaces with these data?

- Should health care providers be required to inform patients how much their out-of-pocket costs for a service will be before those patients are furnished that service? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? What can be done to better inform patients of these obligations? Should health care providers play any role in helping to inform patients of what their out-of-pocket obligations will be?

- Should CMS require health care providers to provide patients with information on what Medicare pays for a particular service performed by a health care provider? If CMS were to finalize a requirement that this information be made available to beneficiaries by health care providers, what changes would need to be made by health care providers? What corresponding regulatory changes would be necessary?

CMS also asks for input on the following questions that it is considering for future rulemaking:

- What is the most appropriate mechanism for CMS to enforce price transparency requirements?
- Should CMS require hospitals to attest to meeting requirements in the provider agreement or elsewhere?
- How should CMS assess hospital compliance?
- Should CMS publicize complaints regarding access to price information or review hospital compliance and post results?
- What is the most effective way for CMS to publicize information regarding hospitals that fail to comply?
- Should CMS impose civil money penalties on hospitals that fail to make standard charges publicly available as required by section 2718(e) of the Public Health Service Act?
- Should CMS use a framework similar to the Federal civil penalties under 45 CFR §158.601 that apply to issuers that fail to report information and pay rebates related to medical loss ratios, as required by sections 2718(a) and (b) of the Public Health Service Act, or would a different framework be more appropriate?

In addition, CMS requests public comment on the following to improve its understanding of out-of-pocket costs for patients with Medigap coverage:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care?
- What challenges do providers face in providing information about out-of-pocket costs to patients with Medigap?
- What changes would be needed to support providers sharing out-of-pocket cost information with patients that reflects the patient's Medigap coverage?
- Who is best situated to provide patients with Medigap coverage clear information on their out-of-pocket costs prior to receipt of care?
- What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

The rule also notes that CMS includes a file its website with total Medicare discharges, average covered charges, average total payments, and average Medicare payments by hospital. The data is augmented to include provider characteristics and hospital referral region. Data are currently

available for FYs 2011 through 2015 for more than 3,000 IPPS hospitals within the 50 United States and District of Columbia. These data are available at:

https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Inpatient.html

## 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 revising 42 CFR §424.11(c) to relocate the statement indicating where in the medical record the information can be found to the end of the immediately preceding paragraph (b), which describes similar kinds of flexibility that are currently afforded in terms of completing the required statement.

## XII. Request for Information on Promoting Electronic Interoperability

CMS discusses the status of adoption of health IT among Medicare and Medicaid participating providers. It says that as of 2015, 96 percent of hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care, yet significant obstacles to electronic exchange of health information remain. It reviews CMS and Office of National Coordinator (ONC) initiatives and regulatory activities aimed at advancing health information exchange. The January 2018 ONC draft Trusted Exchange Framework and Common Agreement (TEFCA)[36] is highlighted.

CMS is interested in feedback from stakeholders on how it should use the Conditions of Participation (CoPs), Conditions of Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities to advance electronic exchange of health information in support of care transitions between hospitals and community providers. As an example, CMS says it might consider revising the hospital CoPs to require that hospitals electronically transfer medically necessary patient information to the other facility when a patient is transferred. Similarly, they might require that hospitals electronically send discharge information to a patient's community provider when possible, and to provide discharge instructions electronically to patients or a third-party application, if requested.

[36] The draft is available at https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement

Relevant provisions of proposed CoP regulations are discussed including the November 3, 2015 proposed rule to implement provisions of the IMPACT Act (80 FR 68126), June 16, 2016 proposed changes to CoPs for hospitals and CAHs (81 FR 39448), and an October 4, 2016 final rule on requirements for LTC facilities (81 FR 68688).

In this rule, CMS requests stakeholder feedback on the following questions:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?
- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?
- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?
- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid HER Incentive Programs)?
- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?
- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?
- Are there any other operational or legal considerations (for example, HIPAA), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?
- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements, should be allowed under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP including CEHRT hardship or small practices be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

In addition, CMS discusses the MyHealthEData initiative to promote patient access to their medical records and the Blue Button 2.0 initiative for beneficiary access to Medicare claims information through API technology.

CMS seeks ideas from the public on how best to accomplish the goal of fully interoperable health IT and EHR systems for providers and suppliers and how to advance the MyHealthEData initiative for patients. In particular, it would like to identify fundamental barriers to interoperability and patient access and how they might be reduced through revisions to the CoPs, CfCs, and RfPs for hospitals and other Medicare providers and suppliers. CMS has a particular interest in hearing about issues for providers and suppliers who are ineligible for the Medicare and Medicaid EHR Incentives program, such as long-term care and post-acute care providers, behavioral health providers, clinical laboratories and social service providers.

