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PROPOSED RULE
Fiscal Year 2020 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule

SUMMARY

On April 23, 2019, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule describing federal fiscal year (FY) 2020 policies and rates for Medicare's prospective payment systems for acute care inpatient hospitals (IPPS) and the long-term care hospital prospective payment system (LTCH PPS).

The payment rates and policies described in the IPPS/LTCH proposed rule (CMS-1716-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 3, 2019. **Written or electronic comments on the proposals must be submitted to CMS by close of business June 24, 2019**. A final rule will be published around August 1, 2019, with the rates and policy changes generally taking effect on October 1, 2019.

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/FY2020-IPPS-Proposed-Rule-Home-Page-Items/FY2020-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/FY2020-IPPS-Proposed-Rule-Home-Page-Items/FY2020-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 3,300 acute care hospitals paid under the IPPS by about $4.7 billion in FY 2019 compared to FY 2018. The rule indicates that the increase results from an additional $4.4 billion in IPPS operating and uncompensated care payments and $0.3 billion in IPPS capital, new technology add-on payments and low volume hospital payments.

A. Inpatient Hospital Operating Update

The proposed rule would increase IPPS operating payment *rates* by 3.2 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 3.2 percent rate increase is the net result of a market basket update of 3.2 percent less an annual multi-factor productivity (MFP) adjustment of 0.5 percentage points; and an 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 payment increase will apply to the national operating standardized amounts and also to the hospital-specific rates on which some sole community hospitals (SCHs) and Medicare Dependent Hospitals (MDHs) are paid. However, the documentation and coding adjustment does not apply to the hospital-specific rates resulting in a 2.7 percent increase rather than a 3.2 percent increase.

Factor	Percent Change
FY 2020 Market Basket	3.2
Multifactor productivity adjustment	-0.5
MACRA Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	3.2

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 2020, 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 3.2 percent or -0.8 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 2.4 percentage points.

CMS estimates that 39 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; 211 hospitals because they are not meaningful EHR users; and 32 hospitals are estimated to be subject to both reductions.

The proposed update for hospitals that have not successfully submitted quality data will be 1.9 percent for FY 2020. The reduction to the update is applied before application of the MACRA documentation and coding adjustment and equals the 2.7 percent less 0.8 percentage points.

Hospitals that do not qualify as meaningful EHR users will receive an update of 0.3 percent for FY 2020. This update is also applied before application of the MACRA documentation and coding adjustment and equals 2.7 percent less 2.4 percentage points.

Hospitals that have neither successfully submitted quality data or qualified as meaningful EHR users will receive an update of -0.5 percent or 2.7 percent less 3.2 percentage points (the entire market basket).

B. Payment Impacts

CMS' impact table for IPPS operating costs shows proposed FY 2020 payments increasing 3.5 percent. Not all policy changes are reflected in this total. For example, increases in uncompensated care payments are not included in this total. The factors that are included in this total are:

Contributing Factor	National Percentage Change
FY 2019 increase in proposed payment rates	+3.1[1]
Frontier hospital wage index floor and out-migration wage adjustment	+0.1[2]
Residual	+0.3
Total	+3.5[3]

[1]Weighted average of hospital-specific rate update of 2.7 and 3.2 percent for all other hospitals.
[2]The frontier hospital wage index floor increases payments about $63 million to 45 hospitals and the out-migration adjustment increases payments about $40 million to 171 providers.
[3]CMS explains this as outliers increasing from its 4.6 percent estimate for FY 2019 to 5.1 percent for FY 2020 and the "interactive effects among various factors" that CMS cannot isolate. CMS has no actual FY 2019 claims data upon which to make an estimate of its FY 2019 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 selected hospital categories.

Hospital Type	All Proposed Rule Changes
All Hospitals	3.5%
Large Urban	3.4%
Other Urban	3.7%
Rural	3.6%
Major Teaching	3.5%
Puerto Rico	13.6%

To the extent a given hospital category impact deviates from the national average of 3.5 percent, it suggests that there is a factor resulting in more of an impact on that category of hospital compared with the average for all hospitals. Typically, the impact would be redistributive from a proposal that is budget neutral. The redistributive payment changes are reasonably modest in impact. Generally, most of the redistributive impact appears to be from CMS' proposal to narrow the difference between the highest and lowest wage indexes. This proposal would explain why hospitals in Puerto Rico are seeing a much larger increase than the average for all hospitals nationwide.

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

New Technology Add-On Payments (NTAP). CMS has not yet determined whether the 17 applications it received for FY 2020 meet the criteria for new technology add-on payments. E Estimates will be included in the final rule if any are found to be eligible. New technology add-on payments for three technologies will expire at the end of FY 2019. The rule does not provide an impact estimate for discontinuing payments for these technologies but it does provide an estimate of $291 million for the 9 technologies previously approved for NTAP payments where payment is continuing in FY 2020. CMS is also proposing to raise the amount of its new technology add-on payment (explained more fully in section II. H.) Assuming CMS approves NTAP for all 17 new applications and it continues payment for the 9 already approved, CMS estimates its NTAP proposed payment change would increase spending by $110 million.

Low Volume Hospitals. CMS estimates an increase of $25 million associated with the low-volume hospital policy. This estimate is based on 588 providers receiving approximately $439 million in FY 2020 compared to 588 providers receiving approximately $414 million in FY 2019.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to increase by 2.6 percent or $216 million. More detail on these calculations is in section IV. F.

Hospital Readmissions Reduction Program (HRRP). The HRRP program would reduce FY 2020 payments to an estimated 2,599 hospitals or 85 percent of all hospitals. The readmissions penalty is estimated to affect 0.67 percent of payments to the hospitals that are being penalized for excess readmissions.

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. Performance scores are currently unavailable for FY 2020 and will not be available to be reviewed by hospitals and revised until after the FY 2020 IPPS final rule is completed. CMS includes a table that illustrates how HVBP payments will be distributed based on the FY 2019 program year performance scores.

Hospital Acquired Conditions (HAC) Reduction Program. CMS provides an analysis by hospital category of how hospitals are affected by the HAC reduction program. By law, the penalty applies to 25 percent of all hospitals or 795 of 3,184 non-Maryland hospitals with a HAC score.

Capital IPPS Payments. CMS estimates capital payment per case will increase 1.9 percent. CMS attributes 1.5 percent of this increase to the capital payment rate update and another 0.5 percent an increase in case mix. The actual capital rate itself is going up just under 1.0 percent because various adjustments for budget neutrality.

C. IPPS Standardized Amounts

The following four rate categories continue in FY 2020:

- Hospital Submitted Quality Data and is a Meaningful EHR User (applicable percentage increase [i.e., before adjustments] = 2.7 percent
- Hospital did NOT submit quality data and is a meaningful EHR user (applicable percentage increase = 1.9 percent)
- Hospital submitted quality data and is NOT a meaningful EHR user (applicable percentage increase = 0.3 percent)
- Hospital did NOT submit quality data and is NOT a meaningful EHR user (applicable percentage increase = -0.5 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 2020. Additional budget neutrality adjustments to the standardized amounts are as follows:

- MS-DRG recalibration, 0.998768 (a decrease of 0.12 percent);
- Wage index, 1.000915 (an increase of 0.09 percent);
- Geographic reclassification, 0.986451 (a reduction of 1.35 percent); and
- Rural and imputed floor budget neutrality, 0.996316, a reduction of 0.37 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 0.949.

The net increase in the operating standardized amounts from FY 2019 to proposed FY 2020 is about 3.1 percent including the IPPS update of 2.7 percent. There is an additional MACRA documentation and coding adjustment of +0.5 percent. The additional -0.1 percent residual in the change to the standardized amount may be accounted for by the budget neutrality adjustment for MS-DRG recalibration (-0.12 percent). (Note: On page 1593 of display copy of the proposed rule, CMS indicates that the FY 2019 reclassification budget neutrality adjustment was 0.985932. It was actually 0.985335 per a later a correction to the FY 2019 final rule. This adjustment must be removed from the FY 2019 standard amounts to accurately calculate the FY 2020 standardized amounts).

Including the proposed FY 2020 capital payment rate, which increases 1.0 percent, the operating plus capital standardized amounts will increase by approximately 3.0 percent in FY 2020.

FY 2020 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 2020							
Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.7 Percent)		**Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.3 Percent)**		**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.9 Percent)**		**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.5 Percent)**	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$3,977.31	$1,845.99	$3,884.36	$1,802.85	$3,946.33	$1,831.61	$3,853.38	$1,788.47

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 2020							
Hospital Submitted Quality Data and is a Meaningful EHR User (Update =2.7 Percent)		**Hospital Submitted Quality Data and is a NOT a Meaningful EHR User (Update = 0.3 Percent)**		**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update =1.9 Percent)**		**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.5 Percent)**	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$3,610.45	$2,212.85	$3,526.07	$2,161.14	$3,582.32	$2,195.62	$3,497.95	$2,143.90

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 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 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 $25,743 in FY 2019. 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 2020 outlier threshold. CMS proposes an outlier fixed-loss cost threshold for FY 2020 equal to the prospective payment rate for the MS-DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, and any add-on payments for new technology, plus $26,994. CMS projects that the final outlier threshold for FY 2020 will result

in outlier payments equal to 5.1 percent of operating DRG payments and 5.33 percent of capital payments based on the respective federal rates, and it adjusts the respective operating and capital standardized amounts using those percentages. Accordingly, CMS proposes to apply adjustments of 0.949 to the operating standardized amounts and 0.9466388 to the capital federal rate to fund operating and capital outlier payments respectively.

FY 2020 outlier threshold methodology. CMS proposes to set the target for total outlier payments at 5.1 percent of total operating DRG payments (including outlier and uncompensated care payments but continuing to exclude adjustments for value-based purchasing and the readmissions reduction program). To calculate the proposed FY 2020 outlier threshold, CMS simulated payments by applying FY 2020 payment rates and policies using cases from the FY 2018 Medicare Provider Analysis and Review File (MedPAR) with the hospital charges on the MedPAR claims inflated by 2 years, from FY 2018 to FY 2020 to account for charge inflation.

Noting that commenters on the FY 2019 IPPS/LTCH proposed rule expressed concern about being unable to replicate the charge inflation factor used to update two-year old charge data to set the threshold, CMS is making a change from its prior methodology and will be using fiscal year rather than calendar year data to estimate the charge inflation factor.

For proposed rules, CMS inflates charges using the December update to MedPAR. For final rules, CMS uses the March update to MedPAR. Calendar year charge data is the most recent when CMS is undertaking the IPPS rule as the calendar year ends later than the fiscal year. However, more time has elapsed beyond the end of the 4th fiscal year quarter than the 4th calendar year quarter by December and March when CMS doing the IPPS proposed and final rules respectively. As a result, MedPAR includes more submitted claims for the fiscal year than the calendar year. Further, the three-month lag between the end of the fiscal year and the calendar year allows time for fiscal year MedPAR data to be publicly available when the most recent data for the calendar year is not. CMS indicates that it is proposing to use fiscal year rather than calendar year data for the charge inflation factor because the MedPAR data will be more complete and will be available to the public.

CMS determined the 1-year average annualized rate-of-change in charges per case for FY 2020 by comparing the average covered charge per case of $58,355.91 ($562,621,348,420/9,641,206) for FY 2017 to the average covered charge per case of $61,533.91 ($583,577,793,654/9,483,841) for FY 2018. This rate-of-change is 5.4 percent (1.05446) or 11.2 percent (1.11189) over 2 years.

Doing this same calculation on the basis of a calendar year results in an average covered charge per case of $59,137.57 ($572,976,462,154/9,688,874) from January 1, 2017 through December 31, 2017 and $62,241.46 ($549,618,561,649/8,830,425) from January 1, 2018 through December 31, 2018. This rate-of-change is 5.2 percent (1.05249) or 10.8 percent (1.10775) over 2 years. Thus, the fiscal year methodology produces a slightly higher charge inflation factor (11.2 percent) than the calendar year methodology (10.8 percent).

As the calendar year data is not publicly available, CMS provided the below table with the above figures. If CMS finalizes its proposal to use fiscal year data for the charge inflation factor, CMS will no longer provide the below table in the proposed and final rules.

Quarter	Covered Charges (January 1, 2017, through December 31, 2017)	Cases (January 1, 2017, through December 31, 2017)	Covered Charges (January 1, 2018, through December 31, 2018)	Cases (January 1, 2018, through December 31, 2018)
1	$149,423,349,880	2,550,360	$155,383,152,668	2,507,345
2	$141,253,933,908	2,407,205	$144,511,911,637	2,336,261
3	$137,549,332,685	2,328,520	$138,928,539,807	2,238,344
4	$144,749,845,681	2,402,789	$110,794,957,537	1,748,475
Total	$572,976,462,154	9,688,874	$549,618,561,649	8,830,425

CMS proposes to use hospital CCRs from the December 2018 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 2018) update of the PSF to the national average case-weighted operating and capital CCRs from the same period of the prior year (December 2017 update of the PSF). The methodology uses total transfer-adjusted cases from FY 2018 to determine the national average case-weighted CCRs for both sides of the comparison.

CMS calculates a December 2017 operating national average case-weighted CCR of 0.263267, a December 2018 operating national average case-weighted CCR of 0.256730. The percentage change between these two figures is -2.4 percent or 0.975167. This figure is the proposed national operating CCR adjustment factor. The same methodology applied to the capital CCRs produces a December 2017 capital national average case-weighted CCR of 0.022094 and December 2018 capital national average case-weighted CCR of 0.021121. The percentage change between these two figures is -4.4 percent or 0.955983.

For estimating the proposed outlier threshold for FY 2020, CMS's calculation will continue to reflect application of the floor on the wage index of eligible hospitals in frontier states and adjustments to the wage index for outmigration. For the FY 2020 outlier threshold calculation, CMS will reflect new proposed policies to narrow disparities in the hospital wage index and no longer include the wage index of hospitals reclassifying from urban to rural to calculate the rural floor.

In addition to the charge inflation factor, CMS is making another change to its methodology for determining the outlier threshold. Unlike in past years, CMS will reflect the potential for outlier reconciliation in the determination of the FY 2020 outlier threshold as described below.

Over the course of the year, Medicare makes outlier payments based on hospital data from a prior year. Outlier reconciliation occurs when the hospital's actual CCR for the period changes from the CCR used to make outlier payments by more than 10 percentage points or the hospital

receives more than $0.5 million in outlier payments. For the FY 2020 outlier threshold, CMS proposes to use the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a beginning date on or after October 1, 2013, and on or before September 30, 2014). CMS indicates these are the most recent and complete set of cost reports which are finalized and/or approved by the MAC for the proposed rule. For the FY 2020 proposed rule, CMS is using the December 2018 extract of the Hospital Cost Report Information System (HCRIS). For the FY 2020 final rule, CMS proposes to use the March 2019 HCRIS extract.

CMS proposes to determine reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2014 for FY 2020). It then proposes to subtract that amount (expressed as percentage points) from the 5.1 percent of total operating IPPS payments that CMS is targeting as outlier payments for the payment year. For FY 2014, CMS estimates that reconciliation will result in 16 hospitals being owed $24.3 million or -0.03 percent of total operating IPPS payments. As reconciliation resulted in CMS owing hospitals money rather than hospitals owing CMS money, CMS will add this 0.03 percentage points to 5.1 percent and target outliers as 5.13 percent of total IPPS operating payments. CMS believes targeting outlier payments at 5.13 percent with reconciled outlier payments equaling -0.03 percent of total IPPS operating payment will result in an estimated 5.1 percent of total IPPS operating payments being paid as outliers. CMS proposes to continue to reduce the standardized amounts by 5.1 percent to fund the outlier pool. However, CMS proposes to apply an adjustment of 0.949 (-5.1 percent) rounded to 3 places instead of 6 places as it did previously.

There is not a separate capital outlier threshold. CMS establishes a single unified outlier threshold based on the operating outlier threshold. Accordingly, CMS adjusts the capital rate to reflect the percentage of total payments estimated to be paid as capital outliers. CMS proposes to include reconciled capital outlier payments in the adjustment in the same way as the percentage was calculated for operating payments. For capital, CMS estimates the ratio of reconciled payments to total payments is -0.05 percent.

CMS estimates that the outlier threshold would be $27,154 if it did not incorporate outlier reconciliation into the calculation compared to the $26,994 that CMS is proposing for FY 2020.

FY 2018 Outlier Payments. CMS' current estimate, using available FY 2018 claims data, is that actual outlier payments for FY 2018 were approximately 4.94 percent of actual total MS-DRG payments. Following long-standing policy, the agency will not make retroactive adjustments to ensure that total outlier payments for FY 2018 are equal to the projected 5.1 percent of total MS-DRG payments.

FY 2019 Outlier Payments. CMS indicates that it is unable to provide an estimate of actual outlier payments for FY 2019 based on FY 2019 claims data in the proposed rule because FY 2019 claims data will be unavailable until after September 30, 2019. The rule says CMS will provide an estimate of actual FY 2019 outlier payments in the FY 2020 IPPS/LTCH PPS proposed rule. In the impact section of the rule, CMS indicates that the year to year increase in payments reflects "an estimated increase in outlier payments of 0.5 percent…of approximately 4.6 percent [for FY 2019] to 5.1 percent projected for FY 2020..."

II. MS-DRG Classifications and Relative Weights

A. Background
B. MS-DRG Reclassifications
C. Adoption of MS-DRGs in FY 2018

The FY 2019 proposed rule continues the Medicare severity diagnosis-related group (MS-DRG) classification system used beginning in FY 2008. Proposed changes in specific MS-DRGs for FY 2019 are described in section II.F below.

D. MS-DRG Documentation and Coding Adjustment

CMS provides extensive history regarding the documentation and coding adjustment going back to adoption of the MS-DRGs in FY 2008. In summary, CMS proposed a preemptive negative rate adjustment for FY 2008 to offset increases in IPPS spending due to improvements in documentation and coding. Subsequent statutory amendments required different adjustments over the years since that time. The most recent statutory enactments require CMS to make a series of annual positive adjustments to offset prior negative ones through FY 2023. For FY 2020, consistent with section 414 of the Medicare Access and CHIP Reauthorization Act, CMS is proposing to implement a positive 0.5 percentage point adjustment to the standardized amount.

E. Refinement of the MS-DRG Relative Weight Calculation

CMS calculates the IPPS relative weights by reducing hospital charges reduced to cost using CCRs for 19 distinct cost centers. For FY 2020, CMS does not propose any changes to the CCR methodology. It calculated the proposed MS-DRG weights for FY 2020 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 2020 on the CMS website at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Proposed-Rule-Home-Page-Items/FY2020-IPPS-Proposed-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

Click on File #4 (FY 2020 Proposed Rule: HCRIS Data File).

The proposed FY 2020 CCRs are shown in the table below.

Group	FY 2019 CCR	Proposed FY 2020 CCR
Routine Days	0.442	0.433
Intensive Days	0.368	0.362
Drugs	0.191	0.191

Group	FY 2019 CCR	Proposed FY 2020 CCR
Supplies & Equipment	0.299	0.301
Implantable Devices	0.309	0.308
Therapy Services	0.304	0.297
Laboratory	0.113	0.109
Operating Room	0.179	0.175
Cardiology	0.103	0.099
Cardiac Catheterization	0.110	0.106
Radiology	0.145	0.140
MRIs	0.074	0.073
CT Scans	0.035	0.035
Emergency Room	0.159	0.154
Blood and Blood Products	0.296	0.282
Other Services	0.345	0.344
Labor & Delivery	0.382	0.369
Inhalation Therapy	0.156	0.151
Anesthesia	0.078	0.077

F. 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 2021, comments should be submitted by November 1, 2019.** Comments for FY 2021 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 2020. CMS' MS-DRG analysis is based on ICD-10 claims data from the September 2018 update of the FY 2018 MedPAR file, which contains hospital bills received through September 30, 2018 for discharges occurring through September 30, 2018.

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; and
- 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. Peripheral Extracorporeal Membrane Oxygenation (ECMO)

For FY 2019, three new ICD-10-PCS procedure codes were finalized: 5A1522F – Extracorporeal Oxygenation, Membrane, Central; 5A1522G – Extracorporeal Oxygenation, Membrane, Peripheral Venoarterial; and 5A1522H – Extracorporeal Oxygenation Membrane, Peripheral Venovenous. The new central ECMO procedure code was assigned to the same MS-DRG as predecessor code (MS-DRG 003) and the two new ICD-10-PCS procedure codes for peripheral ECMO procedures were assigned to MS-DRGs 207, 291, 296, and 870. In addition, the peripheral ECMO procedures were designated as non O.R. procedures.

CMS received comments from stakeholders raising concerns with the MS-DRG assignments for the two new procedure codes describing peripheral ECMO. Commenters stated that the MS-DRG assignments for ECMO should not be based on how a patient is cannulated because most of the cost of ECMO can be attributed to the severity of illness. Commenters also expressed concerns that there was lack of opportunity for public comment on the finalized MS-DRG assignments. In addition, the commenters noted that the new procedure codes did not account for an open cut-down approach that may be performed on a peripheral vessel during peripheral ECMO. A few stakeholders agreed with the assignments.

In response to the comment about the opportunity for public comment on the MS-DRG assignment for the new procedure codes, CMS states that the annual review of assigning new procedure codes involves reviewing the predecessor procedure code's MS-DRG assignments but this process does not automatically result in the new procedure code being assigned (or proposed for assignment) to the same MS-DRG as the predecessor code.

CMS examined claims data with the predecessor ICD-10-PCS procedure code procedure code 5A15223 and found that the average length of stay for all cases reported in MS-DRG 003 was 29.6 days and the average length of stay for cases in MS-DRG 003 reporting 5A15223 was 20.2 days. CMS' clinical advisors noted that the length of stay for ECMO may not be a reliable indicator of resources and that a more appropriate measure of resource consumption would be the number of hours or days that a patient received ECMO instead of the hospital length of stay.

CMS reviewed the claims data to identify the diagnosis reported with ECMO and found patients requiring ECMO had a greater severity of illness, presented greater treatment difficulty, had poorer prognosis, and had a greater need for intervention. The clinical advisors concluded that the resource consumption for both central and peripheral ECMO can be primarily attributed to the severity of illness of the patient and the method of cannulation is less relevant for determining overall resources. CMS notes that although it does not yet have Medicare claims data to evaluate the new peripheral ECMO procedure codes, review of limited registry data indicates that the costs for peripheral ECMO appear to be similar to costs for central ECMO.

In response to comments that the new procedure codes do not account for an open cut-down approach, CMS notes that a request to create ICD-10-PCS codes to differentiate peripheral vessel percutaneous and peripheral vessel cutdown according to the ECMO indication (VA or VV) was discussed at the March, 2019 ICD-10 Coordination and Maintenance Committee meeting.[1] A coding option to add duration values to allow the number of hours or the number of days a patient received ECMO was also discussed.

Based on its review, CMS proposes to reassign procedure codes describing peripheral ECMO procedures from their current MS-DRGs to MS-DRG 003. CMS maintains that peripheral ECMO procedures are non-O.R. procedures.

b. Allogeneic Bone Marrow Transplant

CMS received a request to create two new MS-DRGs for allogeneic hematopoietic cell transplant (HCT) procedures based on the donor source. Specifically, the requestor wanted MS-DRG 014 (Allogeneic Bone Marrow Transplant) to be split into a new MS-DRG for cases for allogeneic related match donors and another new MS-DRG for cases for allogeneic unrelated match donors.

CMS examined cases with for ICD-10-PCS procedure codes assigned to MS-DRGs that identified unrelated and unspecified donor source for an allogeneic HCT. Based on the claims analysis of and recommendations from its clinical advisors, CMS is not proposing to split MS-DRG 014 into two MS-DRGs according to whether the allogenic donor source is related or unrelated.

The requestor also suggested that CMS apply a code edit through the inpatient Medicare Code Editor (MCE), similar to the edit in the Integrated Outpatient Code Editor (I/OCE) which requires reporting of revenue code 0815 on the claim with the appropriate procedure code or the claim may be subject to being returned to the provider. CMS notes that the MCE is not designed to include revenue codes for claims editing purposes; it is a software program that detects and reports errors in the coding of Medicare claims data. In reviewing this request, CMS reviewed the billing instructions for stem cell transplantation in Chapter 3 of the Medicare Claims Processing Manual and found Section 90.3.1 instructs providers to report revenue code 0815 but Section 90.3.3 instructs providers to report revenue code 0819. CMS note that instructions (Pub. No. 100-04, Transmittal 3571, Change Request 9674, effective January 1, 2017) state the

[1] Information about this meeting are available at https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/ICD-9-CM-C-an-M-MeetingMAterial.html.

appropriate revenue code for allogeneic stem cell acquisition/donor is revenue code 0815. CMS is considering revising the Medicare Claims Processing Manual.

During the analysis of claims assigned to MS-DRG 014, CMS noted that eight procedure codes for autologous HCP procedures: four procedure codes for HCT procedures with autologous cord blood stem cells as the donor source and four procedures that are clinically invalid and should not be reported on any claim. CMS proposes to reassign the four ICD-10-PCS HCT procedures with autologous cord blood stem cell as the donor source form MS-DRG 014 to MS-DRGS 016 and 016.

CMS also identified 128 clinically invalid codes from the transfusion table in the ICD-10-PCS classification identifying a transfusion using arterial access as listed in Table 6.P.1a associated with the proposed rule).[2] CMS proposes to delete these 128 clinically invalid codes from the transfusion table.

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

CMS received a request to create a new MS-DRG for procedures involving CAR T-cell therapies. The requestor also suggested CMS modify its existing payment mechanisms to use a CCR of 1.0 for charges associated with CAR T-cell therapy. In addition, the requestor also included technical and operational suggestions which CMS will consider in the development of future billing and cost reporting guidelines and instructions.

In the FY 2019 IPPS/LTCH final rule (83 FR 41172 – 41174), CMS stated it would collect more comprehensive clinical and cost data before considering assignment of a new MS-DRG for these therapies. CMS reviewed the FY 2018 MedPAR data file and found some claims that identify CAR T-cell therapies but the number of cases was limited and the submitted costs varied widely. CMS still believes it may be premature to consider creation of a new MS-DRG for this therapy and proposes not to modify the current MS-DRG assignment for cases reporting CAR T-cell therapy for FY 2020. CMS notes that consistent with section 1886(d)(4)(C)(iii) of the Act, any new MS-DRG would be established in a budget neutral manner.

CMS requests public comments on payment alternatives for CAR T-cell therapies, including payment under any potential new MS-DRG. CMS is interested on how these payment alternatives would affect access to care, as well as how they affect incentives to encourage lower drug prices.

CMS requests specific comments related to the potential creation of a new MS-DRG for CAR T-cell therapy procedures:

1. What is the most appropriate way to develop the relative weight of a new MS-DRG?

- Should the current methodology for setting relative weights be used? CMS states it may be operationally possible to create a relative weight by dividing the average costs of cases including CAR T-cell procedures by the average costs of all cases

[2] Table 6.P.1a is available at https://www.cms.gov/MEdicare/MEdicare/MEdicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

- Should cases in clinical trials be excluded? CMS states that the absence of drug costs on claims for cases involving clinical trials could have a significant impact on the relative weight.
- Should an alternative relative weight be developed using the average sales price (ASP) instead of the costs involved in treating patients with CAR T-cell therapies?

2. Would it be appropriate to geographically adjust payment under a new MS-DRG?

CMS discusses the current methodology for determining the Federal payment rate for operating costs under the IPPS. Using this methodology, the labor-related proportion of the nation standardized amounts is adjusted by the wage index to reflect the relative differences in labor costs among geographic areas. The IPPS Federal payment rate for operating costs is calculated as the MS-DRG relative weight x [(labor-related applicable standardized amount x applicable wage index) + (nonlabor-related applicable standardized amount x cost-of-living adjustment)].

CMS' understanding is that the costs for CAR T-cell therapy does not vary among geographic areas and given the costs for the therapy would be an extremely high portion of the costs of the MS-DRG, a geographic adjustment might not be appropriate. CMS acknowledges that other drug costs might not vary among geographic areas but these do not represent as significant a percentage of the average costs for the case.

- Should CMS geographically adjust the payment for cases assigned to a new MS-DRG?
- Should CMS apply the geographic adjustment to a lower proportion of payments under a new MS-DRG? If yes, then how should that lower portion be determined?
- CMS requests comments on the use of its exceptions and adjustments authority under section 1886(d)(5)(I) of the Act (or other relevant authorities) to implement any changes in the geographic adjustment.

3. What, if any, adjustments should be made for IME and DSH payments for cases assigned to a new MS-DRG?

CMS discusses the additional payments under both the indirect medical education (IME) adjustment (section 1886(d)(5)(B) of the Act and 42 CFR 412.105) and the Medicare disproportionate hospital (DSH) adjustment (section 1886(d)(5)(F) of the Act and 42 CFR 412.107). CMS states that these add-on payments could result in unreasonably high additional payment for CAR T-cell therapy cases unrelated in any significant empirical way to the costs of providing care. For example, for a teaching hospital that has an IME adjustment factor of 0.25 and a DSH adjustment factor of 0.10, CMS calculates that in a new MS-DRG for CAR T-cell therapies that resulted in an average IPPS Federal payment rate for operating costs of $400,000, the hospital would receive an IME payment of $100,000 and a DSH payment of $40,000. In this example, the total IPPS Federal payment rate for operating costs including IME and DSH payments would be $540,000.

- Should the IME and DSH payments be made for cases assigned to any new MS-DRG for CAR T-cell therapy?

- Should the applicable percentage used to determine IME and DSH payments be reduced? If yes, then how should those lower percentages be determined?
- CMS requests comments on the use of its exceptions and adjustments authority under section 1886(d)(5)(I) of the Act (or other relevant authorities) to implement any changes in the geographic adjustment.

CMS also requests **comments about establishing a specific CCR** for reporting procedures involving the use of CAR T-cell therapies. For example, stakeholders have suggested a CCR of 1.0 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. CMS notes that in section II.G.7 of the preamble it also requests comments about other payment alternatives, including eliminating the use of the CCR in calculating the new technology add-on payments for KYMRIAH and YESCARTA by making a uniform add-on payment, that is 65 percent of the cost of the technology (consistent with the proposed increase in the calculation of the maximum new technology add-on payment discussed in section II.H.9).

3. MDC 1 (Diseases and Disorders of the Nervous System): Carotid Artery Stent Procedures

CMS identified 144 ICD-10-PC procedure codes related to dilation of the carotid artery that were not properly assigned in the ICD-10 MS-DRG Version 36 Definitions Manual.

CMS identified 46 ICD-10-PCS procedure codes in the second logic list for procedure codes for O.R. procedures involving dilation of a carotid artery (common, internal or external) with intraluminal device(s) that are not properly assigned. Based on analysis form the FY 2018 MedPAR file and input from CMS' clinical advisors, CMS proposes to remove these procedure codes from MS-DRGs 034, 035, and 036 (Carotid Artery Stent Procedures). CMS also identified that these 46 ICD-10-PCS procedure codes were also assigned to MS-DRGs 037, 038, and 039 (Extracranial Procedures).

During the review of claims data for MS-DRGs 037, 038, and 039, CMS identified another 96 ICD-10-PCS procedure codes describing dilation of a carotid artery with an intraluminal device in these MS-DRGs. These procedure codes are also included in the logic for MS-DRGs 034, 035, and 036. CMS notes that of these 96 procedure codes, 48 codes include the qualifier term "bifurcation". As discussed in section II.F.14.f of the preamble, CMS proposes to delete a number of procedure codes that include the qualifier term "bifurcation". If the proposal to delete procedure codes with the term "bifurcation" is finalized, then these 48 codes will be deleted effective October 1, 2019. CMS proposes to remove the remaining valid procedure codes from MS-DRGs 037, 038, and 038.

4. MDC 4 (Diseases and Disorders of the Respiratory System): Pulmonary Embolism

CMS received a request to reassign three ICD-10-CM diagnosis codes for pulmonary embolism with acute cor pulmonale (I26.01, I26.02, and I26.09) from MS-DRG 175 (Pulmonary Embolism without MCC) to the higher severity level MS-DRG 175 (Pulmonary Embolism with MCC). The requestor stated that patients with pulmonary embolism and acute cor pulmonale often represent a more severe set of patients with pulmonary embolism).

Based on claims data analysis and input from its clinical advisors, CMS proposes to reassign cases reporting diagnosis code I I26.01, I26.02, or I26.09 to the higher severity level MS-DRG 175 and to revise the title for this MS-DRG to "Pulmonary Embolism with MCC or Acute Cor Pulmonale".

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

a. Transcatheter Mitral Valve Repair (TMVR) with Implant

CMS received a request to modify the MS-DRG assignment for transcatheter mitral valve repair (TMVR) with implant procedures.[3] This procedure is described by ICD-10-PCS procedure code 02UGJZ (Supplement mitral valve with synthetic substitute, percutaneous approach) and is assigned to MS-DRGs 228 and 229 (Other Cardiothoracic Procedure with and without MCC, respectively). The requestor also recommended that cases reporting procedure codes describing an endovascular cardiac valve repair with implant be reassigned to MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with and without MCC, respectively) and the titles be revised to Endovascular Cardiac Valve Interventions with Implant with and without MCC, respectively. According to the requestor, there are substantial clinical and resource differences between the TMVR procedure and other procedures grouping to MS-DRGs 228 and 229 and that procedure code 02UGJZ is the only endovascular valve intervention with implant that maps to MS-DRGs 228 and 229. The requestor also notes that other procedure codes describing procedures for endovascular (transcatheter) cardiac valve repair with implant map to MS-DRGs 273 and 274 or to MS-DRGs 216, 217, 218, 219, 220, and 221; and procedure codes for endovascular cardiac valve replacement procedures map to MS-DRGs 266 and 267.

The requestor provided numerous analyses and believes the results support their request to group TMVR procedures with endovascular cardiac replacements (MS-DRGs 228 and 229) from both a resource and clinical coherence perspective because TMVR procedures are more similar to the endovascular valve replacements compared to the other procedures in MS-DRGs 228 and 229. As for the recommendation that CMS reclassify other endovascular cardiac valve repair with implant procedures involving the aortic, pulmonary, tricuspid and other non-TMVR to MS-DRGs 266 and 267, the requestor acknowledged that these other cardiac valves have lower volumes in comparison to the TMVR procedure which makes analysis of these procedures difficult. The requester notes, however, that movement of these procedures would maintain clinical coherence for all endovascular cardiac valve interventions and there is anticipated increase in volume for all these procedures.

CMS analyzed claims data from the FY 2018 MedPAR file for cases reporting procedure code 02UG3JZ in MS-DRGs 228 and 229 as well as one of the procedure codes describing a transcatheter cardiac valve repair with implant and also analyzed the procedure codes describing a transcatheter cardiac valve replacement in MS-DRGs 266 and 267. CMS' clinical advisors stated that transcatheter cardiac valve repair procedures are not the same as transcatheter

[3] CMS received a similar request to modify the MS-DRG assignments for TMVR with implant procedures for FY 2015 (79 FR 28008-28010) and FY 2018 (81 FR 24985-24989). CMS also refers readers to detailed discussions of MitraClip for TMVR in previous rulemakings including the FY 2017 IPPS/LTCH PPS proposed (81 FR 24985-24989 and final rules (81 FR 56809-56813).

(endovascular) cardiac valve replacement. The clinical advisors agreed with the requestor that these procedures are more clinically coherent because they describe endovascular cardiac valve interventions with implants and are similar in terms of average length of stay and average costs to cases in MS-DRGs 266 and 267. CMS analyzed the impact of grouping the endovascular cardiac valve repair with implant (supplement) procedures with the endovascular cardiac valve replacement procedures; this included applying the criteria to create subgroups for a 2-way severity level split (with MCC and without MCC).

CMS clinical advisors identified other (non-supplement) transcatheter (endovascular) procedures that are involved with cardiac valves and CMS analyzed claims form the FY 2018 MedPAR for cases reporting any of the procedure codes listed in the proposed rule in MS-DRGs 216, 217, 218, 219, 220, and 221, MD-DRGs 228 and 229 (23 procedure codes), and MS-DRGs 273 and 274 (20 procedure codes). After reviewing this analysis, the clinical advisors suggested that these other cardiac valve procedures should be grouped together because they are generally more complicated and resource-intense and form a clinically coherent group. CMS analyzed the impact of grouping the other cardiac valve procedures with a 2-way severity level split (with MCC and without MCC).

For FY 2020, CMS proposes to modify the structure of MS-DRGs 266 and 267 by reassigning the 28 procedure codes describing a transcatheter cardiac valve repair (supplement) procedure (listed in the proposed rule). To reflect the proposed restructuring, CMS also proposes to revise the title of MS-DRG 266 to "Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC" and to revise the title of MS-DRG 267 to "Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC".

CMS also proposes to create two new MS-DRGs with a two-way severity level split for the remaining (non-supplement) transcatheter cardiac valve procedures (listed in the proposed rule). CMS proposes to reassign the procedure codes from their current MS-DRGs to the new MS-DRGs. The proposed new MS-DRGs are:

- MS-DRG 319 (Other Endovascular Cardiac Valve Procedures with MCC) and
- MS-DRG 320 (Other Endovascular Cardiac Valve Procedures with MCC).

b. Revision of Pacemaker Lead

CMS was informed that ICD-10-PCS procedure code 02H60JZ (Insertion of pacemaker lead into right atrium, open approach) was omitted from the GROUPER logic for MS-DRGs 260, 261, and 262. CMS proposes to add procedure code 02H60JZ to the list of non-O.R. procedures that would impact MD-DRGs 260, 261, and 262 when reported as a stand-alone procedure.

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

a. Knee Procedures with Principal Diagnosis of Infection

CMS received a request to add ICD-10-CM diagnosis codes M00.9 (Pyogenic arthritis, unspecified) and A54.42 (gonococcal arthritis) to the list of principal diagnoses for MS-DRGs 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection). Currently, cases

reporting these diagnosis codes as a principal diagnosis group to MS-DRGs 488, 489, and 450 (Knee Procedures without Principal Diagnosis of Infection) when a knee procedure is also reported on the claim. CMS notes that neither ICD-10-CM diagnosis code is specific to the knee.

CMS analyzed data for claims assigned to medical MS-DRGs 548, 549, and 550 (Septic Arthritis) and for claims assigned to MS-DRGs 485, 486, 487, 488, and 489. CMS noted that the average costs and average length of stay for cases reporting a principal diagnosis of pyogenic arthritis (M00.9) in MS-DRG 488 are higher than the average costs and average length of stay for all cases in MS-DG 488. Similar results were observed for MS-DRG 489 for cases reporting diagnosis code M00.9 and A54.42 as the principal diagnosis. Because the code description for these diagnosis codes are not specific to the knee, CMS examined the ICD-10-CM Alphabet Index to review the entries that refer and correspond to these diagnosis codes. This review found entries for diagnosis code M00.9 included infection of the knee but diagnosis code A54.42 was not specifically indexed to include the knee or any infection in the knee. CMS proposes to add only ICD-CM diagnosis code M00.9 to the list of principal diagnosis codes for MS-DRGs 485, 486, and 487.

CMS' clinical advisors identified eight ICD-10-CM diagnosis codes currently included on the list of principal diagnosis codes MS-DRGs 485, 486, and 487. Index entries for these diagnosis codes are not specific to the knee. Based on the results of claims analysis and input from its clinical advisors, CMS proposes to remove these eight diagnosis codes from MS-DRGS 485, 486, and 487. CMS maintains the current assignment of these diagnosis codes in MS-DRGs 559, 560, and 561.

CMS' clinical advisors also identified ten ICD-10-CMS diagnosis codes on the list of principal diagnosis codes MS-DRGs 485, 486, and 487. Index entries for these diagnosis codes describe or include an infection that is specific to the knee. CMS proposes to add these ten diagnosis codes to MS-DRGs 485, 486, and 487.

b. Neuromuscular Scoliosis

CMS received a request to add five ICD-10-CM diagnosis codes describing neuromuscular scoliosis to the list of principal diagnosis codes for MS-DRGs 456, 457, and 458 (Spinal Fusion except Cervical with Spinal Curvature or Malignancy or Infection of Extensive Fusions). The requestor stated that all levels of neuromuscular scoliosis, except cervical, should group to the non-cervical spinal fusion MS-DRGs for spinal curvature. These diagnosis codes are currently assigned to MS-DRGs 459 and 460 (Spinal Fusion except Cervical).

CMS' analysis of claims data showed that a small number of cases reported neuromuscular scoliosis either as a principal diagnosis in MS-DRGs 459 and 460 (3 cases in each) or as a secondary diagnosis in MS-DRGs 456, 457, and 458 (6 cases, 12 cases, and 3 cases, respectively). CMS' clinical advisors agree that while the case volume is low, the average costs and average length of stay for cases reporting neuromuscular scoliosis are more aligned with MS-DRGs 456, 457 and 458. CMS proposes to add the five ICD-10-CMS codes describing neuromuscular scoliosis to the list of principal diagnosis codes for MS-DRGs 456, 457, and 458.

c. Secondary Scoliosis and Secondary Kyphosis

CMS received a request to add ICD-10-CM diagnosis codes describing secondary scoliosis (5 codes) and secondary kyphosis (3 codes) to the list of principal diagnosis codes for MS-DRGs 456, 457, and 458 (Spinal Fusion except Cervical with Spinal Curvature or Malignancy or Infection of Extensive Fusions). The requestor stated that in cases of with secondary scoliosis or kyphosis, the underlying case of the condition is not treated or is not responsible for the admission for surgery to correct non-cervical spinal curvature. These diagnosis codes are currently assigned to MS-DRGs 459 and 460 (Spinal Fusion except Cervical).

Based on CMS' analysis and input from its clinical advisors, CMS proposes to add the requested ICD-10- CM diagnosis codes describing secondary scoliosis and secondary kyphosis to the list of principal diagnosis codes for MS-DRGs 456, 457, and 458.

During the review of MS-DRGs 456, 457, and 458, CMS' clinical advisors also identified 34 ICD-10-CMS diagnosis codes that describe conditions involving the cervical region and recommended the removal of these codes from the MS-DRG logic for these MS-DRGs. CMS proposes to remove these ICD-10-CM diagnosis codes involving the cervical region from MS-DRGs 456, 457, and 458.

7. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Extracorporeal Shock Wave Lithotripsy (ESWL)

CMS received two separate but related requests to add ICD-10-CM diagnosis code N13.6 (Pyonephrosis) and ICD-10-CM diagnosis code T83.192A (Other mechanical complication of indwelling ureteral stent, initial encounter) to the list of principal diagnosis codes for MS-DRGs 691 and 692 (Urinary Stones with ESWL). The requestor stated that diagnosis code N13.6 should be grouped to MS-DRGs 691 and 692 when reported as a principal diagnosis because this grouping will more appropriately reflect resource consumption for patients undergoing an ESWL procedure and treatment for urinary tract infections. The requestor believed that diagnosis code T83.192A is similar to an ESWL procedure performed for the treatment of urinary calculi and should be grouped to MS-DRGs 691 and 692. Diagnosis code N13.6 current groups to MS-DRGs 689 and 690 (Kidney and Urinary Tract Infections) and diagnosis code T83.192A groups to MS-DRGs 698, 699, and 700 (Other Kidney and Urinary Tract Diagnoses). Procedures involving ESWL are identified by seven ICD-10-PCS procedure codes, designated as non-O.R. procedures.

CMS reviewed the reporting of the diagnosis codes within the ICD-10-CM classification. Diagnosis code N13.6 is to be assigned for conditions identified in the code range N13.0 – N13.5 with infection (codes describing hydronephrosis). The ICD-10-CM classification instructs that when both a urinary obstruction and a genitourinary infection co-exist, the correct code assignment is N13.6 which appropriately groups to MS-DRGs 689 and 690, because it describes a type of urinary tract infection. CMS' clinical advisors agree with this classification and the MS-DRG assignments. The clinical advisors also believe the resources uses for a case involving an infection and an obstruction are clinical distinct from cases that only involve an obstruction and do not agree with the request.

CMS analyzed what factors may be contributing to longer lengths of stays and higher costs for cases that reported a secondary diagnosis of ESWL. Based on the results of this data analysis and input from clinical advisors, CMS believes that cases for diagnosis code N13.6 reported as a principal diagnosis or as a secondary diagnosis with an ESWL procedure should not be utilized as an indicator for increased utilization of resources based on the performance of an ESWL procedure. CMS believes that the resource consumption is more likely the result of secondary diagnosis CC and/or MCC diagnosis codes. CMS does not propose to add diagnosis codes N13.6 to MS-DRGs 691 and 692.