The usual disclaimers applied to a Request for Information are included.

## XIII. MedPAC Recommendations

CMS reports that it reviewed MedPAC's March 2018 "Report to the Congress: Medicare Payment Policy" and considered the report's recommendations in developing the policies included in this proposed rule. CMS addresses MedPAC's recommendations for the IPPS for FY 2019 in Appendix B of the proposed rule.

## XIV. Other Required Information

This section includes a listing and description data files that are available with the proposed rule. All of those files are available at the link provided at the front of this summary or in links provided in the part of the summary that describe the relevant provision.

In addition, this section describes the information collection requirements associated with specific provisions of this proposed rule. Any relevant issues associated with the information collection requirements described in this section are included elsewhere in this summary where the issue is otherwise described.

# Appendix: IPPS Regulatory Impact Analysis Table

## TABLE I.—IPPS OPERATING IMPACT ANALYSIS: PROPOSED RULE FY 2019

| | Number of Hospitals[1] | Proposed Hospital Rate Update and Adjustment under MACRA (1)[2] | Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3] | Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3) [4] | FY 2019 MGCRB Reclassifications (4) [5] | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6] | Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6) [7] | All Proposed FY 2019 Changes (7) [8] |
|---|---|---|---|---|---|---|---|---|
| **All Hospitals** | 3,257 | 1.7 | 0 | 0 | 0 | 0 | 0.1 | 2.1 |
| **By Geographic Location:** | | | | | | | | |
| Urban hospitals | 2,480 | 1.7 | 0 | 0 | -0.1 | 0 | 0.1 | 2.1 |
| Large urban areas | 1,310 | 1.7 | 0.1 | 0 | -0.7 | -0.1 | 0 | 2.1 |
| Other urban areas | 1,170 | 1.7 | 0 | 0 | 0.5 | 0.1 | 0.2 | 2.1 |
| Rural hospitals | 777 | 1.4 | -0.3 | -0.1 | 1.4 | -0.2 | 0.1 | 1.1 |
| **Bed Size (Urban):** | | | | | | | | |
| 0-99 beds | 638 | 1.6 | -0.3 | 0 | -0.7 | 0 | 0.2 | 1.4 |
| 100-199 beds | 763 | 1.7 | 0 | 0 | -0.2 | 0.1 | 0.2 | 1.7 |
| 200-299 beds | 438 | 1.7 | 0 | 0 | 0.2 | 0 | 0.1 | 2.1 |
| 300-499 beds | 427 | 1.7 | 0 | 0 | 0 | -0.1 | 0.1 | 2.1 |
| 500 or more beds | 214 | 1.7 | 0.1 | 0 | -0.2 | 0 | 0 | 2.5 |
| **Bed Size (Rural):** | | | | | | | | |
| 0-49 beds | 299 | 1.2 | -0.8 | 0.1 | 0.5 | -0.1 | 0.3 | 0.8 |
| 50-99 beds | 279 | 1.4 | -0.5 | -0.1 | 0.7 | -0.1 | 0.2 | 1 |
| 100-149 beds | 116 | 1.4 | -0.3 | 0.2 | 1 | -0.1 | 0 | 1 |