For the diagnosis ICD-10-CM diagnosis code T83.192A, the clinical advisors noted that the code is a nonspecific code and is not necessarily indicative of a patient having urinary stones and do not support adding the code to the list of principal diagnosis codes for MS-DRGs 691 and 692. Based on the results of data analysis and input from the clinical advisors, CMS is not proposing to add diagnosis code T83.192A to the list of principal diagnosis codes for MS-DRGs 691 and 692.

CMS' clinical advisors recommended evaluation of the frequency that ESWL is reported across all the MS-DRGs. CMS analyzed claims data and identified 48 MS-DRGs; analysis of these MS-DRGs indicated that generally, the subset of cases reporting an ESWL procedure appear to have a longer length of stay and higher average costs when compared to all the cases in their assigned MS-DRG. CMS notes, however, that this same subset of cases also reported one O.R. procedure and/or diagnosis designated as a CC or an MCC. CMS' clinical advisors believe these factors are contributing to the longer average lengths of stay and higher costs (except for the case assigned to MS-DRG 700 which has no CC or MCC conditions in the logic) and does not believe that an ESWL is an indication of increase resource consumption.

CMS' clinical advisors also suggested evaluation of the reporting of ESWL procedures over the past few years and CMS analyzed claims data for MS-DRGs 691 and 692 from the FY 2012 through the FY 2016 MedPAR files. The data show a steady decline in the number of cases reporting urinary stones with as ESWL procedure. Because an ESWL procedure is a non-O.R. procedure and due to decreased utilization of this procedure for the treatment of urinary stones, the clinical advisors believe there is no longer a clinical reason to subdivide the MS-DRGs for urinary stones (MS-DRGs 691, 692, 693, and 694) based on ESWL procedures. CMS proposes to delete MS-DRGs 691 and 692 and to revise the titles for MS-DRGs 693 and 694 from "Urinary Stones with ESWL, with MCC and without MCC" to "Urinary Stones, with MCC and without MCC).

8. MDC 12 (Diseases and Disorders of the Male Reproductive System): Diagnostic Imaging of Male Anatomy

CMS received a request to review four ICD-10-diagnosis codes describing abnormal radiologic findings on diagnostic imaging of the testicle that are currently assigned to MDC 5 (Diseases and Disorders of the Circulatory System) in MS-DRGs. 302 and 303 (Atherosclerosis). The requestor recommended the diagnosis codes should be reassigned to MDC 12 (Diseases and Disorders of the Male Reproductive System) but did not suggest a specific MS-DRG assignment.

CMS' clinical advisors reviewed this request and determined that the assignment of these diagnosis codes was a result of replication from the ICD-9-CM diagnostic codes. Based on the recommendation of its clinical advisors, CMS proposes to reassign these diagnosis codes to MS-DRGs 729 and 730 (Other Male Reproductive System Diagnoses).

9. MDC 14 (Pregnancy, Childbirth and the Puerperium): Proposed Reassignment of Diagnosis Code O99.89

CMS received a request to review the MS-DRG assignment for cases reporting ICD-10-CM diagnosis code O99.89 (Other specified diseases and conditions complicating pregnancy, childbirth and puerperium). The requestor noted that claims reporting diagnosis code O99.89 as a principal diagnosis are for conditions described as occurring during the antepartum period that are reported with an O.R. procedure are grouping to postpartum MS-DRGs.

CMS discusses the structure of the MS-DRGs with MDC 14 and the new GROUPER logic. As part of that restructure, diagnosis code O99.89 was classified as a postpartum condition. CMS acknowledges that the description for diagnosis code O99.89 describes conditions that may occur antepartum, during childbirth, or during the postpartum period; it is not clear what stage the patient is in by this single code. CMS analyzed claims data and found that diagnosis code O99.89 is reported more often as a secondary diagnosis within the antepartum MS-DRGs than it is reported as a principal or secondary diagnosis with the post-partum MS-DRGs.

Based on CMS' analysis and input from its clinical advisors, CMS proposes to reclassify diagnosis code O99.89 from a postpartum condition to an antepartum condition under MDC 14. CMS' medical advisors also recommended that CMS consider a proposal to expand ICD-10-CM diagnosis code O99.89 to become a sub-subcategory that would result in the creation of unique codes with a sixth digit character to specify which obstetric related stage the patient is in.

10. MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs): Skin Graft to Perineum for Burn

CMS received a request to add seven ICD-10-PCS procedure codes that describe a skin graft to the perineum to MS-DRG 927 (Extensive Burn or Full Thickness Burns with MV >96 Hours with Skin Graft) and MS-DRGs 928 and 929 (Full Thickness Burn with Skin Graft or Inhalation Therapy) in MDC 22. These seven procedures are assigned to MS-DRGs 746 and 777 (Vagina, Cervix and Vulva Procedures). When reported with a variety of other principal diagnoses, these procedures group to MS-DRGs in other MDCs.

CMS analyzed claims from the FY 2018 MedPAR file for cases reporting any of the seven procedure codes in MS-DRGs 746, 747, 907, 908, 909, 957, 959, 907, 988, and 989. CMS' clinical advisors reviewed the claims and noted that none of the cases grouped to MS-DRGs 746, 907, 908, 988, and 989 had a principal or secondary diagnosis of a burn, suggesting that these skin grafts were not performed to treat a burn. The advisors believe that the seven diagnosis codes describing a skin graft to the perineum are more clinically aligned with the other procedures in MS-DRGs 746 and 747, and CMS is not proposing to reassign these procedure codes.

11. MDC 23 (Factors Influencing Health Status and Other Contacts with Health Services): Proposed Assignment of Diagnosis Code R93.89

CMS received a request to reassign ICD-10-CM diagnosis code R98.89 (Abnormal finding on diagnostic imaging of other specified body structures) from MDC 5 (Diseases and Disorders of the Circulatory System) in MS-DRGs 302 and 303 (Atherosclerosis) to MDC 23. The requestor did not suggest a specific MS-DRG assignment.

CMS' clinical advisors reviewed this request and determined that the assignment of these diagnosis codes was a result of replication from the ICD-9-CM diagnostic codes. Based on the recommendation of the clinical advisors, CMS proposes to reassign diagnosis code R93.89 to MDC 23 in MS-DRGs 947 and 948 (Signs and Symptoms).

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

a. Adding Procedure and Diagnosis Codes into MDCs

CMS annually reviews procedures grouping to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) or MS-DGs 987 through 989 (Nonextensive O.R. Procedure Unrelated to Principal Diagnosis) on the basis of volume and by procedure to see if it would be appropriate to move these procedure codes into one of the surgical MS-DRGs for the MDC related to the principal diagnosis. CMS looks at both the frequency count of each major operative procedure code and compares procedures across MDCs by the volume of procedure codes within each MDC.

CMS proposes to move the cases reporting the procedures and/or principal diagnosis codes described below from MS-DRGs 981 through 983 and 987 through 989 into one on the surgical MS-DRGs for the MDC which the principal diagnosis or procedure is assigned. The relevant ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes are listed in each section.

(1) Gastrointestinal stromal tumors (GIST) with Excision of Stomach and Small Intestine. CMS proposes to move seven GIST diagnosis codes from MDC 8 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) to MDC 6 (Diseases and Disorders of the Digestive System) within MS-DRGs 326, 327, and 328. Cases reporting a principal diagnosis of GIST would group to MS-DRGs 326, 327, and 328 (Stomach, Esophageal and Duodenal Procedures).

(2) Peritoneal Dialysis Catheter Complications. CMS proposes to add eight procedure codes that describe removal, revision and/or insertion of new peritoneal dialysis catheters or revision of synthetic substitutes to MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs) in MS-DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries). Cases reporting a principal diagnosis of complications of peritoneal dialysis catheters with a procedure describing removal, revision, and/or insertion of a new peritoneal dialysis catheters or revision of synthetic substitutes would group to MS-DRGs 907, 908, and 909.

(3) Bone Excision with Pressure Ulcers. CMS proposes to add five procedure codes describing excision of the sacrum, pelvic bones, and coccyx to MDC 9 (Diseases and Disorders of the Skin,

Subcutaneous Tissue and Breast) in MS-DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures). Cases reporting a principal diagnosis in MDC 9 (such as pressure ulcers) with a procedure describing excision of the sacrum, pelvic bones, and coccyx would group to MS-DRGs 579, 580, and 581.

(4) Lower Extremity Muscle and Tendon Excision. CMS proposes to eight add procedure codes describing excision of lower extremity muscles and tendons to MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders). Cases reporting these procedure codes with a principal diagnosis in MDC 10 would group to MS-DRGs 622, 623, and 624 (Skin Grafts and Wound Debridement for Endocrine, Nutritional and Metabolic Disorders).

(5) Kidney Transplantation Procedures. CMS proposes to the add procedure codes for transplantation of allogeneic kidneys (ICD-10-PCS 0TY00Z0 and 0TY10Z0) to MS-DRG 264 in MDC 5. (Disease and Disorders of the Circulatory System). Cases reporting a principal diagnosis in MDC 5 with a procedure describing a kidney transplantation would group to MS-DRG 264 (Other Circulatory System O.R. Procedures) in MDC 5. Because MDC 5 covers the circulatory system, and kidney transplants generally group to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), **CMS requests comments on whether the procedure codes should instead continue to group to MS-DRGs 981 through 983**.

(6) Insertion of Feeding Device. CMS proposes to add the procedure code for insertion of feeding tube into the stomach (ICD-10-PCS procedure code 0DH60UZ) to MDC 1 (Diseases and Disorders of the Nervous System) and MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders). Cases reporting procedure code 0DH60UZ with a principal diagnosis in MDC 1 would group to MS-DRGs 040, 041, and 042 (Peripheral, Cranial Nerve and Other Nervous System Procedures) and cases reporting procedure code 0DH60UZ with a principal diagnosis in MDC 10 would group to MS-DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures).

(7) Basilic Vein Reposition in Chronic Kidney Disease. CMS proposes to add three ICD-10-PCS procedure codes describing reposition of the basilic vein to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). Cases reporting procedure codes describing reposition of the basilic vein with a principal diagnosis in MDC 11 would group to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures).

(8) Colon Resection with Fistula. CMS proposes to add the procedure code for the resection of sigmoid colon (ICD-10-PCS 0DTN0ZZ) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract). Cases reporting procedure code 0DTN0ZZ with a principal diagnosis of vesicointestinal fistula (diagnosis code N321) in MDC 11 would group to MS-DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures).

b. Reassignment of Procedures.

CMS proposes to maintain the current structure of MS-DRGs 981 through 983 and MS-DRGs 987 through 989.

c. Proposed Additions Diagnosis or Procedure Codes to MDCs.

CMS received requests for reassigning cases grouping to MS-DRGs 981 through 983 or MS-DRGs 987 through 989 to determine if it would be appropriate to add procedure codes into one of the surgical MS DRGs.

(1) Stage 3 Pressure Ulcers of the Hip. CMS proposes to add the procedure codes for the transfer of the hip muscles (ICD-10-PCS procedure codes 0KP0ZZ and 0KXN0ZZ) to MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast). Cases reporting these procedure codes with a principal diagnosis in MDC 9 would group to MS-DRGs 573, 574, and 575 (Skin Graft for Skin Ulcer or Cellulitis).

(2) Gastrointestinal Stromal Tumor. This topic is discussed above in section *a* (Adding Procedure and Diagnosis Codes into MDCs).

(3) Finger Cellulitis. CMS proposes to add 12 procedure codes describing excision and resection of phalanx to MS-DRGs 579, 580, and 581. Cases reporting these procedures with a principal diagnosis from MDC 9 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) would group to MS-DRGs 579, 589, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures).

(4) Multiple Trauma with Internal Fixation of Joints. CMS received a request to reassign cases involving multiple significant trauma with internal fixation of joints. CMS believes that any potential reassignment of these cases requires significant analysis and will consider this issue for future rulemaking.

(5) Totally Implantable Vascular Access Devices. CMS received a request to reassign cases for the insertion of totally implantable vascular devices (TIVADs). Because these procedures were newly designated as O.R. procedures (effective October 1, 2018), CMS does not have sufficient data to analyze this request. It will consider this issue in future rulemaking.

(6) Gastric Band Procedure Complications of Infections. CMS proposes to add procedure codes for the revision and removal of an extraluminal device in the stomach (ICD-10-PCS procedure codes 0DW64CZ and ODP64CZ) to MDC 6 (Diseases and Disorders of the Digestive System). Cases reporting these procedure codes with a principal diagnosis of K95.01 (Infection due to gastric band procedure) or K95.09 (Other complications of gastric band procedure) would group to MS-DRGs 326, 327, and 328 (Stomach, Esophageal, and Duodenal Procedures).

(7) Peritoneal Dialysis Catheters. CMS received a request to reassign cases for complications of peritoneal dialysis catheters. This topic is discussed above in section *a* (Adding Procedure and Diagnosis Codes into MDCs).

(8) Occlusion of Left Renal Vein. CMS proposes to add the procedure for varicose veins in the pelvic region (ICD-10-PCS procedure code 06LB3DZ) to MDC 12 (for male patients) in MS-DRGs 715 and 716 (Other Male Reproductive System O.R. Procedures for Malignancy) and 717, and 718 (Other Male Reproductive System O.R. Procedures Excluding Malignancy) and to MDC 13 (female patient) in MS-DRGs 749 and 750 (Other Female Reproductive System O.R.

Procedures). Cases reporting diagnosis code I86.2 (Pelvic varices) with procedure code 06LB3DZ would group to MDC 12 and MDC 13.

13. Operating Room (O.R.) and Non-O.R. Issues

CMS has a list of procedures that are considered O.R. procedures. CMS discusses how historically this list was developed using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.)

CMS describes the current process used to determine whether and in what way each ICD-10-PCS procedure code on a claim impacts the MS-DRG assignment. First, each procedure code is either designated as an O.R. or non-O.R. procedure.[4] Second, each O.R. procedure is further classified as either extensive or non-extensive. Third, each non-O.R. procedure is further classified as either affecting or not affecting the MS-DRG assignment (CMS refers to these as "non-O.R. affecting the MS-DRG"). For new procedure codes that have been finalized through the ICD-10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS-DRG, CMS' clinical advisors recommend the MS-DRG assignment which are listed in Table 6B (New Procedure Codes) and subject to public comment.[5] CMS notes these proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes.

CMS plans to conduct a multi-year comprehensive, systematic review of the O.R. and non-O.R. ICD-10-PCS procedure codes. CMS believes there may be other factors, such as resource utilization, besides whether or not a procedure is performed in an operating room for determining these designations. **CMS requests comments on what factors or criteria should be considered in determining whether a procedure is designated as an O.R. procedure**. Commenters should submit their recommendations by November 1, 2019 to MSDRGClassificationChange@cms.hhs.gov. CMS will provide more information in future rulemaking.

For review of requests for FY 2020 consideration, CMS' clinical advisors considered the following for each procedure:

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or nonextensive procedure; and
- To which MS-DRG the procedure should be assigned.

In addition, cases that contain O.R. procedures will map to MS-DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) or MS-DRGs 987, 988, or 989

[4] CMS refers readers to the ICD-10 MS-DRG Version 36 Definitions Manual for detailed information regarding the designation of procedures as O.R. or non-O.R. affecting the MS-DRG. This is available at https://www.cms.gov/MEdicare/MEdicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Softwar.html.

[5] Table 6B is available at https://www.cms.gove/Medicare/Medicare-Fee-for-Service-PAyment/AcuteInpatientPPS/index.html.

(Non-Extensive O.R, Procedure Unrelated to Principal Diagnosis) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. Thus, these procedures do not need to be assigned to MS-DRGs 981 through 989.

CMS received several requests to change the O.R. designation of specific ICD-10-PCS procedure codes. Some of these are discussed below. The relevant ICD-10-CM diagnosis codes and ICD-10-PCS procedure codes are listed in each section. CMS' clinical advisors believe it is appropriate to consider the remaining requests as part of its comprehensive review.

a. O.R. Procedures to Non-O.R. Procedures

(1) Bronchoalveolar Lavage. CMS proposes to remove 14 procedure codes from the FY 2020 ICD-10 MS-DRGs Version 37 Definitions Manual in Appendix E – Operating Room Procedures and Procedure Code/MS-DRG Index as O.R. procedures. These procedures would no longer impact MS-DRG assignment.

(2) Percutaneous Drainage of Pelvic Cavity. CMS proposes to remove two procedure codes that describe percutaneous drainage of the pelvic cavity (0W9J3ZX and 0W9J3ZZ) from Appendix E as O.R. procedures. These procedures would no longer impact MS-DRG assignment.

(3) Percutaneous Removal of Drainage Device. CMS proposes to remove the procedure code for percutaneous placement (0F9G30Z) and the procedure code for percutaneous removal (0FPG30Z) from Appendix E as O.R. procedures. These procedures would no longer impact MS-DRG assignments.

b. Non O.R. Procedures to O.R. Procedures

(1) Percutaneous Occlusion of Gastric Artery. CMS proposes to add the procedure code for occlusion of the gastric artery with intraluminal device (04L23DZ) to Appendix E as an O.R. procedure. CMS details the list of 12 assigned MS-DRGs for this procedure.

CMS notes that the procedure code for restriction of gastric artery with intraluminal device (04V23DZ) is already recognized as an O.R. procedure for MS-DRG assignment.

(2) Endoscopic Insertion of Endobronchial Valves. CMS discusses its review of a request to designate eight procedure codes for endobronchial valve procedures as O.R. procedures. Claims data analysis showed a wide variation for average costs for reporting endoscopic insertion of an endobronchial valve without an O.R. procedure. CMS' clinical advisors believe that the subset of patients undergoing these procedures are complex and may have multiple comorbidities that impact the hospital length of stay. The clinical advisors are not convinced that the endoscopic insertion of an endobronchial valve is a key contributing factor to resources. They also believe, that further refinements of MS-DRGS 163, 164, and 165 (Major Chest Procedures) and 166, 167, and 168 (Other Respiratory System O.R. Procedures) may be warranted. CMS is not proposing to change the current non-O.R. designation of the eight procedure codes describing endoscopic insertion of an endobronchial valve. **CMS requests comments on the specific MS-DRGs that cases reporting the endoscopic insertion of an endobronchial valve should affect.**

14. Proposed Changes to the MS-DRG Diagnosis Codes for FY 2020

a. Proposed Changes to Severity Levels.

CMS performed a comprehensive CC/MCC analysis that resulted in its clinical advisors recommending changes in severity level designations for 1,492 ICD-10-CM diagnosis codes. Table 6P.1c. associated with the proposed rule shows CMS' proposed changes to severity level designation. There is also a supplementary file containing the data describing the impact on resource use when reported as a secondary diagnosis for all 1,492 ICD-10-CM diagnosis codes for which CMS proposes changes.[6] The table below (reproduced from proposed rule) summarizes the proposed changes in severity level. The vast majority of the proposed changes (over 85 percent) would result in lower severity level designation (e.g., CC to a Non-CC). Overall, these changes represent about 2 percent of all CC codes by severity level.

Current Version 36 Severity Level	Proposed Version 37 Severity Level	Number of Codes
Non-CC	CC	183
CC	Non-CC	1,148
CC	MC	8
MCC	Non-CC	17
MCC	CC	136
Total		**1,492**

CMS' proposals on categorization of CC codes are based on a review of the data as well as consideration of the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses. 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. We summarize these changes in the table below along with a brief description discussing the nature of the changes. More detail can be found in the proposed rule.

Summary of Severity Level Changes for Certain Categories of Codes			
ICD-10-CM Classification	**Severity Level Changes**	**Details of ICD-10-CM Code Changes**	**Reasoning**
Neoplasms chapter (C00-D49)	767 codes	Proposes changing the severity level for all 767 codes designated as CC to non-CC.	CMS' clinical advisors noted that when a neoplasm is reported as a secondary diagnosis, because it is not the condition that occasioned the patient's admission to the hospital, it does not significantly impact resource use.

[6] This table and associated data are also available at the CMS web site at: http://cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

Summary of Severity Level Changes for Certain Categories of Codes			
ICD-10-CM Classification	**Severity Level Changes**	**Details of ICD-10-CM Code Changes**	**Reasoning**
Diseases of the Circulatory System Chapter (I00-I99)	13 codes	Proposes changing the severity level designation for 13 diagnosis codes from categories I21 (Acute myocardial infarction to I22 (Subsequent ST elevation (STEMI) and Non-ST elevation (NSTEMI) myocardial infarction) from an MCC to a CC	Data suggests that the resources involved in their care are not aligned with those of an MCC and that the resources are more consistent with CC status.
Diseases of the Skin and Subcutaneous Tissue Chapter (L00-L99)	150 codes	Proposes changing the 150 diagnosis codes describing pressure ulcers: proposes changing all codes to a CC than either a non-CC or an MCC. Specifically, proposes to designate as CCs both the 50 diagnosis codes that are currently designated as MCCs and the 100 diagnosis codes currently designated as non-CCs.	Clinical advisors believe that the fact that the ulcer developed in the first place is more important than the stage of the ulcer in determining the impact on the costs of the hospitalization.
Diseases of the Genitourinary System Chapter (N00-N99)	8 codes	Proposes increasing the severity level designation from a CC to an MCC for one code, and from a non-CC to a CC for seven codes	CMS states, for example, that patients with end-stage renal disease (ICD-10-CM code N18.6) would typically require dialysis in addition to these resources, which clinical advisors believe is more aligned with an MCC.
S32.5 (Fracture of pubis)	19 codes	Proposes changing the severity level designation from CC to non-CC for 19 diagnosis codes that specify fractures of the pubic bone.	CMS notes that if patients are admitted for treatment of an acute or nonunion fracture of the pubic bone, the fracture is the principal diagnosis, and other complicating or comorbid conditions, reported as secondary diagnoses would determine the appropriate severity level for each particular case.
S72 (Fracture of femur)	35 codes	Proposes changing the severity level designation from MCC to CC for 35 diagnosis codes specifying fractures of the hip from an MCC to a CC.	Data suggest that when fracture of the hip codes are reported as a secondary diagnosis, the resources involved in caring for patients with these conditions are more aligned with a CC than an MCC.
Factors Influencing Health Status and Contact with Health Services (Z00-Z99)	18 codes	Proposes changing the severity level designation from non-CC to CC for four codes specifying anti-microbial drug resistance and one code specifying homelessness. Proposes changing the severity level designation from CC to non-CC for 3 codes specifying adult body mass index ranges and 11 codes indicating that the patient	CMS states that, for example, the presence of a BMI within a stated range or the fact that a patient has previously undergone a transplant or cardiac device implant is not by itself a clinical indication or increased severity of illness.

Summary of Severity Level Changes for Certain Categories of Codes			
ICD-10-CM Classification	**Severity Level Changes**	**Details of ICD-10-CM Code Changes**	**Reasoning**
		had previously undergone an organ transplant or cardiac device implantation with no current complications.	

CMS notes that under the Hospital-Acquired Condition (HAC) payment provision, hospitals no longer receive additional payment for cases in which one of the selected conditions occurred but was not present on admission (POA). If the proposed severity level designations for the pressure ulcer diagnosis codes are finalized, the 100 ICD-10-CM diagnosis codes that would switch from non-CC to CCs would be subject to the HAC-POA payment provision. The diagnosis codes describing a stage 3 or 4 ulcer would continue to be subject to the HAC-POA payment provisions as CCs. CMS also proposes a technical change to revise the title of the HAC 04 category from "Pressure Ulcer – Stages III & IV" to "Pressure Ulcers".

b. Results of Impact Analysis.

CMS used the claims data from the September 2018 update of the FY 2018 MedPAR file to determine the impact of changing severity level designation for the 1,492 ICD-10-CM diagnosis codes. CMS first analyzed the severity level distribution of 8.9 million claims before the proposed changes using Version 36 ICD-10 MS-DRG GROUPER to determine the current distribution of severity level designation. Over 41 percent of cases reporting one or more secondary diagnosis codes were assigned to the MCC severity level. CMS next made the proposed severity level changes to the 1,492 ICD-10-CM codes (as described above), and then reprocessed the claims using these proposed changes (details of proposed changes shown below). With the proposed changes, for example, the percent of cases reporting one or more secondary diagnosis codes assigned the MCC severity level dropped from 41 percent to 36.3 percent.

Severity Level Distribution before and after Proposed Changes– 8.908 Million Claims Analyzed		
	Before Proposed Changes	After Proposed Changes
Number of cases reporting one or more secondary diagnosis codes assigned to the MCC severity level	3,648,331 (41.0%)	3,236,493 (36.3%)
Number of cases reporting one or more secondary diagnosis codes assigned to the CC severity level	3,612,600 (40.5%)	3,589,677 (40.3%)
Number of cases reporting no secondary diagnosis codes assigned to the MCC or CC severity level	1,647,473 (18.5%)	2,082,234 (23.4%)

The overall statistics by CC group for the proposed Version 37 MS-DRGs are shown in the table below (reproduced from proposed rule). Cases in the MCC subgroup have average costs that are 62 percent higher than the average costs for cases in the CC subgroup. The CC subgroup has the largest share of cases among the subgroup (40.3%).

Overall Statistics for Proposed MS-DRGs			
CC subgroup	**Number of Cases**	**Percent**	**Average Costs**
Major	3,236,493	36.3	$16,890
CC	3,589,677	40.3	$10,518
Non-CC	2,082,234	23.4	$10,166

c. Requested Changes to Severity Levels.

CMS received seven requests for changes to severity levels of ICD-10-CM diagnosis codes for FY 2020.

- Received a request to change the severity level ICD-10-CM diagnosis codes of I50.811 (Acute right heart failure) and I50.813 (Acute on chronic right heart failure) from a non-CC to an MCC. CMS clinical advisors believe that the resources appear to be more aligned with those of a CC. **CMS solicits comment on whether a CC severity level designation is appropriate for these codes.**
- CMS is not proposing a change to the severity level for ICD-10-CM diagnosis code I50.812 (Chronic right heart failure) from a non-CC to a CC.
- CMS is not proposing a change to the severity level for ICD-10-CM diagnosis codes K70.11, K70.31, and K71.51 related to alcohol liver disease and toxic liver disease.
- CMS is not proposing changes to certain diagnosis associated with factitious disorder imposed on self, F68.11 or F68.13.
- CMS is not proposing changes to certain diagnosis associated with nonunion and malunion of physeal metatarsal fracture, S99.101B, S99.101K, S99.101P, S99.132B, S99.132K, and S99.132P.
- CMS is not proposing any change to the severity level for diagnosis code G93.49 (Other encephalopathy).
- Received a request to change the severity level for 94 ICD-10-CM diagnosis codes in the Obstetrics chapter of the ICD-10-CM diagnosis classification that describe a variety of complications of pregnancy, childbirth and the puerperium. CMS proposes changes to the severity level for 14 diagnosis codes: 4 from MCC to CC and 10 from non-CC to CC.

d. 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 2020:

- 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.

e. 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 37 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

15. Changes to the MS-DRG Diagnosis Codes for FY 2020

To identify new, revised and deleted diagnosis and procedure codes for FY 2020, 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 6E - Revised Diagnosis Code Titles;
- Table 6F - Revised Procedure Code Titles;
- Table 6G.1 - Proposed Secondary Disorders Order Additions to the CC Exclusion List;
- Table 6G.2 - Proposed Principal Disorders Order Additions to the CC Exclusion List;
- Table 6H.1 - Proposed Secondary Disorders Order Deletions to the CC Exclusion List;
- Table 6H.2 - Proposed Secondary Disorders Order Deletions to the CC Exclusion List;
- Table 6I.1 – Proposed Additions to the MCC List;
- Table 6I.2 – Proposed Deletions to the MCC List;
- Table 6J.1 – Proposed Additions to the CC List; and
- 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.

16. Proposed Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, 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 Version 36 manual file, along with the link to the mainframe and compute software for the MCE Version 36 (and ICD-10 MS-DRGs) are posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

CMS discusses requests it received by November 1, 2018 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,
- Unacceptable Principal Diagnosis Edit, and
- Non-covered Procedure Edit.

CMS has 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 is considering whether the inclusion of coverage edits in the MCE necessarily aligns with the MCE goals to ensure that errors and inconsistences in the coded data are recognized during claims processing.

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, 2019 for FY 2021.

17. Proposed 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 5 (Diseases and Disorders of the Circulatory System) CMS proposes corresponding changes to the surgical hierarchy for MDC 5.

18. Maintenance of 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 to: nchsicd10cm@cdc.gov.
- For procedure codes send questions and comments to: ICDProcedureCodeRequest@cms.hhs.gov.

The official list of ICD-10-CM and ICD-10-PCS codes can be found at http://www.cms.gov/Medicare/Coding/ICD10/index.html.

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 proposes to create new MS-DRGs 319 and 320 (Other Endovascular Cardiac Valve Procedures, with and without MCC, respectively). A subset of procedures currently assigned to MS-DRGs 216 through 221 are proposed for assignment to proposed new MS-DRGs 319 and 320. CMS proposes that if these proposed MS-DRG changes are finalized, it would add proposed new MS-DRGs 319 and 320 to the list of MS-DRGs subject to the policy for replaced devices offered without cost or with a credit. CMS also proposes to revise the titles of MS-DRGs 266 and 267 from "Endovascular Cardiac Valve Replacement with and without MCC, respectively" to "Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively". These proposals are reflected in the table below (reproduced from the proposed rule).

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

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 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC
MDC 03	129	Major Head & Neck Procedures with CC/MCC or Major Device
MDC 03	130	Major Head & Neck Procedures without CC/MCC
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC
MDC 5	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC
MDC 5	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC
MDC 5	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC
MDC 5	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC
MDC 5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC
MDC 5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC
MDC 5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC
MDC 5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC
MDC 5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
MDC 5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
MDC 5	242	Permanent Cardiac Pacemaker Implant with MCC
MDC 5	243	Permanent Cardiac Pacemaker Implant with CC
MDC 5	244	Permanent Cardiac Pacemaker Implant without CC/MCC
MDC 5	245	AICD Generator Procedures
MDC 5	258	Cardiac Pacemaker Device Replacement with MCC
MDC 5	259	Cardiac Pacemaker Device Replacement without MCC
MDC 5	260	Cardiac Pacemaker Revision Except Device 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 5	261	Cardiac Pacemaker Revision Except Device Replacement with CC
MDC 5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
MDC 5	265	AICD Lead Procedures
MDC 5	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
MDC 5	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
MDC 5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
MDC 5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
MDC 5	270	Other Major Cardiovascular Procedures with MCC
MDC 5	271	Other Major Cardiovascular Procedures with CC
MDC 5	272	Other Major Cardiovascular Procedures without CC/MCC
MDC 5	319	Other Endovascular Cardiac Valve Procedures with MCC
MDC 5	320	Other Endovascular Cardiac Valve Procedures without MCC
MDC 8	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
MDC 8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
MDC 8	466	Revision of Hip or Knee Replacement with MCC
MDC 8	467	Revision of Hip or Knee Replacement with CC
MDC 8	468	Revision of Hip or Knee Replacement without CC/MCC
MDC 8	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC
MDC 8	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC

G. Recalibration of the MS-DRG Relative Weights

The Secretary is required by statute to revise the MS-DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. In developing relative weights for the FY 2020 proposed rule, CMS used two data sources:

FY 2018 MedPAR data based on bills received through December 31, 2018 from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). Medicare Advantage claims and claims from facilities currently classified as critical access hospitals (CAH) were excluded. CMS used data from approximately 9.4 million Medicare discharges regrouped using the proposed FY 2020 MS-DRG classifications.

Medicare cost report data files from HCRIS, principally for FY 2017 cost reporting periods, using the December 31, 2018 update of the FY 2017 HCRIS. As in the past, CMS uses the HCRIS dataset that is three years prior to the IPPS fiscal year.

The proposed cost-based relative weights were normalized by an adjustment factor of 1.788337 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.

H. Add-On Payments for New Services and Technologies

1. Background

Sections 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 the 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, beginning with FY 2020, CMS includes the MS-DRG thresholds applicable to the next fiscal year in the data files associated with the prior fiscal year; this information was previously included in Table 10 of the annual IPPS PPS rules. The MS-DRG thresholds applicable to FY 2020 are included in the data files associated with the FY 2019

IPPS final rule on the CMS website.[7] The proposed thresholds for applications for FY 2021 are presented in a data file associated with the FY 2020 proposed rule on the CMS website.[8]

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 the full DRG payment, including payments for IME and DSH but excluding outlier payments); 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 payments 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 2021, 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 2021.

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 these processes, can contact the Council on Technology and Innovation (CTI) at CTI@cms.hhs.gov.[9]

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

On December 4, 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 December 14, 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

[7] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2019-IPPS-Final-Rule-Home-Page-Items/FY2019-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLSort=0&DLSortDir=ascending.
[8] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.
[9] 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.

improvement" criterion are not summarized in this proposed rule. Commenters can resubmit their comments in response to proposals in this proposed rule.

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. 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. Proposed FY 2020 Status of Technologies Approved for FY 2019 New Technology Add-On Payments

CMS' policy is that a medical service or technology may be considered new within 2 or 3 years after 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 fiscal year and it generally follows a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend an add-on payment for an additional fiscal year. In general, CMS extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the US market occurs in the later half of the fiscal year.

As discussed below, for FY 2020, CMS proposes to discontinue new technology add-on payments for Defitelio® (Defibrotide), Ustekinumb (Stelara®) and Bezlotuxumab (ZINPLAVA™).

CMS proposes to continue new technology add-on payments for AndexXa™ (andexanet alfa), the AQUABEAM System, Giapreza™, KYMRIAH™ (Tisagenleclucel), the remedē® System, the Sentinel® Cerebral Protection System, VABOMERE™ (meropenem-vaborbactam), VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection), and ZEMDRI™ Plazomicin.

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.

Because the 3-year anniversary date of the entry of Defitelio® on the US market will occur during FY 2019 (April 4, 2019), CMS proposes to discontinue the new technology add-on payments for FY 2020.

b. 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.

Because the 3-year anniversary date of the entry of Stelara® on the US market will occur during FY 2019 (September 23, 2019) CMS proposes to discontinue the new technology add-on payments for FY 2020.

c. 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.

Because the 3-year anniversary date of the entry of ZINPLAVA™ on the US market will occur in the first half of FY 2020 (February 10, 2020), CMS proposes to discontinue the new technology add-on payments for FY 2019.

d. 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.[10] Both of these technologies are CD-19 directed T-cell immunotherapies used for treating patients with aggressive variants of non-Hodgkin lymphoma (NHL). On October 18, 2017, YESCARTA® received FDA approved for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two of more lines of systemic therapy. On May 1, 2018, KYMRIAH® received FDA approval for a second indication: treatment of adult patients with r/r large B-cell lymphoma after two or more lines of systemic therapy.

As discussed in the FY 2019 IPPS proposed and final rules, CMS considers these two technologies as substantially similar to each other and it evaluated both technologies as one application. CMS continues to believe that KYMRIAH® and YESCARTA® are substantially similar to each other. CMS notes that for FY 2020, the pricing for KYMRIAH® and YESCARTA® remains the same and therefore, for FY 2020, there is no payment impact regarding the determination that the two technologies are substantially similar to each other.

[10] Kite Pharma 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.

CMS welcomes comments regarding whether KYMRIAH® and YESCARTA® are substantially similar to each other.

CMS considers the beginning of the newness period for both KYMRIAH® and YESCARTA® as November 22, 2017. Because the 3-year anniversary date of the entry of the technology on the US market (November 22, 2020) will occur after FY 2020, CMS proposes to continue the new technology payment for KYMRIAH® and YESCARTA® for FY 2020. As discussed below in section H.9.[11], CMS proposes that the maximum new technology add-on payment amount for case involving KYMRIAH® and YESCARTA® would be increased to $242,450 for FY 2020 (65 percent of the average cost of the technology). Using this maximum add-on payment, CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $93,585,700 (based on 386 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $186,500 for FY 2020.

As discussed in section II.F.2. of this proposed rule, CMS is not proposing to modify the current MS-DRG assignment for cases reporting CAR-T cell therapies for FY 2020. **CMS invites comments on payment alternatives for CAR-T cell therapies**. Alternatives include adjusting the CCRs used to calculate new technology add-on payments for cases involving KYMRIAH® and YESCARTA® by making a uniform add-on payment that equals the proposed maximum add-on payment (based on the proposal to increase the add-on payment to 65 percent of the cost of the technology) or perhaps a higher percentage than the proposed 65 percent to calculate the maximum new technology add-on payment amount.

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

VYXEOS™, is a nano-scale liposomal formulation containing a fixed combination of cytarabine and daunorubicin used to treat adult newly diagnosed therapy-related AML (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

Because the 3-year anniversary date of the entry of the VYXEOS™ onto the US market (August 3, 2020) will occur in the second half of FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using VYXEOS™ would be $47,353.50 for FY 2020 (65 percent of the average cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $45,458,4000 (based on 960 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $36,425 for FY 2020.

f. VABOMERE™ (meropenem-vaborbactam)

VABOMERE™ 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.

[11]In Section H.9., CMS proposes to increase the maximum new technology add-on payment to 65 percent of the cost of the new technology.

Because the 3-year anniversary date of the entry of the VABOMERE™ onto the US market (August 29, 2020) will occur in the second half of FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using VABOMERE™ would be $7,207.20 for FY 2020 (65 percent of the average cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $19,084,666 (based on 2,648 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $5,544 for FY 2020.

VABOMERE™ is the first approved new technology approved for the new technology add-on payment (aside from as oral drug) with no uniquely assigned inpatient procedure code. FY 2019 cases involving VABOMERE™ that are eligible for the FY 2019 new technology add-on payment are identified by the NDC 65293-009-01 (VABOMERE™ Meropenem-Vaborbactam Vial) used in data element LIN03 of the 837i Health Care Claim Institutional form. Effective October 1, 2019 two new ICD-10-PCS codes (XW033N5 and XW043N5) will identify cases involving VABOMERE™. CMS is concerned that for FY 2020 some providers may inadvertently continue to bill some claims with the NDC codes instead of the new ICD-10-PCS codes. Thus, for FY 2020, CMS proposes that it would use the new ICD-10-PCS codes and also the NDC codes to identify cases for the new technology add-on payments.

g. remedē® System

The remedē® System is as a transvenous phrenic nerve stimulator used in the treatment of adult patients with moderate to severe central sleep apnea (CSA).

Because the 3-year anniversary date of the entry of the remedē® System onto the US market (October 6, 2020) will occur after FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using the remedē® System would be $22,425 for FY 2020 (65 percent of the average cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $1,794,000 (based on 80 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $17,250 for FY 2020.

h. ZEMDRI™ (Plazomicin)

ZEMDRI™ is an aminoglycoside antibiotic used in the treatment of adults diagnosed with cUTIs, including pyelonephritis.

Because the 3-year anniversary date of the entry of ZEMDRI™ onto the US market (June 25, 2021) will occur after FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using ZEMDRI™ would be $3,539.25 for FY 2020 (65 percent of the average cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020

payments by $8,848,125 (based on 2,500 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $2,722.50 for FY 2020.

i. GIAPREZA™

GIAPREZA™, a synthetic human angiotensin II, is used in the treatment of adults diagnosed with septic or other distributive shock as an intravenous (IV) infusion to increase blood pressure.

Because the 3-year anniversary date of the entry of GIAPREZA™ onto the US market (December 21, 2020) will occur after FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using GIAPREZA™ would be $1,950 for FY 2020 (65 percent of the average cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $11,173,500 (based on 5,730 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $1,500 for FY 2020.

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

The Cerebral Protection System (Sentinel® Cerebral Protection System) is used as an embolic protection (EP) device to capture and remove thrombus and debris during transcatheter aortic valve replacement (TAVR) procedures. The De Novo request for the Sentinel® Cerebral Protection System was granted on June 1, 2017 and the FDA concluded this device should be classified into Class II (moderate risk).

Because the 3-year anniversary date of the entry of the Sentinel® Cerebral Protection System onto the US market (June 1, 2020) will occur in the second half of FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using the Sentinel® Cerebral Protection System would be $1,820 for FY 2020 (65 percent of the average cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $11,830,000 (based on 6,500 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $1,400 for FY 2020.

k. The AQUABEAM System (Aquablation)

The AQUABEAM System is a device used in the treatment of patients with lower urinary tract symptoms caused by benign prostatic hyperplasia (BPH). The FDA granted the applicant's De Novo request on December 21, 2017 for use of the system in the resection and removal of prostate tissue in patients suffering from lower urinary tract symptoms due to BPH.

Because the 3-year anniversary date of the entry of the AQUABEAM System onto the US market (December 21, 2020) will occur after FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using AQUABEAM would be $1,625 for FY 2020 (65 percent of the average

cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $677,625 (based on 417 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $1,250 for FY 2020.

l. AndexXA™ (Adexanet Alfa)

AndexXa™ is indicated for use in the treatment of patients receiving rivaroxabab and apixabam when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding.

Because the 3-year anniversary date of the entry of AndexXA™ onto the US market (May 3, 2021) will occur after FY 2020, CMS proposes to continue the new technology payment for FY 2020. Under the proposed change to the calculation of the new technology add-on payment, CMS proposes that the maximum new technology add-on payment amount for a case using AndexXA™ would be $18,281.25 for FY 2020 (65 percent of the average cost of the technology). CMS estimates that the new technology add-on payments would increase overall FY 2020 payments by $98,755,313 (based on 5,402 patients). If this proposal is not finalized, the maximum new technology add-on payment would remain at $14,062.50 for FY 2020.

5. Proposed FY 2020 Applications for New Technology Add-On Payments

CMS received 18 applications for new technology add-on payments for FY 2020. 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. One applicant withdrew its application prior to the issuance of the proposed rule.

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. **CMS invites public comment on whether these technologies meet the newness, cost and substantial clinical improvement criteria.**

a. AZEDRA® (Ulratace® 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 iobenguane avid malignant and/or recurrent and/or unresectable pheochromocytoma and paragangliona[12]. AZEDRA® contains a small 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.)

The applicant states 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

[12] An application for AZEDRA® was submitted for FY 2019 and withdrawn prior to the issuance of the FY 20199 IPPS final rule.

of ^{131}I-MIBG compared to compounded formulations of ^{131}I-MIBG that are not currently approved by the FDA.

Newness. AZEDRA® was approved by the FDA on July 30, 2018 for the treatment of adult and pediatric patients 12 years and older diagnosed with iobenguane scan positive, unresectable, locally advance or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy through a New Drug Approval (NDA) filed under Section 505(b)(1) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.50. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures involving the administration of AZEDRA®; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), 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 (same or different MS-DRG), the applicant noted there are no specific MS-DRGs for the assignment of cases involving the treatment of patients diagnosed with pheochromocytoma and paraganglioma. For the third criterion (same or similar disease or patient population), the applicant states that AZEDRA® is 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. The applicant also discusses how AZEDRA® can be distinguished from other available treatments.

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.

Cost. The applicant searched the FY 2015 MedPAR file 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. The applicant identified six MS-DRGs but due to privacy concerns, the applicant assumed an equal distribution between the 6 MS-DRGs. The applicant provided an estimated charge of $151,000 per therapeutic dose per patient with a total cost be patient estimated to be approximately $980,900. After including the cost of the technology, the applicant determined an inflated average case-weighted standardized charge per case of $1,078,631 (which exceeds the average case weighted threshold amount) and concluded that AZEDRA® meets the cost criterion.

CMS acknowledges the difficulties in obtaining cost data for a rare condition, but it is concerned about the limited number of cases the applicant analyzed.

Substantial Clinical Improvement. The applicant stated that AZEDRA® reduced the incidence of hypertensive episodes and 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 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 the lack of comparison of the treatment to other treatment options used 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. CMS 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.

b. CABLIVI® (caplacizumab-yhdp)

The Sanofi Company submitted an application for CABLIVI®, a humanized bivalent nanobody[13] administered through IV and subcutaneous (SC) injection to inhibit microclot formation in adult patients diagnosed with acquired thrombotic thrombocytopenic purpura (aTTP). According to the applicant, aTTP is caused by inhibitory autoantibodies to von Willebrand Factor-cleaving protease (VWFCP) and metalloprotease with thrombospondin type 1 motif, member 13 (ADAMSTS13) resulting in a severe deficiency in vWFCP which causes extensive clot formation in small blood vessels throughout the body. CABLIVI® is an anti-vWF nanobody designed to inhibit the interaction between and platelets. CABLIVI® is administered as an adjunct to plasma exchange (PE) treatment and immunosuppressive therapy.