| | Number of Hospitals[1] | Proposed Hospital Rate Update and Adjustment under MACRA (1)[2] | Proposed FY 2019 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3] | Proposed FY 2019 Wage Data with Application of Wage Budget Neutrality (3) [4] | FY 2019 MGCRB Reclassifications (4) [5] | Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6] | Proposed Application of the Frontier Wage Index and Outmigration Adjustment (6) [7] | All Proposed FY 2019 Changes (7) [8] |
|---|---|---|---|---|---|---|---|---|
| 150-199 beds | 44 | 1.5 | -0.2 | -0.4 | 1.9 | -0.2 | 0.2 | 1 |
| 200 or more beds | 39 | 1.6 | 0 | -0.1 | 2.8 | -0.2 | -0.1 | 1.5 |
| **Urban by Region:** | | | | | | | | |
| New England | 113 | 1.7 | 0 | -0.5 | 1.3 | 2.2 | 0.1 | 2.8 |
| Middle Atlantic | 310 | 1.7 | 0.1 | 0 | 0.2 | -0.3 | 0.1 | 1.9 |
| South Atlantic | 401 | 1.7 | 0 | -0.1 | -0.4 | -0.2 | 0 | 1.9 |
| East North Central | 385 | 1.7 | 0.1 | -0.3 | -0.3 | -0.3 | 0 | 1.9 |
| East South Central | 147 | 1.7 | 0.1 | 0 | -0.2 | -0.3 | 0 | 2.2 |
| West North Central | 158 | 1.7 | 0 | 0 | -0.7 | -0.2 | 0.6 | 2 |
| West South Central | 378 | 1.7 | 0 | 0.2 | -0.6 | -0.2 | 0 | 2.1 |
| Mountain | 163 | 1.7 | -0.1 | -0.6 | -0.1 | 0.1 | 0.3 | 1.2 |
| Pacific | 374 | 1.7 | 0 | 0.8 | 0.2 | 0.3 | 0.1 | 3.1 |
| Puerto Rico | 51 | 1.8 | -0.3 | -1.2 | -1.1 | 0.2 | 0.1 | 0.5 |
| **Rural by Region:** | | | | | | | | |
| New England | 20 | 1.4 | 0 | -0.5 | 1.7 | -0.2 | 0 | 0.7 |
| Middle Atlantic | 53 | 1.3 | -0.2 | 0 | 0.8 | -0.1 | 0 | 1.2 |
| South Atlantic | 122 | 1.5 | -0.3 | 0.1 | 2 | -0.2 | 0.1 | 1.1 |
| East North Central | 114 | 1.4 | -0.4 | 0.1 | 0.9 | -0.1 | 0 | 1 |
| East South Central | 150 | 1.6 | -0.1 | -0.3 | 2.7 | -0.2 | 0 | 1.6 |
| West North | 94 | 1.2 | -0.6 | 0.1 | 0.1 | -0.1 | 0.2 | 0.7 |

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|---|---|---|---|---|---|---|---|---|
| Central | | | | | | | | |
| West South Central | 147 | 1.6 | -0.5 | 0.3 | 1.6 | -0.2 | 0.1 | 1.2 |
| Mountain | 54 | 1.1 | -0.5 | -0.8 | 0.1 | -0.1 | 0.8 | 0.8 |
| Pacific | 23 | 1.2 | -0.4 | -0.3 | 1 | -0.1 | 0 | 0.9 |
| **By Payment Classification:** | | | | | | | | |
| Urban hospitals | 2,281 | 1.7 | 0 | 0 | -0.5 | 0 | 0.1 | 2 |
| Large urban areas | 1,325 | 1.7 | 0.1 | 0 | -0.6 | -0.1 | 0 | 2.1 |
| Other urban areas | 956 | 1.7 | 0 | -0.1 | -0.2 | 0.2 | 0.2 | 1.9 |
| Rural areas | 976 | 1.6 | -0.1 | 0 | 1.7 | -0.1 | 0.1 | 2.1 |
| **Teaching Status:** | | | | | | | | |
| Nonteaching | 2,162 | 1.7 | -0.1 | 0.1 | 0.2 | 0 | 0.1 | 1.7 |
| Fewer than 100 residents | 846 | 1.7 | 0 | 0 | -0.2 | 0 | 0.2 | 1.9 |
| 100 or more residents | 249 | 1.7 | 0.1 | 0 | 0 | 0 | 0 | 2.6 |
| **Urban DSH:** | | | | | | | | |
| Non-DSH | 520 | 1.7 | -0.2 | -0.1 | -0.3 | -0.2 | 0.2 | 1.6 |
| 100 or more beds | 1,483 | 1.7 | 0.1 | 0 | -0.5 | 0 | 0.1 | 2.1 |
| Less than 100 beds | 365 | 1.7 | -0.2 | 0.2 | -0.5 | 0.1 | 0.1 | 1.7 |
| **Rural DSH:** | | | | | | | | |
| SCH | 258 | 1.2 | -0.6 | 0 | 0 | 0 | 0 | 0.7 |