Newness. CABLIVI® received FDA approval on February 6, 2019, for the treatment of adult patients diagnosed with aTTP, in combination with PE and immunosuppressive therapy. The applicant states CABLIVI® was previously granted Fast Track and Orphan Drug designation by the FDA. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures involving CABLIVI®; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant discusses how CABLIVI® is a first-in-class therapy with an innovative mechanism of action. The applicant highlighted that the immediate platelet-protective effect differentiates CABLIVI® from slowing acting therapies, such as PE and immunosuppressants, which need days to take effect. The applicant explants that PE acts by removing ultra-large vWF and other circulating auto-antibodies while immunosuppressants aim to stop or reduce the formation of auto-antibodies. For the second criterion (same or different MS-DRG), the applicant stated that potential cases representing patients who may be eligible for CABLIVI® would be assigned to the same MS-DRG as patients who receive standard of care (SOC) treatment (PE and immunosuppressants) for aTTP. For the third criterion (same or similar disease or patient population), the applicant stated there are no other specific therapies approved for the treatment of patients with aTTP. The applicant notes there are no studies specifically comparing SOC treatment options and that these treatment options are not specifically approved for the treatment of aTTP.

[13] Nanobodies are therapeutic proteins based on single-domain antibody fragments that contain the unique structural and functional properties of naturally occurring heavy chain only antibodies.

CMS notes it is not clear that CABLIVI® would involve the treatment of a different type of disease or a different patient population that currently available treatment options.

Cost. The applicant searched the FY 2017 MedPAR file for claims submitted with appropriate ICD-10 CM diagnosis codes and ICD-10-PCS procedure codes and identified 360 cases spanning 61 MS-DRGs, with approximately 67 percent of all potential cases mapping to 5 MS-DRGs. The applicant standardized the average case-weighted unstandardized charges per case and removed historic charges for items expected to be avoided for patients receiving treatment involving CABLIVI®. The anticipated price for CABLIVI® in combination with PE and immunosuppressive therapy had yet to be determined, and no charges for CABLIVI® were added. Because the final inflated average case-weighted standardized charge per case exceeds the average case weighted threshold amount, the applicant concluded that CABLIVI® meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that CABLIVI® is a significant clinical improvement to SOC because it significantly reduces the time to obtain a platelet count response; reduces the number of aTTP-related death or major thromboembolic event; reduces mortality, reduces the proportion of patients with a recurrence of aTTP; reduces the proportion of patients who develop refractory disease; reduces the number of days of PE, the length of ICU stay, and the length of hospitalization; and shows a trend of more rapid normalization of organ damage markers. The applicant presented information from the results of Phase II TITAN and Phase III HERCULES studies and an integrated efficacy analysis of both studies. CMS acknowledges the challenges with constructing robust clinical studies due to the extremely rare occurrence of patients diagnosed with aTTP. CMS states it is not clear if the response rate in the studies may differ in those who have a de novo diagnosis versus those with recurrent disease. Because CABLIVI® is given in combination with SOC, CMS is concerned that it may not have sufficient information to determine the extent to which the results are attributable to CABLIVI®. CMS is also concerned about the lack of long-term data. Another issue raised by CMS is that although both the studies included key secondary endpoints such as death or major thromboembolic events, it is concerned these endpoints were not clearly defined, and that other defined endpoints, such as heart attack, stroke and a bleeding episode, were not evaluated.

In response to questions raised during the New Technology Town Hall meeting, CMS received a written comment from the applicant providing additional information about the Phase III HERCULES study.

c. CivaSheet®

CivaTech Oncology, Inc. submitted an application for CivaSheet®, a "sealed source" intended to be placed into a body cavity or tissue for the delivery of radiation therapy. CivaSheet® is indicated for use as a brachytherapy source for the treatment of selected localized tumors, either for primary treatment or treatment of residual disease after excision of the primary tumor. CivaSheet® may be used concurrently or sequentially with other treatment modalities.

Newness. CivaSheet® was approved as a "sealed source" by the Nuclear Regulatory Commission (NRC) and added to the Registry of Radioactive Sealed Source and Devices on October 24, 2014. On May 9, 2018, CivaSheet® was registered by the American Association of Physicists in

Medicine (AAPM) on the "Joint AAPM/IROC Houston Registry of Brachytherapy Sources Complying with AAPM Dosimetric Prerequisites." The applicant stated that inclusion on this AAPM registry is a long-standing requirement imposed on brachytherapy sources used in NIH clinical trials. According to the applicant, the "newness' period for CivaSheet® should begin on May 9, 2018. **CMS seeks comments on whether inclusion on the AAPM registry an appropriate indicator of the first availability of the CivaSheet on the US market and whether the date of inclusion on the AAPM registry is appropriate to consider as the beginning of the newness period for CivaSheet®.** There are no approved ICD-10-PCS procedure codes to uniquely identify procedures using CivaSheet®; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant stated that CivaSheet® does not have a similar mechanism of action in comparison to existing brachytherapy technologies. The unique construction and configuration of the CivaSheet® device permits delivery of radiation intra-operatively in a highly targeted fashion. In addition, the applicant states the CivaSheet® configuration substantially reduces the dose delivered to neighboring radiosensitive structures. The applicant concludes that the CivaSheet® is the first low-dose radiation (LDR) brachytherapy device designed specifically for the delivery of IORT and does not have a similar mechanism of action when compared to existing LDR brachytherapies. For the second criterion (same or different MS-DRG), the applicant provided a list of 32 MS-DRGs that would include patients eligible for treatment with CivaSheet®. For the third criterion (same or similar disease or patient population), the applicant states that clinical conditions that may require the use of CivaSheet® include treatment of the same patient population diagnosed with a variety of cancers.

Cost. The applicant searched the FY 2017 MedPAR file and identified 22,855 potential cases. The applicant limited its analysis to the most relevant 32 MS-DRGs, which represented 80 percent of all cases and excluded statistical outliers, HMO cases, claims submitted only for GME payments, and cases at hospitals not included in the FY 2019 IPPS final rule impact file (the applicant noted these are predominately cancer hospitals not subject to the IPPS). The applicant conducted analysis on the remaining 17,173 cases. The applicant indicated the current average cost of CivaSheet® is $24,132.86. The calculated average case-weighted standardized charge per case was $188,897 (using the percent distribution of MS-DRGs as case weights) and because the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold amount, the applicant concluded that CivaSheet® meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that CivaSheet® represents a significant clinical improvement over existing technologies because it improved local control of different cancers; reduced rate of device-related complications; reduced rate of radiation toxicity; decreased future hospitalizations; decreased rate of subsequent therapeutic interventions; improved back pain and appetite in patients with pancreatic cancer; and improved local control for pancreatic cancer patients. The applicant provided numerous case reports, including long-term outcome patient report, and numerous case series. CMS is concerned that all of the supporting data appear to be feasibility studies substantiating the use of CivaSheet® in different cancers and different anatomic locations. In addition, CMS is concerned that there are no

comparisons to other current treatments, nor any long-term follow-up with comparisons to currently available therapies.

d. CONTEPO™ (Fosfomycin for Injection)

Nabriva Therapeutics US, Inc. submitted an application for CONTEPO™ for treatment of (cUTIs caused by multi-drug resistant (MDR) pathogens in hospitalized patients. According to the applicant, CONTEPO™ is an epoxide IV antibiotic that eradicates bacteria by inhibiting the bacteria's ability to form cell walls and offers a broad spectrum of bactericidal Gram-negative and Gram-positive activity, including activity against Extended-spectrum ß-lactamase (ESBL)-producing Enterobacteriaceae, as well as other MDR organisms.

Newness. CONTEPO™ has not yet received FDA approval; the FDA has accepted the applicant's NDA using its Priority Review expedited program. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures using CONTEPO™; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant stated that CONTEPO™'s mechanism of action is unique in comparison to all other injectable antibiotics because it inhibits a different and earlier stage of cell wall synthesis and lacks cross resistance with other existing classes of IV antibiotics. For the second criterion (same or different MS-DRG), the applicant stated that patients who may be eligible to receive treatment with CONTEPO™ include hospitalized patients diagnosed with cUTIs and would likely be assigned to the same MS-DRGs with cases involving treatment with comparator drugs. With respect to the third criterion (same or similar disease or patient population), the applicant asserted that CONTEPO™ would treat a different patient population than existing available treatment options. The applicant states that CONTEPO™ unique mechanism of action allows the drug to reach different and expanded patient populations, particularly patients with a cUTI due to pathogens resistant or suspected resistance to ESBL or fluoroquinolone resistance.

CMS is concerned that CONTEPO's mechanism of action may be similar to other drugs that inhibit cell wall development, including penicillins, cephalosporins, and carbapenems. CMS also believes that potential cases using CONTEPO™ would be assigned to the same MS-DRGs as cases involving comparator antibiotics and is concerned that hospitalized patients diagnosed with cUTIs, including those with MDR pathogens, does not constitute a unique patient population because there are existing treatment options for these patients.

Cost. The applicant used the FY 2017 MedPAR file to identify potential cases and identified 199 ICD-10-CM diagnosis code combinations. A search of the FY 2017 MedPAR file, identified 508,821 potential cases; the applicant excluded MS-DRGs with 10 cases or less and did analysis of 508,602 cases across 461 MS-DRGs. The applicant identified 5 antibiotics used for treatment of cUTI and removed these charges. The applicant calculated an average case-weighted standardized charge per case of $71,333 using the percent distribution of MS-DRGs as case weight. The applicant concluded that the final inflated average case-weighted standardized charge per case for CONTEPO™ exceeded the average case-weighted threshold amount and meets the cost criterion. The applicant also conducted three additional sensitivity analyses which also demonstrated that CONTEPO™ meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that CONTEPO™ offers a treatment option for a patient population unresponsive to, or ineligible for, available treatments and significantly improves clinical outcomes for this population. The applicant cited the ZEUS Study, a multi-center, randomized, parallel-group, double-blind PhaseII/III trial of 464 patients at 92 global sites in 16 countries. CMS discusses several concerns with this study including whether or not patients were from the US (given the geographic variability of antibiotic resistance); if the proper treatments were used as the comparator; and methodological concerns with the analysis of the ZEUS study. CMS is also concerned that the applicant assertions regarding the efficacy of CONTEPO™ on MDR gram-negative pathogens comes from *in vitro* studies or may be speculative.

In response to a question raised during the New Technology Town Hall meeting about post-hoc reanalysis from the ZEUS study, CMS received a written comment from the applicant providing additional information.

e. DuraGraft® Vascular Conduit Solution

Somahlution, Inc submitted an application for DuraGraft®, a solution used for vein graft storage and prevention of vascular graft disease (VGD) and vein graft failure (VGF) which reduces the clinical complications associated with graft failure.[14] DuraGraft® is used during standard graft handling, flushing and bathing steps of graft harvesting.

Newness. The applicant has applied for FDA approval and anticipates approval of its premarket application by July 1, 2019. The applicant indicated that ICD-10-PCS code XY0VX83 would identify procedures using the DuraGraft® technology.

For the first criterion (same or similar mechanism of action), 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. For the second criterion (same or different MS-DRG) the applicant stated that cases involving patients receiving treatment involving DuraGraft® would be assigned to the same MS-DRGs as patients receiving treatments involving heparinized blood, saline, and electrolyte solutions. For the third criterion (same or similar disease or patient population) the applicant indicated that heparinized blood, saline and electrolyte solutions involve treatment of the same disease process and the same patient population as DuraGraft®.

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.

Cost. The applicant searched the FY 2017 MedPAR file for claims that identified potential cases identified by 16 ICD-10-PCS procedure codes. The applicant identified 100 MS-DRGs with potential cases, approximately 93 percent of potential cases (66,553) 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. The applicant added

[14] An application for DURAGRAFT® was submitted for FY 2018 and FY 2019, which were withdrawn.

$4,751 in charges for the cost of the technology. The final average case-weighted standardized charge per case of $195,799 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® significantly reduces clinical complications associated with VGF following coronary artery bypass grafting (CABG) surgery. CMS summarizes the information the applicant presented from the PREVENT IV analysis; the European Retrospective Pilot Study (unpublished); a VA Hospital retrospective study and the SWEDEHEART 2016 Annual Report (a report on data extracted from the Swedish Cardiac Surgery Registry).

CMS discusses concerns with the information provided. It is concerned that the European Retrospective Pilot Study and the VA Hospital Study are unpublished, retrospective, and have too many variables unaccounted for that could affect vein integrity, such as vein harvest and post-operative care. CMS is also concerned about many of the study designs including the fact that the statistical plan did not include adjustments for multiple comparisons, nor did it include power calculations for the expected differences in endpoints that would be biologically important.

f. Eluvia™ Drug-Eluting Vascular Stent System

Boston Scientific submitted an application for the Eluvia™ Drug-Eluting Vascular Stent System which is comprised of an implantable endoprothesis and a stent delivery system (SDS). The drug-eluting stent system is indicated for improving luminal diameter in the treatment of peripheral artery disease (PAD) with symptomatic de novo or restenotic lesions in the native superficial femoral artery (SFA) and or proximal popliteal artery (PPA) with reference vessel diameters (RVD) ranging from 4.0 to 6.0 mm and total lesion lengths up to 190 mm. According to the applicant, the Eluvia™ stent is coated with the drug pacilitaxel, which helps prevent the artery from restenosis, and the drug delivery system is designed to sustain the release of pacilitaxel beyond 1 year to match the restenotic process in the SFA.

Newness. The Eluvia™ Drug-Eluting System received FDA approval (PMA) on September 18, 2018. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures using the device; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant states the Eluvia™ stent uses a unique mechanism of action which involves a polymer that carries and protects the drug (paclitaxel) and ensures the drug is released into the tissue in a controlled, sustained manner for 12 to 15 months. This is different than other drug-coated balloons or drug-coated stents that deliver the drug to the artery for approximately 2 months. For the second criterion (same or different MS-DRG), the applicant states that potential cases may map to multiple MS-DRGs, the most likely being MS-DRGs 252, 253, and 254 (Other Vascular Procedures); the same MS-DRGs for patients with PAD and treated with current technologies. For the third criterion (same or similar disease or patient population), the applicant states that clinical conditions that may require use of the Eluvia™ stent includes treatment of the same patient population identified with forty diagnosis codes from the ICD-10-CM category 170 (Atherosclerosis) group.

CMS is concerned that the Eluvia™ stent's mechanism of action may be similar to the paclitaxel-coated Zilver® Drug-Eluting Peripheral Stent (Cook Medical), which is indicated for the treatment of de novo or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference vessel diameter from 4 to 7 mm and total lesion lengths up to 300 mm per patient.

Cost. The applicant searched the FY 2017 MedPAR file in MS-DRGs 252, 253, and 254 for cases reporting the ICD-10-PCS procedure codes the applicant believed would represent potential cases for the Eluvia™ stent. The applicant initially identified 109,747 claims for potential cases and after applying several trims identified 73,861 claims. The applicant removed all device-related charges and added charges for the Eluvia™ stent by taking the cost of the device and converting it to a charge by dividing the costs by the national average CCR of 0.309 for devices. The applicant calculated an average case-weighted standardized charge per case of $86,950 using the percent distribution of MS-DRGs as case weight. The applicant concluded that the final inflated average case-weighted standardized charge per case for Eluvia™ stent exceeded the average case-weighted threshold amount and meets the cost criterion. The applicant also conducted additional sensitivity analyses which also demonstrated that the device meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that the Eluvia™ stent is a substantial clinical improvement because it achieves superior primary patency; reduces the rate of subsequent therapeutic interventions; decreases the number of future hospitalizations or physician visits; reduces hospital readmissions; reduces the rate of device-related complications; and achieves similar functional outcomes and EQ-5D index values while associated with half the rate of target lesion revascularization (TLRs). The applicant submitted the results of the MAJESTIC study, a prospective, multi-center, single-arm, open-label study (57 patients) and the results of the IMPERIAL study which compared the Eluvia™ stent to the Zilver® Drug-Eluting Peripheral Stent in a global, multi-center randomized control study (465 subjects). CMS is concerned the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for non-inferiority and not superiority.

CMS also notes the result of recent published meta-analysis of randomized controlled trials of the risk of death associated with the use of paclitaxel-coated balloons and stents in the femoropopliteal artery of the knee which found an increased death following application of paclitaxel-coated balloons and stents in the femoropoliteal artery of the lower limbs and urged that further investigations are warranted.[15] Although the Eluvia™ stent was not included in the meta-analysis, **CMS invites comments on the implications of the meta-analysis results to a finding of substantial clinical improvement for the Eluvia™ stent**.

CMS also summarizes a written public comment it received in response to the New Technology Town Hall meeting. The commenter raised several concerns about the information presented by the applicant at the meeting. The commenter does not believe the data demonstrated the use of

[15] Katsanos, K., et al. "Risk of Death Following Applications of Paclitaxel-Coated Balloons and Stents in the Femoropoliteal Artery of the Leg: A Systematic Review and Meta-Analysis of Randomized Controlled Trial," J*AHA*, vol. 7(24).

the Eluvia™ stent results in a sustained clinical improvement compared to the Zilver® Drug-Eluting Peripheral Stent.

g. ELZONRIS™ (tagraxofusp, SL-401)

Stemline Therapeutis submitted an application for ELZONRIS™ a targeted IV therapy for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a rare, highly aggressive hematologic malignancy, previously known as blastic natural killer (NK) cell leukemia/lymphoma. ELZONRIS™ is a recombinant protein composed of human interleukin-3 (IL-3) genetically fused to a truncated diphtheria toxin (DT) payload. The applicant states that ELZONRIS™ binds to the IL-3 receptor (also known as CD123) on CD123-expressing cells is internalized into the cell endosome; inactivates elongation factor 2 (EF-2), a key protein involved in protein synthesis, and this leads to the termination of protein synthesis and ultimately cell death. The applicant stated that are no approved therapies for the treatment of BPDCN and that current drug treatments might temporarily help to slow disease progression but fail to eradicate cancer stem cells.

Newness. The FDA granted ELZONRIS™ Breakthrough Therapy, Priority Review, and Orphan Drug designations, and approved ELZONRIS™ on December 21, 2018 for the treatment of BPDCN in adults and pediatric patients 2 years old and older. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures using ELZONRIS™; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant states the drug has a unique mechanism of action by attacking cells with CD123 which is overexpressed in cancer stem cell and minimally expressed or absent on normal hematopoietic stem cells. Current treatment options are not targeted specifically to CD123-expressing cells. For the second criterion (same or different MS-DRG), the applicant stated that cases representing patients receiving ELZONRIS™ would not be assigned to the same MS-DRG(s) when compared to cases receiving existing therapies. CMS notes that in the discussion of the cost criterion, the applicant stated that cases eligible for treatment with ELZONRIS™ would be assigned to MS-DRGs that contain cases representing patients receiving chemotherapy without acute leukemia as a secondary diagnosis. For the third criterion (same or similar disease or patient population), the applicant stated that the use of ELZONRIS™ would involve treatment of a dissimilar patient population as compared to other therapies. The applicant notes that the patient population is distinguishable from other diseases by the ICD-10-CM diagnosis code specific to BPDCN (C86.4, Blastic NK-cell lymphoma).

Cost. The applicant used the FY 2017 MedPAR file and identified 65 cases reporting ICD-10-CM diagnosis code C86.4 mapping to 28 different MD-DRGs. The applicant stated that cases representing patients eligible for ELZONRIS™ would most likely be in MS-DRGs 847 and 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis) and accounted for 24 (37 percent) of the 65 cases with diagnosis code C86.4. The applicant increased the sample size by using an additional 18 cases identified in the FY 2016 MedPAR file mapping to the same MS-DRGs, for a combined total of 42 cases. The applicant performed analysis under two different scenarios: for the first scenario predecessor charges were not removed (the applicant noted it

would be extreme to assume no products or services would be replaced if ELZONRIS™ were used), and for the second scenario all charges were removed so that only ELZONRIS™ was used as the cost of the case. Charges for ELZONRIS™ were added in both scenarios. For both scenarios, the final inflated case-weighted standardized charge per case ($1,066,165 for scenario one and $1,1010,455 for scenario two) exceeded the average case-weighted threshold amount and the applicant concludes the cost criterion was met.

Substantial Clinical Improvement. The applicant stated that ELZONRIS™ represents a substantial clinical improvement because it is the only treatment indicated specifically for patients with BPDCN; offers a treatment option for a patient population ineligible for aggressive chemotherapy regimens used to treat BPDCN; treatment is associated with a high complete remission rate that is potentially superior to other treatments; significantly improves overall survival (OS) in these patients; improves clinical outcomes because it may allow more patients to bridge to stem cell transplantation; is a well-tolerated targeted therapy; and is more efficient than other chemotherapy at killing BPDCN cells. The applicate submitted review articles from 2016, retrospective case studies from 2013, and a 2011 retrospective study. In addition, the applicant provided information from the prospective clinical trial data from ELZONRIS™'s pivotal trial and from a 2015 preclinical study. CMS discusses several concerns with the submitted information including the fact that some of the evidence is based on preclinical studies, the number of patients is small and the lack of baseline data against which to compare this technology. CMS also notes that the clinical trial is ongoing, and the final outcomes are not available. In addition, because of differences between the information in the application and information presented at the Town Hall meeting, CMS is not sure which results reflect the most current available information.

h. Erdafitinib

Johnson & Johnson (on behalf of Janssen Oncology, Inc) submitted an application for Erdafitinib an oral pan-fibroblast growth factor receptor (FGFR) tyrosine kinase inhibitor being evaluated in Phase II and III clinical trial is patients with advanced urothelial cancer. FGFRs are a family of receptor tyrosine kinases, which may be upregulated in various tumor cell types and may be involved in tumor cell differentiation, proliferation, and survival. Erdafitinib is a pan-fibroblast FGFR inhibitor with potential antineoplastic activity.

Newness. Erdafitinib was granted Breakthrough Therapy designation by the FDA on March 15, 2018 for the treatment of patients with urothelial cancer whose tumors have certain FGFR genetic alterations. It has not yet received FDA premarket approval. There are no approved ICD-10-PCS procedure codes to uniquely identify procedures using Erdafitinib. A request for approval for a unique code was submitted and at the September 11, 2018 ICD-10 Committee meeting CMS recommended the establishment of a "X" code to identify cases involving the administration of Erdafitinib.

For the first criterion (same or similar mechanism of action), the applicant asserted that Erdafitinib is a first-in-class FGFR inhibitor with a novel mechanism of action. For the second criterion (same or different MS-DRG) the applicant stated that potential cases representing

patients potentially eligible for treatment may be assigned to the same MS-DRGs as cases with patients treated with available treatment for urothelial cancer. For the third criterion (same or similar disease or patient population), treatment involving Erdafitinib will be a specific subset of patients with FGFR genetic alterations.

Cost. The applicant searched the FY 2017 MedPAR file for cases representing patients who may be eligible for treatment using Erdafitinib. The applicant assumed that most hospitals would not utilize Erdafitinib for short-stay hospitalizations and eliminated all identified potential cases of 3 days of less. The applicant also assumed that any hospitalization of 4 days or longer would involve the daily administration of Erdafitinib. Using a combination of ICD-10 diagnosis codes the applicant identified 2,844 cases mapping to a wide range of MS-DRGs and limited its analysis to twenty-one MS-DRGs which more than 1 percent of the total identified cases were assigned. The applicant did not remove any charges for prior therapies because the applicant did not believe the use of Erdafitinib would replace any other therapies. The applicant added the charges for the cost of the drug and obtained a reported average case-weighted standardized charge per case of $111,713. The applicant concluded that Erdafitinib meets the cost criterion.

Substantial Clinical Improvement. The applicant asserts that Erdafitinib provides a substantial clinical improvement for a select group of patients diagnosed with locally advanced or metastatic urothelial carcinoma who have failed first-line treatment and have limited second-line treatment options by reducing mortality, decreasing pain and reducing recovery time. Erdafitinib will be the first available treatment option for patients who have FGFR genetic alterations detected by an FDA-approved test. The applicant submitted the results of a Phase I dose-escalation study for the use of Erdafitinib and data from a multi-center, open-label Phase II study. The applicant also referenced an ongoing Phase III study, but data was not available at the time of the application's submission. CMS has several concerns with the information presented including there was no information comparing Erdafitinib to existing therapies and the available data is based on a small sample size. CMS is concerned it may not have enough information to determine if Erdafitinib represents a substantial clinical improvement over existing technologies.

i. ERLEADA™ (Apalutamide)

Johnson & Johnson (on behalf of Janssen Oncology, Inc) submitted an application for ERLEADA™, an oral drug that is an androgen receptor inhibitor indicated for the treatment of patients diagnosed with non-metastatic castration-resistant prostate cancer (nmCRPC). ERLEADA™ blocks the effect of androgens on the tumor in order to delay metastases, a major cause of complications and death associated with prostate cancer.

Newness. ERLEADA™ was granted Fast Track and Priority Review designations under FDA's expedited programs and received FDA approval on February 14, 2018 for the treatment of nmCRPC. There are no approved ICD-10-PCS procedure codes to uniquely identify the administration of ERLEADA™; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant maintains that ERLEADA™ is new because it is the first drug approved with its mechanism of action. The applicant stated that in non-clinical studies ERLEADA™ was shown to have a higher binding affinity to the androgen receptor than bicalutamide, a first-generation anti-androgen used off-

label in clinical practice for the treatment of nmCRPC. The applicant states that ERLEADA™ has a different mechanism of action than bicalutamide. For the second criterion (same or different MS-DRG), the applicant noted that patients who may be eligible to receive ERLEADA™ are likely to be assigned to a wide variety of MS-DRGs. For the third criterion (same or similar disease or patient population), the applicant maintains that ERLEADA™ was the first FDA-approved treatment option for nmCRPC and there are no other FDA-approved treatment options for patient with nmCRPC to delay the onset of metastasis.

Cost. The applicant searched the FY 2017 MedPAR file for cases representing patients who may be eligible for treatment using ERLEADA™ by using two ICD-10-CM diagnosis code combinations (C61 (Malignant neoplasm of prostate) with R97.2 (Rising PSA following treatment for malignant neoplasm of prostate) or C61 with Z19.2 (Hormone resistant malignancy status)). The applicant assumed that short stays would not involve treatment with ERLEADA™ and removed all hospital stays of fewer than 4 days from its analysis. The applicant also assumes that any hospital stay 4 days or longer would involve daily treatment with ERLEADA™. The analysis found 493 cases in 152 MS-DRGs with approximately 33 percent of all cases mapping to 9 MS-DRGs. The applicant did not remove any charges for the current treatment during the inpatient stay. The applicant added the charges for the cost of the drug and obtained a reported average case-weighted standardized charge per case of $76,901. The applicant submitted an additional cost analysis including hospital stays shorter than 4 days and the average case-weighted standardized charge per case ($57,150) also exceeded the average case-weighted threshold among and concluded that Erdafitinib™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserts that Erdafitinib™ represents a substantial clinical improvement because the technology offers a treatment for a patient population previously ineligible for treatments because Erdafitinib™ is the first FDA-approved treatment for patients with nmCRPC and the use of the technology significantly improves clinical outcomes, including improvement in metastasis-free survival (MFS). The applicant cited the SPARTAN trial, a randomized, double-blind, placebo-controlled, Phase III trial which included men diagnosed with nmCRPC and a prostate-specific antigen doubling time of 10 months or less. The applicant also included the results of additional secondary endpoints as evidence of substantial clinical improvement, including a suggested overall survival benefit; demonstrated safety profile; maintained quality of life; and decreased PSA levels.

CMS discusses several concerns with the information submitted. In response to CMS' concern that the SPARTAN trial design may not be representative of the US population as only 6 percent of patients were black (African-American patients are disproportionately affected by prostate cancer), the applicant submitted additional information claiming a consistent treatment effect across all subpopulations and regions. In addition, CMS notes that a total of 7.0 percent of patients in the Erdafitinib™ group and 10.6 percent of patients in the placebo group withdrew consent from the trial and CMS is interested in the impact of these withdrawals on the study results. In response to CMS' concerns about the primary endpoints used in the SPARTAN trial, MFS, the applicant explained that MFS was determined to be a reasonable end point because of the difficulty in using OS as a primary endpoint in patients. CMS notes that MFS is not identical to OS and it may be difficult to conclude that Erdafitinib™ improves OS. The applicant provided additional information on MFS as a surrogate clinical endpoint for OS. **CMS invites comments**

on the substantial clinical improvement criterion, **specifically additional information and comments on whether the SPARTAN trial results are generalizable to the US population and in particular, African-American patients**.

j. SPRAVATO (Esketamine)

Johnson & Johnson (on behalf of Janssen Oncology, Inc) submitted an application for SPRAVATO, a drug administered through a nasal spray for the treatment of treatment-resistant depression (TRD). According to the applicant, SPRAVATO is a non-competitive, subtype non-selective, activity-dependent glutamate receptor modulator that helps to restore connections between brain cells in people with TRD.

Newness. SPRAVATO HCL nasal spray was granted a Breakthrough Therapy designation in 2013 and was approved by the FDA on March 5, 2019. There are no approved ICD-10-PCS procedure codes to uniquely identify the administration of SPRAVATO; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), according to the applicant, SPRAVATO's unique mechanism of action through glutamate receptor modulation is different than existing approved anti-depressants which primary modulate nomoamine systems (norepinephrine, serotonin, or dopamine). For the second criterion (same or different MS-DRG), the applicant states it is likely that potential cases representing patients eligible for treatment with SPRAVATO would be assigned to the same MS-DRG as patients being treated with current anti-depressants. For the third criterion (same or similar disease or patient population), the applicant asserts that patients receiving treatment with SPRAVATO will be a subset of patients receiving current anti-depressants. CMS notes the applicant did not provide additional information about this subpopulation.

Cost. The applicant used the FY 2017 MedPAR file to identify potential cases identified by four ICD-10-CM diagnosis codes for major depressive disorder (MDD). The applicant excluded claims if they had one or more diagnoses for conditions that would preclude the use of SPRAVATO. The applicant also assumed hospitals would not allow administration of SPRAVATO for short-stays and excluded hospitalizations of fewer than 5 days. The applicant assumed that patients would be administered their first dose on the 5th day and every 7 days thereafter. The applicant identified a total of 3,437 potential cases mapping to 439 MS-DRGs with approximately 54.7 percent of cases mapping to 10 MS-DRGs. The applicant further reduced the potential cases in each MS-DRG by one-third. The applicant stated that clinical data indicates that approximately one-third of patients diagnosed with MDD also have TRD. The applicant did not remove any charges for prior treatments and added charges for SPRAVATO. The applicant calculated a final inflated average case-weighted standardized charge per case of $74,738, which exceeds the average case-weighted threshold amount and the applicant concluded that SPRAVATO meets the cost criterion.

CMS is concerned about the reduction of cases used in the cost analysis to one-third of the total potential cases identified. Although the statistical data provided by the applicant suggest that one-third of patients diagnosed with MDD often also have TRD, it is unclear which cases should be removed. It is possible that patients with MDD are covered by all 439 MS-DRGs, but

patients with TRD may only exist in a certain subset of these MS-DRGs. CMS is also concerned that patients with TRD could account for the costliest of patients diagnosed with MDD. CMS states it may not be able to verify the assumption that patients with TRD compromise one-third of the identified cases and are evenly distributed across all of the MS-DRG identified cases.

Substantial Clinical Improvement. The applicant asserts that SPRAVATO represents a substantial clinical improvement because it provides a treatment option for a patient population that failed available treatments and have shown inadequate response to at least two anti-depressants in their current episode of MDD. According to the applicant, there is only one other FDA approved drug (Symbyax®) used for the treatment of TRD but its use is limited because of tolerability concerns. The applicant provided several studies in support of the substantial clinical improvement criterion. CMS summarizes the information and discusses several concerns. CMS is concerned that the use of the placebo in combination with a newly prescribed anti-depressant may not be the most appropriate comparator and states that comparisons with existing treatments for TRD might be better for evaluating the clinical improvements associated with SPRAVATO. CMS is also uncertain about how the findings apply to the broader Medicare population and notes there are few statistically significant improvements in depression outcomes with SPRAVATO treatment among the Medicare-aged population. In addition, the studies have limited racial diversity and excluded patients with significant comorbidities through exclusion criteria with are likely to be increased among patients with a mental health disorder and the elderly. CMS has additional concerns including the primary and secondary endpoints for several of the studies and the potential for physician behavior to have introduced bias. In addition, given SPRAVATO is comprised of the drug ketamine, CMS is concerned with the potential for abuse and the paucity of long-term studies to assess whether chronic usage of this product may increase the likelihood of abuse. CMS is concerned that despite any short-term clinical benefits, there may be potential negatives associated with the long-term use of this drug.

k. XOSPATA® (gilteritinib)

Astellas Pharma US Inc submitted an application for XOSPATA®, an oral small molecule FMS-like tyrosine kinase 3 (FLT3) used for the treatment of adult patients with r/r acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test. The applicant states that XOSPATA® inhibits FLT3 receptor signaling and proliferation in cells exogenously expressing FLT3 which is normally expressed on the surface of hematopoietic progenitor cells but is over expressed in the majority of AML cells. Several chemotherapy regimens have been used for treatment of r/r AML but these are dose-intensive and cannot always be easily administered to older patients because of a high-risk of unacceptable toxicity. The applicant indicated that patients with AML with FLT3 positive mutations are a well-established subpopulation of AML patients but there are no approved therapies for patients with R/R AML with FLT3 mutations.

Newness. XOSPATA® received FDA approval November 28, 2018. There are no approved ICD-10-PCS procedure codes to identify the administration of XOSPATA®; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), the applicant states that XOSPATA® is the only FLT3 target agent approved by the FDA for the treatment of R/R FLT3mut+ AML. For the second criterion (same or different MS-DRG), the applicant indicates that cases involving treatment with XOSPATA® would map to the same MS-DRGs as existing therapies. For the third criterion (same or similar disease or patient population) the applicant stated that XOSPATA® is used for a subset of adult patients with R/R AML with a FLT3 mutation.

Cost. The applicant searched the FY 2017 MedPAR file for cases reporting ICD-10 CM diagnosis codes C92.02 (AML, in relapse) and C92.A4 (AML with multilineage dysplasia in relapse) as a primary or secondary diagnosis that mapped to MS-DRGs 834, 835 and 836. After applying trims to the cases, which included the exclusion of cases for bone marrow transplant, 407 potential cases remained. The applicant removed all pharmacy charges and reduced blood charges. The applicant calculated an average case-weighted standardized charge per case of $157,034 using the percent distribution of MS-DRGs as case-weights. This exceeded the average case-weighted threshold amount and the applicant concluded the technology meets the cost criterion.

Substantial Clinical Improvement. The applicant submitted one central study to support its assertion that XOSPATA® represents a substantial clinical improvement because it offers a treatment option for FLT3mut+ AML patients ineligible for current treatment. The ADMIRAL study is a multi-national, active-controlled, Phase III study. CMS notes the applicant did not provide direct numbers for the comparator arm of the ADMIRAL study and is concerned that without this information, it may be difficult to determine XOSPATA®'s comparative effectiveness.

l. 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.[16] GammaTile™ is biocompatible and bioabsorbable, and is in the body permanently without the need for future surgical removal.

Newness. The applicant received FDA clearance under section 510(k) as a Class II medical device on July 6, 2018 for use to provide radiation therapy for patients diagnosed with recurrent intercranial neoplasms. ICD-10-PCS procedure code 00H004Z identifies procedures involving the use of GammaTile™.

For the first criterion (same or similar mechanism of action), 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, (same or different MS-DRG), patients that may

[16] An application for GammaTile™ was submitted in FYs 2018 and 2019 and withdrawn in both years. For FY 2019, the technology did not receive FDA approval by February 1, 2018 and was not eligible for consideration for new technology add-on payments.

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 (same or similar disease or patient population), 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 calculated an estimate for ancillary charges associated with placement of the GammaTile™ device.[17] 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 $253,876 exceeds the average case-weighted threshold amount 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 cited several sources of data to support the substantial clinical improvement criterion. CMS is concerned that the findings appear to be derived from relatively small case studies with limited clinical efficacy and safety data. In addition, the findings are not data from FDA approved clinical trials. CMS notes there is a lack of analyses, meta-analyses or statistical tests that indicate seeded brachytherapy procedures represented a statistically significant improvement over alternative treatments. In addition, CMS is concerned with the lack of studies involving the actual manufactured device. Finally, while the FDA cleared GammaTile™ under section 510(k) authorization to market the device for the cleared indications, the FDA's issuance of a "substantially equivalent determination" did not indicate a review of any specific superiority claims to a predicate device.

m. Imipeneum, Cilastatin, and Relabactam (IMI/REL) Injection

Merck & Co. submitted as application for IMI/REL, an antibiotic indicated for the treatment of patients 18 years of age and older diagnosed with complicated intra-abdominal infections (cIAI) and cUTIs, including pyelonephritis, caused by susceptible gram-negative microorganisms where limited or no alternative therapies are available. According to the applicant, IMI/REL is a fixed-dose combination of imipenem/cilastatin (IMI) a ß-lactam (BL) antibacterial (specifically, a carbapenem) and relebatam (REL) a novel ß-lactamase inhibitor (BLI).

[17]In response to a previous concern raised by CMS, the applicant noted its analysis does not include a reduction in costs due to reduced operating times because while the device will reduce operating times relative to the freehand placement of seeds in other brain brachytherapy procedures, none of the claims in the cost analysis involve such freehand placement.

Newness. A new drug application for IMI/REL was submitted to the FDA and approval is anticipated prior to the July 1, 2019 deadline. The applicant stated that procedures involving the administration of IMI/REL could be identified with ICD-10-PCS codes for introduction of other anti-infective into peripheral (3E03329) or central vein (3E04329) however, neither code would uniquely identify the administration of IMI/REL. The applicant has submitted a request for a specific ICD-10-PCS procedure code.

For the first criterion (same or similar mechanism of action), the applicant states that IMI/REL's mechanism of action differentiates it from other approved antibiotics and asserts that the combination of REL and IMI would be most efficacious in most imipenem-resistant strains at clinically achievable doses and concentrations. For the second criterion (same or different MS-DRGs) cases involving IMI/REL would most likely be assigned to the same MS-DRGs as cases involving comparator treatments. For the third criterion (same or similar disease or patient population), the applicant asserted that IMI/REL would treat a different patient population than available treatment options. The applicant also compared IMI/REL to other comparator antibiotics.

CMS is concerned that IMI/REL's mechanism of action may be similar to the mechanism of action of other BL/BLI antibiotics. CMS recognizes that REL is used as a unique molecular structure with respect to other BLIs in BL/BLI combinations, but the fundamental mechanism of action of IMI/REL may be similar to other BL/BLIs. In addition, CMS has concerns with the assertion that IMI/REL would treat a different patient population than existing treatment options. CMS states that non-uniform resistance patterns among patients necessitates a range of drugs to treat the same disease but this may not constitute a new patient population.

Cost. Using the FY 2017 MedPAR file, the applicant identified all MS-DRGs containing cases that reported ICD-10-CM diagnosis codes for cUTI or cIAI, as a primary or secondary diagnosis, as well as a diagnosis code for carbapenem-resistant bacteria (CRE). The applicant identified 21,111 cases which mapped to 441 unique MS-DRGS. After trimming the cases that were mapped to low-volume MS-DRGs (fewer than 11 cases), there were 19,973 cases that mapped to 134 MS-DRGs. The applicant removed 100 percent of the drug charges from the relevant cases and then added charges for the administration of IMI/REL. The applicant calculated an average case-weighted standardized charge per case of $74,778 using the percent distribution of MS-DRGs as case-weights. The applicant repeated the cost analysis to create one analysis of cases with cUTI and another analysis of cases with cIAI. In each of these additional sensitivity analyses, the applicant determined the final inflated average case-weighted standardized charge per case exceeded the final average case-weighted threshold amount.

Substantial Clinical Improvement. The applicant believes that the efficacy and safety results of the Phase III trial RESTORE-IMI 1 demonstrates the substantial clinical improvement of IMI/REL. RESTORE-IMI 1 included 47 subjects randomized in a double -blind, active-controlled, parallel group, multi-center Phase III trial. CMS has several concerns regarding the evidence presented including the comparator chosen for the RESTORE-IMI 1 trial; the clinical conditions included besides cUTI and cIAI; methodological concerns about the different endpoints; and assessments at day 28. In addition, CMS notes it is not clear that IMI/REL induces less nephrotoxicity compared to other available treatments.

n. JAKAFI™ (Ruolitinib)

Incyte Corporation submitted an application for JAKAFI™, an oral Janus-associated kinase (JAK) inhibitor for the treatment of acute graft-versus-host-disease (aGVHD) in patients with an inadequate response to corticosteroids. According to the applicant there are no FDA-approved treatments for patients with steroid-refractory aGVHD and despite available treatment options patients do not always achieve a positive response. The applicant states the American Society for Blood and Marrow Transplantation (ASBMT) does not provide any recommendations for second-line therapy for patients with steroid-refractory aGVHD.

Newness. JAKAFI™ received FDA approval in 2011 for treatment of patients with myelofibrosis and in 2014 for treatment of patients diagnosed with polycythemia vera. The applicant submitted a supplemental new drug application with Orphan Drug and Breakthrough Therapy designations seeking FDA approval for a new indication for JAKAFI™ for the treatment of patients with steroid-refractory aGVHD. The applicant expects FDA approval prior to the July 1, 2019 deadline. There are no approved ICD-10-PCS procedure codes to identify the administration of JAKAFI™; a request for approval for a unique code was submitted.

For the first criterion (same or similar mechanism of action), applicant asserts there are no products that use JAK inhibition to achieve the same therapeutic outcome. According to the applicant, JAKAFI™'s regulation of the activities of immune cells involved in aGVHD etiology is different from the mechanism of action of other agents (such as methotrexate) used as second-line treatment for patients with steroid-resistant aGVHD. For the second criterion (same or different MS-DRG), the applicant states that JAKAFI™ would not be assigned to the same MS-DRG as existing technologies. For the third criterion (same or similar disease or patient population), the applicant states JAKAFI™ represents a new treatment option for a patient population without existing or alternative options.

CMS notes that there are a number of available second-line treatment options for a diagnosis of aGVHD that treat the same patient population as JAKAFI™ and that a number of these treatment options suppress the immune response similar to the mechanism of JAKAFI™. CMS would also expect patient cases to be generally assigned to the same MS-DRGs as patients with steroid-resistant aGVHD receiving current treatment options.

Cost. The applicant searched the FY 2017 MedPAR file for cases reporting ICD-10-CM diagnosis codes for acute or unspecified GVHD in combination with ICD-10-CM diagnosis codes for associated complications of bone marrow transplant or ICD-10-CM procedure codes for transfusion of allogeneic bone marrow. The applicant identified a total of 210 cases mapping to four MS-DRGs. The applicant provided two scenarios to demonstrate that JAKAFI™ meets the cost criterion: in the first scenario the applicant removed 100 percent of the pharmacy charges and in the second scenario the pharmacy charges were not removed. The applicant added charges for JAKAFI™. In both scenarios, the final average case-weighted standardized charge per case ($261,512 for scenario one and $377,494 for scenario two) exceeded the average case-weighted threshold amount. The applicant concluded JAKAFI™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserts that JAKAFI™ represents a substantial clinical improvement because it would be the first FDA-approved treatment for patients with

steroid-resistant aGVHD and significantly improves clinical outcomes in this patient population. The applicant stated there are few prospective studies evaluating second-line therapy for a diagnosis of steroid-refractory aGVHD and interpretation of these studies is hampered by the heterogeneity of the patient population, small sample sizes, and lack of standardization in the study design.