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|---|---|---|---|---|---|---|---|---|
| RRC | 367 | 1.6 | 0 | 0.1 | 2.1 | 0 | 0.1 | 2.5 |
| 100 or more beds | 27 | 1.7 | -0.1 | -0.1 | 1 | -0.3 | 0.1 | 1.6 |
| Less than 100 beds | 127 | 1.6 | -0.1 | 0.1 | 0.8 | -0.3 | 0.6 | 1.9 |
| **Urban teaching and DSH:** | | | | | | | | |
| Both teaching and DSH | 818 | 1.7 | 0.1 | 0 | -0.5 | 0 | 0.1 | 2.2 |
| Teaching and no DSH | 88 | 1.8 | 0 | -0.1 | -0.6 | -0.2 | 0 | 1.8 |
| No teaching and DSH | 1,030 | 1.7 | 0 | 0.1 | -0.2 | 0.1 | 0.1 | 1.9 |
| No teaching and no DSH | 345 | 1.7 | -0.2 | -0.2 | -0.5 | -0.2 | 0.2 | 1.6 |
| **Special Hospital Types:** | | | | | | | | |
| RRC | 328 | 1.7 | 0 | 0.1 | 2.3 | -0.1 | 0.2 | 2.8 |
| SCH | 311 | 1.2 | -0.4 | 0 | -0.1 | 0 | 0 | 0.9 |
| MDH | 135 | 1.4 | -0.5 | 0 | 0.8 | -0.1 | 0.2 | 0.9 |
| SCH and RRC | 133 | 1.2 | -0.2 | -0.1 | 0.5 | -0.1 | 0 | 1.1 |
| MDH and RRC | 14 | 1.4 | -0.5 | 0.1 | 0.9 | -0.1 | 0 | 1.1 |
| **Type of Ownership:** | | | | | | | | |
| Voluntary | 1,901 | 1.7 | 0 | 0 | 0 | 0 | 0.1 | 2.1 |
| Proprietary | 854 | 1.7 | 0 | -0.1 | -0.1 | -0.1 | 0.1 | 1.7 |

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|---|---|---|---|---|---|---|---|---|
| Government | 501 | 1.6 | 0 | 0.2 | -0.1 | 0 | 0 | 2.2 |
| **Medicare Utilization as a Percent of Inpatient Days:** | | | | | | | | |
| 0-25 | 546 | 1.7 | 0.1 | 0 | -0.4 | -0.1 | 0 | 1.9 |
| 25-50 | 2,121 | 1.7 | 0 | 0 | 0 | 0 | 0.1 | 2.2 |
| 50-65 | 477 | 1.6 | -0.2 | 0 | 0.3 | 0 | 0.2 | 1.3 |
| Over 65 | 73 | 1.1 | 0.1 | 0 | -0.3 | -0.2 | 0.1 | 2 |
| **FY 2019 Reclassifications by the Medicare Geographic Classification Review Board:** | | | | | | | | |
| All Reclassified Hospitals | 911 | 1.7 | 0 | 0.1 | 2 | -0.1 | 0.1 | 2.3 |
| Non-Reclassified Hospitals | 2,346 | 1.7 | 0 | -0.1 | -1 | 0.1 | 0.1 | 1.9 |
| Urban Hospitals Reclassified | 633 | 1.7 | 0 | 0.2 | 1.9 | -0.1 | 0.1 | 2.5 |
| Urban Non-reclassified Hospitals | 1,795 | 1.7 | 0 | -0.1 | -1 | 0.1 | 0.1 | 2 |
| Rural Hospitals Reclassified Full Year | 278 | 1.5 | -0.2 | -0.1 | 2.3 | -0.2 | 0.1 | 1.3 |

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|---|---|---|---|---|---|---|---|---|
| Rural Non-reclassified Hospitals Full Year | 452 | 1.3 | -0.5 | -0.1 | -0.4 | -0.1 | 0.2 | 0.7 |
| All Section 401 Reclassified Hospitals: | 246 | 1.7 | 0 | 0.1 | 1.9 | 0 | 0.1 | 2.7 |
| Other Reclassified Hospitals (Section 1886(d)(8)(B)) | 47 | 1.6 | -0.3 | 0 | 2.5 | -0.2 | 0 | 1 |

[1]Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2017, and hospital cost report data are from reporting periods beginning in FY 2015 and FY 2014.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 1.25-percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 2.8 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 proposed changes to the Version 36 GROUPER, the proposed 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 proposed recalibration budget neutrality factor of 0.997896 in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2015 and 2014 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The proposed wage budget neutrality factor is 1.001182.

[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 proposed geographic budget neutrality factor of 0.987084.

[6] This column displays the effects of the proposed rural floor and proposed expiration of the imputed floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.994733.

[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 proposed change in payments from FY 2018 to FY 2019.