The applicant provided the results from five clinical studies that include prospective and retrospective studies. CMS has several concerns including the results provided do not include any data directly comparing JAKAFI™ to any second-line treatments. CMS states that recommendations from professional societies for the treatment of aGVHD describe the lack of data demonstrating superior efficacy of any single agent as second line therapy for steroid-resistant aGVHD and suggest that the choice of second-line treatment be guided by clinical considerations. Without any data directly comparing JAKAFI™ to any other second-line treatment, CMS states it may be difficult to directly asses whether JAKAFI™ provides a substantial clinical improvement compared to existing treatments. CMS is also concerned about the small sample sizes and that the variable amount of detail provided on the studies makes it difficult to fully assess the generalizability of the results to the Medicare patient population. In addition, CMS expressed concern that several patients enrolled in each study had safety-related complications.

o. 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).[18] According to the applicant, SSO_2 Therapy is used for patients receiving treatment for an ST-segment elevation myocardial infarction (STEMI). 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.

Newness. SSO_2 Therapy received premarket approval from the FDA on April 4, 2019. The applicant states that the use of SSO_2 Therapy can be identified by the ICD-10-PCS procedure codes 5A0512C and 5A0522C.

For the first criterion (same or similar mechanism of action), the applicant stated the SSO_2 Therapy increases oxygen levels and re-opens the microcirculatory system within the infarct

[18] An application for SSO_2 Therapy was submitted for FY 2019 which was withdrawn.

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 with AMI restore blood flow at the macrovascular level and do not treat hypoxemic damage at the microvascular or microcirculatory level. For the second criterion (same or different MS-DRG), stated there are no specific MS-DRG assignments for SSO_2 Therapy. For the third criterion (same or similar disease or patient population), the applicant stated that because SSO_2 Therapy is administered following a PCI, its target patient population includes a subset of patients with the same or similar type of disease as patients treated with PCI with stent placement. The applicant believes that SSO_2 Therapy offers a treatment option for a different type of disease since it delivers hyperbaric oxygen to reduce the extent of myocardial necrosis instead of the PCI with stent that reopens a blocked artery.

CMS believes that potential cases involving the SSO_2 Therapy may be assigned to the same MS-DRGs as other cases involving percutaneous coronary intervention (PCI) with stent placement used to treat patients with AMI.

Cost. The applicant searched the FY 2017 MedPAR file for claims reporting four ICD-10-CM diagnosis codes for anterior ST-Elevation Myocardial Infarction (STEMI) and identified 11,668 potential cases across four 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 added charges for the technology and additional supplies used in the administration of SSO_2 Therapy, including procedure room time, technician labor, and additional blood tests. The inflated average case-weighted standardized charge per case was $144,364. 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 which improves mortality outcomes and improves heart failure outcomes; reduces infarct size; prevents left ventricular dilation; and reduces death and heart failure at 1 year. The applicant submitted results from five clinical studies that it believes demonstrate the substantial clinical benefit associated with SSO_2 Therapy. 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. CMS summarizes these studies and discusses several concerns. CMS notes that the standard-of-care (SOC) for STEMI has evolved since two studies (AMIHOT I and AMIHOT II) were conducted and it is not clear whether the use of SSO_2 Therapy would demonstrate the same clinical improvement when compared to current SOC. For these studies, CMS is also concerned that there is no long-term data demonstrating the validity of these findings and that infarct size has not been completely validated as a surrogate marker. CMS also discusses concerns about another study, the IC-HOT study, including the lack of a control and the safety data being limited to 30 days post-MI.

p. T2Bacteria® (T2 Bacteria Test Panel)

T2 Biosystems submitted an application for the T2Bacteria® Panel, a multiplex disease panel that detects five major bacterial pathogens (*Enterococcus faecium, Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa,* and *Staphylococcus aureus*) associated with sepsis. According to the applicant, the T2Bacteria® Panel can detect bacterial pathogens directly in whole blood more rapidly and with greater sensitivity as compared to the SOC, blood culture. The panel runs on the T2DX Instrument that utilizes advances in magnetic resonance and nanotechnology to detect pathogens directly in small amounts of whole blood.

Newness. The T2Bacteria® Panel received 510(k) clearance on May 24, 2018, based on a determination of substantial equivalence to a legally marketed predicate device. The applicant noted the use of the T2Bacteria® Panel may be identified by thousands of ICD-10-CM diagnosis codes; a request for approval for a unique ICD-10-PCS code to describe procedures with the T2Bacteria® Panel was submitted.

For the first criterion (same or similar mechanism of action), the applicant asserted that the T2Bacteria® Panel has a different mechanism of action than the SOC, blood culture. The applicant noted that the only product on the U.S. market using the same mechanism of action is the T2Candida Panel, which detects five clinically relevant species of the fungal pathogen, *Candida*. For the second criterion (same or different MS-DRG), the applicant did not provide any information but, CMS believes that cases involving the T2Bacteria® Panel would be assigned to the same MS-DRGs as cases involving blood cultures. For the third criterion, the applicant states the T2Bacteria® Panel would be used as a diagnostic aid in the treatment of similar diseases and patient populations as blood cultures.

CMS is concerned that the mechanism of action of the T2Bacteria® Panel may be similar to the mechanism of action of blood cultures or other available diagnostic tests since both the T2Bacteria® Panel and other tests, including blood cultures, use DNA to identify bacterial species.

Cost. The applicant identified the MS-DRGs to which potential cases available for the use of the T2Bacteria® Panel would most likely map and a selection of ICD-10-CM diagnosis codes associated with the five bacteria identified with the panel. Using the FY 2017 MedPAR file, the applicant provided 16 cost analysis scenarios and supplemental analysis for eight additional scenarios. In all the analysis, the applicant noted the average case-weighted standardized charge per case for potential cases using the T2Bacteria® Panel exceeded the average case-weighted threshold amount. The applicant concluded the T2Bacteria® Panel meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted the T2Bacteria® Panel represents a substantial clinical improvement because it is the only FDA-cleared diagnostic aid that rapidly and accurately identifies sepsis-causing bacteria directly from whole blood within 3 to 5 hours, instead of the 1 to 5 days required by SOC technology. According to the applicant, T2Bacteria® Panel provides more rapid resolution of the disease process by enabling faster treatment which can reduce hospital length-of-stay and death. The applicant provided results from several studies, including results from the T2Bacteria® Panel pivotal trial. CMS is concerned that there is not sufficient evidence to demonstrate that early identification of the bacteria by the

T2Bacteria® Panel without information about antibiotic susceptibility is enough to prevent unnecessary empiric therapy because antibiotic susceptibilities obtained by blood cultures may still be required to adequately treat sepsis. CMS notes that it is also possible for organism not detected by the panel could be contributing to the sepsis. In addition, the supplemental labeling information provided by the applicant indicates that the use of the T2Bacteria® Panel would not replace blood cultures for specific organisms. CMS discusses other concerns with the information provided and is not sure that the panel alters the clinical course of treatment. CMS also believes a stronger comparator for the T2Bacteria® Panel would be other DNA based test used to identify bacterial infection. CMS is concerned that the use of the T2Bacteria® Panel may not be a substantial clinical improvement over blood cultures.

q. VENCLEXTA® (venetoclax)

AbbVie Pharmaceuticals submitted an application for VENCLEXTA®, an oral anti-cancer drug. VENCLEXTA® was previously approved by the FDA for the treatment of patients diagnosed with chronic lymphocytic leukemia (CLL) with 17p deletion, as detected by am FDA-approved test, who had received at least one prior therapy. The new technology add-on payment is for the additional indication approved by the FDA for (1) treatment of adult patients diagnosed with CLL with and without 17p deletion, who have received at least one prior therapy, and (2) treatment of adult patients, in combination with azacytidine or decitabine or low-dose cytarabine, for newly-diagnosed AML in adults 75 years of older, or who have comorbidities that preclude use of intensive induction chemotherapy.

Newness. VENCLEXTA® received additional FDA approval for the new indication on November 21, 2018. The applicant submitted a request for approval for a unique ICD-10-PCS code to identify procedures involving the administration of VENCLEXTA®.

For the first criterion (same or similar mechanism of action), the applicant asserted that VENCLEXTA® is the first and only FDA-approved, selective oral anti-apoptotic B-cell lymphoma 2 (BCL-2) inhibitor. VENCLEXTA® works by inhibiting the BCL-2 protein which regulates cell death and is associated with chemotherapy-resistance and poor outcomes in patients with AML. The applicant indicated that because the combination of drugs in the recently-approved indication for the treatment of AML is new and VENCLEXTA® works synergistically when administered as part of this treatment combination, this creates a unique mechanism of action. For the second criterion (same or different MS-DRG) the applicant stated that potential cases using VENCLEXTA® for patients with AML would be different than potential cases for patients with CLL. For the third criterion (same or different disease or patient population), the applicant states that there are currently no curative treatments for elderly patients newly diagnosed with AML who are ineligible for intensive chemotherapy.

CMS believes that potential cases representing patients with AML and potential cases representing patients with CLL could both be assigned to the same MS-DRGs (MS-DRGs 820, 821 and 822 (Lymphoma and Leukemia with Major OR Procedure). In addition, CMS notes that as the applicant indicated, there are lower-intensity chemotherapeutic regimens available for patients with newly diagnosed AML who are ineligible for intensive chemotherapy.

Cost. The applicant used the 2017 MedPAR file to assess the MS-DRGs for potential cases representing potential patients with AML who may receive treatment with VENCLEXTA®. In order to limit impact from MS-DRGs with probable low relevance, the applicant removed a number of high-volume MS-DRGs from the analysis. The applicant used MS-DRGs 808, 809, 834-836, and 839 to determine the average length of stay, which resulted in 7.25 days. The applicant noted two limitations with this methodology: (1) the average length-of-stay may have changed since FY 2017; and (2) the potential cases identified may not adequately capture patients who are not ineligible for intensive chemotherapy. The applicant provided analyses with the VENCLEXTA® charges under six separate cost threshold scenarios. In addition, the applicant produced separate cost threshold calculations based on the three diagnosis code selections pending the final VENCLEXTA® label. For each cost threshold scenario, the applicant also applied a reduction of 50 percent of pharmacy charges for the replacement of hospital expenditures when VENCLEXTA® is used as first-line therapy. The applicant produced cost threshold results for 6 scenarios, each with 4 MS-DRGs, for a total of 24 cost threshold calculations. For all the calculations, the average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. The applicant concluded VENCLEXTA® meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that VENCLEXTA® in combination with either azacytidine or decitabine, and VENCLEXTA® in combination with low-dose cytarabine, both constitute a substantial clinical improvement over current treatments for patients with newly diagnosed AML who are ineligible for intensive chemotherapy. The applicant submitted two main studies which CMS summarizes. CMS notes that the data provided on outcomes used historical controls of other chemotherapeutic regimens and that the data lacks information about outcomes associated with a direct comparator. In addition, the studies did not detail the demographics and outcomes for patients over the age of 75 versus younger patients. CMS is concerned about the fatal adverse drug reactions and the lack of conclusive data on the efficacy of VENCLEXTA®.

6. Request for Information on the New Technology Add-On Payment Substantial Clinical Improvement Criterion

CMS is considering potential revisions to the substantial clinical improvement criterion under the IPPS new technology add-on payment and the OPPS transitional pass-through payment policy for devices and requests comments on the type of additional detail and guidance that the public and applicants would find helpful. This request is intended to be broad in scope and provide information for potential rulemaking in the future. As discussed in greater detail below (section H.7.), CMS is also proposing specific changes and clarifications to the IPPS and OPPS substantial clinical improvement criterion to provide greater clarity and predictability.

In applications for both the IPPS new technology add-on payment and the OPPS transitional pass-through for devices, CMS lists the following criteria it uses to determine substantial clinical improvement:

1. The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

2. The technology offers the ability to diagnose a medical condition in a patient population where the medical condition is currently undetectable to offer the ability to diagnose a medical condition earlier in a patient population.
3. Use of the technology significantly improves clinical outcomes for a patient population as compared to current treatments. Some examples of outcome are: reduced mortality rate with the device; reduced rate of device-related complications; decreased rate of subsequent diagnostic or therapeutic interventions; decreased number of future hospitalizations or physician visits; more rapid beneficial resolution of the disease because of the device; decreased pain, bleeding, or other quantifiable symptom; and reduced recovery time.

CMS is requesting feedback on whether new or changed regulatory provisions or guidance regarding additional aspects of the substantial clinical improvement evaluation process would be helpful. **CMS requests comments in response to the following general questions**:

- What role should substantial clinical improvement play in payment policies to ensure these policies do not discourage appropriate utilization of new medical services and technologies?
- How should CMS determine what existing technologies are appropriate comparators to new technologies? How should CMS evaluate a new technology when its comparators have different measured clinical outcomes?
- Should CMS provide more specificity or clarity on the types of evidence or study designs that may be considered in evaluating substantial clinical improvement?
    - For example, what data should be used to demonstrate whether the use of the technology substantially improves clinical outcomes? To what extent, if any, should the data be focused on the Medicare population? What clinical outcomes data and patient reported measures data should be assessed to demonstrate substantial clinical improvement?
    - What particular types of study designs, types of inclusion and exclusion criteria, or types of statistical methodologies, could a new technology use to demonstrate substantial clinical improvement?
    - Are there certain study designs that are technically or ethically challenging specific to medical technologies and, if so, should that be more explicitly reflected in the regulations?
    - Should potential limitations related to cross-trial comparisons with any existing therapies be more explicitly reflected in the regulations?
    - Are there particular instances where non-inferiority studies should be considered sufficient for an evaluation for substantial clinical improvement because a non-inferiority study is the most appropriate study design for a given technology?[19]

[19] CMS states that the goal of a non-inferiority study is to show that the difference between the new and active control treatment is small, small enough to allow the known effectiveness of the active control (based on its performance in past studies and the assumed effectiveness of the active control in the current study) to support the conclusion that the new technology is also effective.

- Are there instances where it would be appropriate to infer substantial clinical improvement (for example, technical or financial challenges to study accrual?
- Should CMS consider evidence regarding off-label use of a new technology? If yes, what is the appropriate use of that evidence when evaluating a new technology for an FDA approved or cleared indication? Are there other new technology add-on payment or device pass-through payment changes that should be considered regarding off-label use?
- CMS notes that additional specificity and guidance may be helpful but may also have the unintended consequence of limiting future flexibility in the evaluation of applications. How should CMS balance these considerations in the evaluation of new technologies as it considers potential future steps? Would it be helpful to the goal of both predictability and flexibility if the agency explained the types of information of evidence that are *not* required for a finding of substantial clinical improvement?
- Currently, the results of new technology add-on payment determinations are made as part of the annual updates and changes to the IPPS. Should new technology add-on payment determination be announced annually in the Federal Register separate from the annual updates and changes to the IPPS.

7. Potential Revisions to the New Technology Add-On Payment and Transitional Device Pass-through Payment Substantial Clinical Improvement Criterion for Applications Received Beginning to FY 2020 for IPPS and CY 2020 for OPPS

In addition to the request for comments for CMS to consider in future rulemaking, **CMS requests comments to the following potential regulatory changes, that could be adopted in regulation or through sub-regulatory guidance, to the substantial clinical improvement criterion** for applications received beginning in FY 2020 (FY 2021 and subsequent new technology add-on payment) and CY 2020 for OPPS:

- Adopting a policy that explicitly specifies that the requirement for substantial clinical improvement can be met if the applicant demonstrates that the new technology would be broadly adopted among applicable providers and patients. A broad adoption criterion would reflect the choices of patient and providers (the marketplace), in determining whether a technology represents a substantial clinical improvement. CMS is also interested in particular suggestions about how in implementing this provision it could provide guidance regarding how "broad adoption" could be measured and demonstrated prospectively.
    - CMS would add a provision at §412.87(b)(1) and §419.66(c)(1) stating that "substantially improves" means *inter alia*, broad adoption by applicable providers and patients.
    - Should CMS specify that a "majority" is the appropriate way to define "broad adoption" or is some other measure of "broad" (for example, more than the current standard-of-care, more than a particular percentage) is more appropriate?
    - Should CMS specify that "broad adoption" is in the context of applicable providers and patients for the technology and does not mean broadly adopted across the entire IPPS or OPPS?

- Adopt a definition that the term "substantially improves" means, *inter alia*, new technology has demonstrated positive clinical outcomes that are different from existing technologies. CMS would also specify that the term "improves" can always be met by comparison to existing technology and that such improvement may always be demonstrated by reference and comparison to the diagnosis or treatment achieved by existing technologies. CMS believes this policy would provide a standard for innovators that is predictable and provide clarity about how existing and new technologies are compared.
- Adopt a policy specifying that "substantially improves" can be met through real-world data and evidence, including a non-exhaustive list of such data and evidence, but that such evidence is not a requirement.
    - CMS would provide a non-exhaustive list of sufficient data and findings, including: a decreased mortality rate; a reduction in length of stay; a reduced recovery time; a reduced rate of at least one significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a reduction in at least one clinically significant adverse events; a deceased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment; an improvement in one or more activities of daily living; or, an improved quality of life.
    - CMS seeks comments on whether, as a general matter, data exists on patients' experience with new medical devices outside of the clinician's office, on the effects of a treatment on patients' activities of daily living, or on any of the other areas listed above.
- Adopt a policy that the relevant information for purposes of a finding of substantial clinical improvement may not require a peer-reviewed journal article. CMS seeks comments on whether it would be helpful to include a non-exhaustive list of particular formats or sources of information, such as consensus statements, white papers, patient surveys, editorials and letters to the editor, systematic reviews, meta-analysis, inferences from other literature or evidence, and case studies, reports or series, in addition to randomized clinical trials, study results, or letters from major associations, whether published or not.
- Adopt a policy that if there is a demonstrated substantial clinical improvement for any subset of beneficiaries, the criterion may be met regardless of the size of that subset patient population.
    - CMS requests comments on whether it should also specify that the add-on payment would be limited to use in that subset of patient population. If not, why not? If limited to a select subset of Medicare beneficiaries how would that patient population be defined and in what circumstances should there be an exception to any such limitation? How could this policy be written not to create new limitations or obstacles to innovation?
    - Are there special approaches that CMS should adopt for new technologies that treat low-prevalence medical conditions in which substantial clinical improvement may be more challenging to evaluate? CMS seeks comments about how to categorize and specify these conditions, including how to define "low-prevalence".

- Adopt a policy that specifically addresses that the substantial clinical improvement criterion can be met without regard to the FDA pathway for the technology. CMS would clarify that "improvement" includes situations where there is an extant technology, such as a predicate device for 510(k) purposes, and explicitly state that the agency will not require a device to be approved or cleared through a basis other that a 510(k) clearance in order for the device to be considered a substantial clinical improvement.

8. Proposed Alternative Inpatient New Technology Add-On Payment Pathway for Transformative New Devices

CMS discusses the FDA programs for expediting the development and review of transformative new technologies intended to treat serious conditions and address unmet medical needs. In 2001, when CMS first established the substantial clinical improvement criterion (66 FR 46913), the FDA had three expedited programs (Priority Review, Accelerated Approval, and Fast Track) for drugs and biologicals and no expedited programs for devices. There are now four expedited FDA programs for drugs (the three expedited FDA programs available in 2001 and Breakthrough Therapy, established in 2012) and one expedited FDA program for devices, the Breakthrough Devices Program.[20] The 21st Century Cures Act (Pub. L. 144-255) established the Breakthrough Devices Program to expedite the development of and provide for priority review of medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. In addition, one of the following four criteria are also required: (1) represent breakthrough technologies; (2) no approved or cleared alternatives exist; (3) offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternative, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care, or establish long-term clinical efficiencies; or (4) the availability of which is in the best interest of patients.

For applications for new technology add-on payments for FY 2021 and subsequent fiscal years, CMS proposes if a medical device is part of the FDA's Breakthrough Devices Program and received marketing authorization, it would be considered new and not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS. CMS is also proposing that the medical device would not need to meet the requirements under §412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this proposed alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by the FDA) and that is part of the FDA's Breakthrough Devices Program would need to meet the cost criterion under §412.87(b)(3).

CMS is not proposing an alternative inpatient new technology add-on payment for drugs. As discussed in the Economic Analyses (see Appendix A, I.O.2), CMS considered the application of

[20] FDA guidance is available at https://www.fda.gov/downloads/Drug/Guidance/UCM358301.pdf and https://www.fda.gov/downloads/MEdicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM581664.pdf.

this proposal to drugs but concluded that current drug-pricing provides generous incentives for innovation and often fails to deliver important medications at an affordable cost. CMS believes it is appropriate to distinguish between drugs and devices in its consideration of a proposed policy change for new transformative technologies.

CMS requests comments on the following specific issues:

- Given the lack of an evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization, how should CMS weigh the benefits of this proposed alternative pathway to facilitate beneficiary access to transformative new medical devices against any potential risks, such as the risk of adverse events or negative outcomes that might come be reported later?
- Whether the newness period under the proposed alternative new technology add-on payment pathway for medical devices be limited to a period of time sufficient for the evidence base for the new device to develop to the point where a substantial clinical improvement determination can be made? For example, 1 to 2 years after approval, depending on whether the new device would be eligible for a third year of new technology add-on payments. CMS notes that the newness period cannot exceed 3 years, regardless of whether it is approved under the current eligibility criteria, the proposed alternative pathway, or a combination of the two (section 1886(d)(5)(K)(ii)(II) of the Act).

CMS notes that there have not been any medical devices that were part of the Breakthrough Devices Program and received FDA market authorization, and that applied for a new technology add-on payment under the IPPS and were not approved. Thus, if all future new medical devices that would have applied for the new technology add-on payments would have been approved under the existing criteria, this proposal has no impact. If there are any future medical devices that would have been denied under the current criteria, this proposal is a cost but a cost that CMS cannot estimate. Given this proposal, if finalized, would be effective beginning with new technology add-on payment applications for FY 2021, there would be no impact of this proposal in FY 2020.

9. Proposed Change to the Calculation of the Inpatient New Technology Add-On Payment

The current calculation of the new technology add-on payment is based on the cost to hospitals for new medical service or technology. Specifically, under §412.88 if the costs of the discharge (determined by applying CCRs as described in §412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of (1) 50 percent of the costs of the new medical technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS-DRG payment plus 50 percent of the estimated costs of the new technology or medical services.

CMS states it has received feedback from stakeholders that this policy does not adequately reflect the costs of new technology and does not sufficiently support health care innovations. Specifically, stakeholders have stated that a maximum add-on payment of 50 percent does not

allow for accurate payment of new technology with a precedented high costs such as CAR T-cell technologies.

CMS is proposing that beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology exceed the full DRG payment (determined by applying CCRs as described in §412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of (1) 65 percent of the costs of the new medical technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. Unless the discharge qualifies for an outlier payment, the additional Medicare payment is limited to the full MS-DRG payment plus 65 percent of the estimated costs of the new technology or medical services.

CMS states it is challenging to empirically determine an appropriate payment percentage for the add-on payment. It believes that 65 percent is an incremental increase that would reasonably balance the need to maintain the incentives inherent to the IPPS while also encourage the development and use of new technologies.

CMS estimates that if it finalizes its proposals to continue add-on payments in FY 2020 for 9 technologies currently receiving add-on payments and it determines that all 17 of the FY 2020 new technologies meet the criteria for add-on payments for FY 2020, proposed changes to the inpatient new technology add-on payment, if finalized, would increase IPPS spending by approximately $110 million in FY 2020.

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

A. Background

CMS adjusts a portion of IPPS payments for area differences in the cost of hospital labor. The adjustment is known as the wage index.

Legislative Authority. 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 (fringe benefits) 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 2020 Hospital Wage Index. The areas that are used for the wage index are Office of Management and Budget (OMB) CBSA delineations implemented beginning with FY 2015 and updated by OMB Bulletin numbers 13-01, 15-01 and 17-01. Tables 2 and 3 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 assignment of counties to CBSAs.

B. Worksheet S-3 Wage Data

The proposed wage index values are based on data from FY 2016 submitted cost reports. Categories of included and excluded costs from prior years are unchanged by the FY 2020 proposed rule.

C. Verification of Worksheet S-3 Wage Data

CMS calculates the proposed FY 2020 wage index based on wage data of 3,221 hospitals from Worksheet S-3, Parts II and III of the cost report for cost reporting periods beginning during fiscal year 2016 (referred to as FY 2016 wage data); the data file used to construct the proposed wage index includes FY 2016 data submitted to CMS as of February 7, 2019.

General wage index policies are unchanged from prior years. However, CMS notes that it excludes 81 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 2020.

The proposed rule indicates that 8 of the excluded hospitals are part of a 38-hospital health system in an unnamed state where salaries reflect union negotiated agreements rather than prevailing wages in the local labor market. CMS indicates there is a large gap between the average hourly wage of each of these 8 hospitals and the next closest average hourly wage in their respective CBSAs. The proposed rule argues that section 1886(d)(3)(E) of the Act provides the Secretary with discretion to remove hospital data from the wage index that is not reflective of the relative hospital wage level in the hospitals' geographic area compared to the national average.

CMS further indicates that it has previously removed hospitals from the wage index because their average hourly wages are either extraordinarily high or extraordinarily low compared to their labor market areas, even though their data were properly documented. Examples include wage data from government-owned hospitals and hospitals providing unique or niche services which affect their average hourly wages.

D. Method for Computing the Unadjusted Wage Index

CMS usually refers readers to the FY 2012 IPPS/LTCH final rule for the steps in determining the wage index rather than restating them each year. For FY 2020, CMS is restating the steps of the methodology for computing the wage index to: 1) update outdated references to Medicare CMS Form 2552-96 that are now reflected on Medicare CMS Form 2552-10; 2) propose a change to the calculation of the overhead rate in step 4; 3) propose a methodology for calculating the wage index for urban areas without wage data; and 4) propose to modify the methodology for rounding dollar amounts, hours and other numerical values in wage index calculations.

For step 4 (related to the allocation of overhead to the average hourly wage), there are instructions currently for how to exclude contract labor hours. Previously, CMS felt that contract

labor hours should be excluded because hospitals typically do not provide fringe benefits to contract labor. However, CMS now believes that it is not necessary to exclude contract labor hours if the hospital does not have the associated costs for contract labor fringe benefits (presumably because the costs are either $0 or included in the contract labor cost). If the hospital does have fringe benefit costs for contract labor, the instructions require those costs to be included in the overhead allocation. CMS is proposing a change to step 4 for FY 2020 and subsequent years to no longer exclude contract labor hours from the overhead allocation. The proposed rule provides the current and revised formula CMS proposes:

Current: Overhead Rate (from Worksheet S-3, Part II) = (Lines 26 through 43 – Lines 28, 33 and 35) / ((((Line 1 + Lines 28, 33, 35) - (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 26 through 43)) – (Lines 9, 10, 28, 33, and 35)) + (Lines 26 through 43 – Lines 28, 33, and 35)).

Proposed: Overhead Rate=(Lines 26 through 43 – Lines 28, 33 and 35) / ((((Line 1 + Lines 28, 33, 35) - (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) – (Lines 9 and 10)) + (Lines 26 through 43 – Lines 28, 33, and 35)).

In step 11, CMS indicates that it is proposing to use the statewide urban average as the wage index for urban areas where no wage data was reported rather than "imputing some other type of value using a different methodology."

In response to questions about how it does rounding for the wage index methodology, the proposed rule indicates that CMS proposes that: 1) raw data reported by hospitals will remain unrounded; 2) dollar amounts will be rounded to two decimals; 3) hours will be rounded to the nearest whole number; and 4) other numbers not expressed as dollars or hours will be rounded to five decimals. CMS proposes to continue rounding the wage indexes to four decimals as it has done historically.

E. Occupational Mix Adjustment

Section 1886(d)(3)(E) of the Act requires CMS to collect 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. The current occupational mix survey data from 2016 is used for the occupational mix adjustment applied to the FY 2018 through FY 2020 IPPS wage indexes. CMS is only proposing a change to the rounding rules applied in the calculation of occupational mix adjustment as described above. CMS reports having occupational mix data for 97 percent of hospitals (3,119 of 3,221) used to determine the FY 2020 wage index.

The proposed FY 2020 national average hourly wage, unadjusted for occupational mix, is $44.03. The proposed occupational mix adjusted national average hourly wage is $43.99.

F. Occupational Mix Adjusted Wage Index

The proposed FY 2020 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	$41.54
National LPN and Surgical Technician	$24.67
National Nurse Aide, Orderly, and Attendant	$16.95
National Medical Assistant	$18.14
National Nurse Category	$34.91

Below is selected information from a table CMS includes that shows by type of area how the occupational mix adjustment affects the unadjusted average hourly wage:

Effect of the Occupational Mix Adjustment on the Unadjusted Average Hourly Wage	
Number of Urban Areas Increasing	233 (56.8%)
Number of Rural Areas Increasing	23 (48.9%)
Number of Urban Areas Increasing by 1%<= and <5%	113 (27.6%)
Number of Urban Areas Increasing >5%	7 (1.7%)
Number of Rural Areas Increasing 1%<= and <5%	10 (21.3%)
Number of Rural Areas Increasing >5%	0 (0 %)
Number of Urban Areas Decreasing	175 (42.7%)
Number of Rural Areas Decreasing	24 (51.1%)
Number of Urban Areas Decreasing by 1%<= and <5%	80 (19.5%)
Number of Urban Areas Decreasing >5%	1 (0.2%)
Number of Rural Areas Decreasing by 1%<= and <5%	7 (14.9%)
Number of Rural Areas Increasing >5%	0 (0%)

G. Application of the Rural and Frontier Floors

Rural Floor. The rural floor is a provision of statute that prevents an urban wage index from being lower than the wage index for the rural area of the same state. CMS estimates that the rural floor will increase the FY 2020 wage index for 166 hospitals—87 fewer hospitals than were receiving the rural floor in FY 2019. This impact results, in part, from CMS' proposal to no longer include urban to rural reclassifications in the calculation of the rural wage index (described below).

CMS calculates a proposed national rural floor budget neutrality adjustment factor of 0.996316 (-0.37 percent) applied to hospital wage indexes. CMS projects that rural hospitals in the aggregate will experience a 0.1 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in urban areas would experience no change in payments; and urban hospitals in the New England region can expect a 0.3 percent increase in payments, primarily due to the application of the proposed rural floor in Massachusetts. CMS expects that 10 urban providers in Massachusetts would receive a rural floor wage index value which increases payments overall to Massachusetts by $21 million in FY 2020.

Frontier Floor Wage Index. The Affordable Care Act requires a wage index floor for hospitals in the low population density states of Montana, Nevada, North Dakota, South Dakota and Wyoming. CMS indicates that 45 hospitals will receive the frontier floor value of 1.0000 for FY 2020. This provision is not budget neutral, and CMS estimates an increase of approximately $63 million in IPPS operating payments.

H. Wage Index Tables

Proposed rule wage index tables 2, 3 and 4 can be found at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Proposed-Rule-Home-Page-Items/FY2020-IPPS-Proposed-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

Select #2.

I. Revisions to the Wage Index Based on Hospital Reclassifications

Geographic reclassification describes a process where hospitals apply to use another area's wage index. To use another area's wage index, the applying hospital must be within a specified distance and have comparable wages to that area. The Medicare Geographic Classification Review Board (MGCRB) decides whether hospitals meet the criteria to receive the wage index of another hospital. CMS is not proposing any changes to the geographic reclassification criteria. However, it is proposing to make technical changes to the regulations to clarify that mileage and percentage standards are not rounded when determining whether a hospital meets reclassification criteria. The regulations explicitly specify using unrounded figures in some situations but not others. Under CMS' proposal, unrounded figures must be used in all situations.

Geographic Reclassifications

The MGCRB approved 357 hospitals for a geographic reclassification starting in FY 2020. Because reclassifications are effective for 3 years, a total of 963 hospitals are in a reclassification status for FY 2020, including those initially approved by the MGCRB for FY 2018 (332 hospitals) and FY 2019 (274 hospitals). The deadline for withdrawing or terminating a wage index reclassification for FY 2020 approved by the MGCRB is 45 days from publication of the FY 2020 proposed rule in the *Federal Register* (June 17, 2019). Applications for FY 2021 reclassifications or canceling a previously approved reclassification are due to the MGCRB by September 3, 2019.

Requests must be received by the MGCRB through its electronic system: https://www.cms.gov/Regulations-and-Guidance/Review-Boards/MGCRB/Electronic-Filing.html. CMS is proposing to dispense with the requirement that applications and other information furnished to the MGCRB also be provided to CMS electronically by email. CMS

believes this requirement is burdensome and no longer necessary as the MGCRB's electronic system will facilitate coordination between CMS and the MGCRB.

Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process will be incorporated into the final FY 2020 wage index values.

Provisions Relating to Lugar Hospitals

Interactive Effects of a Lugar Reclassification and the Out-migration Adjustment

A "Lugar" hospital is located in a rural county adjacent to one or more urban areas that is automatically reclassified to the urban area where the highest number of its workers commute. The out-migration adjustment is a positive adjustment to the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index. Out-migration adjustments are fixed for 3 years. A hospital can either be reclassified or receive the out-migration adjustment but not both. Lugar status is automatic and must be declined through an urban to rural reclassification application for the hospital to receive an out-migration adjustment to its home area wage index.

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 (Lugar) 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 of publication 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.

Due to various factors, including hospitals withdrawing or terminating MGCRB reclassifications, reclassifying as rural, or corrections to hospital wage data, a newly proposed (1st year) out-migration adjustment value may fluctuate between the proposed rule and the final rule (and subsequent correction notices). In certain circumstances, after processing varying forms of reclassification, wage index values may change so that a county would no longer qualify for an out-migration adjustment. In particular, when changes in wage index reclassification status alter the state rural floor so that multiple CBSAs would be assigned the same wage index value, an out-migration adjustment may no longer apply as there would be little, if any, differential in nearby wage index values. This can lead to a situation where a hospital has opted to receive a non-existent out-migration adjustment.

CMS is clarifying that it will deny the hospital's request to waive its Lugar status in the final rule in this situation. Final rule wage index values would be recalculated to reflect the hospital's Lugar reclassification, and in some instances, after taking into account this reclassification,

the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification, it would be ineligible to receive the county out-migration adjustment for that year. However, because the out-migration adjustment, once finalized, is locked for a 3-year period under section 1886(d)(13)(F) of the Act, the hospital would be eligible to accept its out-migration adjustment in either the second or third year.

Change to the Determination of a Lugar County

CMS indicates that determination of Lugar county status is based on commuting patterns from the rural county to a central county or counties of an urban area. CMS is proposing to revise that standard to include commuting patterns to outlying counties as well. The proposed rule highlights that CMS is proposing this change based on an alternative interpretation of the statute from a Henderson, Texas hospital. The proposed rule indicates the revised policy would affect 10 counties in Alabama, Georgia, Mississippi, Ohio, Pennsylvania, Texas and Virginia that include a total of 4 IPPS hospitals.

J. Out-Migration Adjustment

CMS proposes to use the same policies, procedures and computation that were used for the FY 2012 out-migration adjustment, and estimates increased payments of approximately $40 million in FY 2020 for 171 hospitals receiving the out-migration adjustment. This provision is not budget neutral.

K. Reclassification from Urban to Rural

Allowing Electronic Applications

A qualifying IPPS hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Regulations require that the application must be mailed to the CMS Regional Office and may not be submitted by facsimile or other electronic means. CMS is proposing to revise § 412.103(b)(3) to allow a requesting hospital to submit an application to the CMS Regional Office by mail or by facsimile or other electronic means.

Cancelling a Rural Reclassification

Under current regulations, an urban hospital that reclassifies as rural to become a rural referral center (RRC) must maintain rural status and be paid as rural for at least one 12-month cost reporting period. This requirement was established to provide a disincentive for hospitals to receive a rural reclassification, obtain RRC status to take advantage of special MGCRB reclassification rules, and then terminate their rural status. However, as a result of adverse litigation, CMS has since changed its rules to allow a hospital to reclassify from urban to rural and then apply for geographic reclassification under the less restrictive rules for rural hospitals. As a hospital can now have a simultaneous urban to rural and MGCRB reclassification, CMS indicates that its rule requiring an RRC to maintain rural status for at least 12 months no longer

has any practical effect. Accordingly, CMS is proposing to revise § 412.103(g) effective October 1, 2019 to eliminate the requirement that an RRC must be paid as rural for at least one 12-month cost reporting period before it can cancel rural status.

CMS is further proposing to set forth uniform requirements applicable to all hospitals for cancelling rural reclassifications. For all hospitals, cancellation of an urban to rural reclassification will be effective on the basis of a federal fiscal year rather than the hospital's cost reporting period. CMS proposes this change because the end dates of cost reporting periods vary among hospitals and cancellation requests may not be processed in time to be accurately reflected in the IPPS final rule appendix tables. In order for a cancellation request to be effective for the following fiscal year, CMS is proposing that the request must be made not less than 120 days prior to the end of a federal fiscal year. CMS believes 120 days is sufficient time for hospitals to assess and review reclassification options, and provides CMS adequate time to incorporate the cancellation into the wage index development process.

In addition, CMS is proposing to codify into regulations a longstanding policy regarding canceling an urban to rural reclassification when a hospital opts to accept and receives its county out-migration adjustment in lieu of its Lugar reclassification. Just as a hospital cannot simultaneously have an MGCRB or Lugar reclassification and out-migration adjustment, a hospital cannot simultaneously have an urban to rural reclassification and an out-migration adjustment. In FY 2012, CMS adopted a policy to allow waiving of Lugar status for the out-migration adjustment to simultaneously waive the hospital's urban to rural reclassification. CMS adopted this policy in the context of hospitals wishing to obtain or maintain SCH or MDH status but CMS' application of the policy has not been limited to these purposes. CMS is proposing to codify this policy in regulation at § 412.103 by specifying that an urban to rural reclassification will be considered cancelled effective for the next federal fiscal year when a hospital opts to accept and receives its county out-migration wage index adjustment in lieu of an MGCRB geographic reclassification. Once an urban to rural reclassification is cancelled, the hospital would have to reapply to again acquire rural status.

CMS notes that, in a case where an urban hospital reclassified as rural wishes to receive its out-migration adjustment but does not qualify for a Lugar reclassification, the hospital would need to formally cancel its rural reclassification by written request to the CMS Regional Office consistent with the procedures in the regulations. Finally, CMS indicates that the hospital must not only opt to accept, but also *receive*, its county out-migration wage index adjustment to trigger cancellation of rural reclassification. In such cases where an out-migration adjustment is no longer applicable based on the wage index in the final rule, a hospital's rural reclassification remains in effect unless otherwise cancelled by written request to the CMS Regional Office.

L. Process for Requests for Wage Index Data Corrections

CMS has established a multistep, 15-month process for the review and correction of the hospital wage data used to create the IPPS wage index for the upcoming fiscal year. The rule describes this process in great detail including when data files were posted and deadlines for hospitals to

request corrections to appeals or revisions to audit adjustments. 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. CMS posts the wage index timetable on its website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files-Items/FY2020-Wage-Index-Home-Page.html?DLPage=1&DLEntries=10&DLSort=1&DLSortDir=descending. This website also includes all of the public use files that CMS has made available during the wage index development process.

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 is currently using a national labor-related share of 68.3 percent. 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. The 68.3 labor share will be effective through the end of FY 2020.

N. Policies to Address Wage Index Disparities

Prior Rulemaking Comments

CMS reviews comments on the FY 2019 IPPS/LTCH PPS proposed rule concerning wage index disparities. One concern expressed by hospitals is the disparity in wage index values between high and low wage index areas. CMS presented a comment typical of this view that was critical of relying exclusively on hospital cost reports as the source to calculate the wage index. The comment indicated that relying on hospital reported data allows higher wage index hospitals to, in turn, pay higher wages to continue a high wage index. Low wage areas cannot afford to pay wages that would allow their hospitals to approach median wage index. Over time this condition of circularity has increased the gap between the high and low wage indexes. CMS refers to this system as the "downward spiral" as that term has been used by some stakeholders to describe the issue.

Some commenters recommended that CMS create a wage index floor for low wage hospitals, and that, in order to maintain budget neutrality, CMS reduce the wage index values for high wage hospitals through the creation of wage index ceiling. There was also concern about

opportunist gaming, especially in the area of urban to rural reclassifications and the rural floor. Providers in some urban areas are able to reclassify to a rural area and substantially raise the rural floor for an entire state. These respondents stated that CMS has the regulatory authority to determine how it calculates the rural floor and suggested CMS only consider geographically rural providers to calculate a state's rural floor.

Other commenters were not critical of wage index disparities. The typical comment representing this view argued that there are disparities in the cost of labor and cost of living between different parts of the country recognized by the wage index. The commenter urged to CMS to continue to adequately account for these resource differences in its payment systems.

Some commenters indicated that further analysis and study of the wage index are needed. A comment typical of this view indicated that a consensus solution to the wage index's shortcomings has not yet been developed and further analysis of alternatives is needed to identify approaches that promote payment adjustments that are accurate, fair, and effective.

Proposals to Address Wage Index Disparities

Narrowing Variation in the Wage Index

Proposal 1 – Allow Time for Low-Wage Hospitals to Raise Wages. CMS and others have indicated in the past that comprehensive wage index reform would require both statutory and regulatory changes, and could require new data sources. However, CMS indicates that addressing this systemic issue does not need to wait for comprehensive wage index reform given growing wage index disparities and that some hospitals, particularly rural hospitals, are in financial distress facing potential closure.

In response to these concerns, CMS is proposing to increase the wage index values for hospitals with a wage index in the lowest quartile. CMS acknowledges that there is no set standard for identifying hospitals as having a low or high wage index but indicates that the proposed quartile approach is reasonable given quartiles are a common way to divide distributions. Based on FY 2020 proposal rule wage index data, the 25th percentile wage index value is 0.8482. CMS proposes to increase wage indexes below this amount by one-half the difference between a low wage index hospital's wage index and the 25th percentile.[21] CMS will update the 25th percentile wage index based on FY 2020 final rule data.

CMS proposed to make the policy effective for at least 4 years in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. CMS selects 4 years as the period for its proposal because there is a 4-year lag between the cost report year used for the wage index and the payment year when that wage index is applied (FY 2016 for FY 2020). Therefore, four years is the minimum time before increases in employee compensation included in the Medicare cost report could be reflected in

[21] For example, if a hospital has a wage index of 0.6663, ½ the difference between 0.6663 and 0.8482 is 0.0910 (0.8482 – 0.6663)/2. This amount is added to 0.6663 to provide a wage index of 0.7573.

the wage index data. CMS indicates the policy may need to be in place for additional time and intends to revisit the duration of the policy in future rulemaking.

Proposal 2: Make Proposal Budget Neutral by Lowering Wage Index for High Wage Hospitals
CMS is declining to establish a wage index floor as some commenters suggested because CMS believes that rank order generally reflects meaningful distinctions between employee compensation costs faced by hospitals in different geographic areas but is exacerbated by the circularity of using hospital reported data for the wage index. However, CMS does believe that it should maintain budget neutrality for increases to low wage index hospital through an adjustment to the wage index of high wage index hospitals.

CMS considered three options for budget neutrality: 1) doing a uniform adjustment for budget neutrality to the standardized amount; 2) reducing wage indexes over the 75th percentile by one-half of the difference between the hospital's wage index and the 75th percentile wage index; 3) applying a uniform reduction to hospital wage indexes above the 75th percentile. CMS proposed the 3rd option. Compressing the wage index for hospitals on the high and low ends increases the impact on existing wage index disparities more than by simply addressing one end. Further, such a methodology ensures those hospitals whose wage index is not considered high or low do not have their wage index values affected by the proposed policy.

Accordingly, in order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile, CMS proposes to apply a uniform reduction of 3.4 percent to the portion of a hospital's wage index above the 75th percentile. Based on proposed rule data, the 75th percentile wage index value is 1.0351. Under CMS' proposal, the portion of a hospital's wage above 1.0351 will be reduced by 3.4 percent to maintain budget neutrality for the proposed wage index increases.[22]

CMS states that it is undertaking the proposed policy under 1886(d)(3)(E) of the Act which gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. Section 1886(d)(3)(E) requires those adjustments to be budget neutral. CMS also indicates that it has authority for the proposed policy using its exceptions and adjustments authority under section 1886(d)(5)(I) of the Act.

Preventing Urban to Rural Reclassifications from Raising the Rural Floor

Public commenters indicated that another contributing systemic factor to wage index disparities is the rural floor. Section 4410(a) of the Balanced Budget Act (BBA) of 1997 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a state may not be less than the area wage index applicable to

[22] For example, if a hospital has a wage index of 1.7351, the portion of the wage index above 1.0351 is 0.700 (1.7351 – 1.0351 = 0.7000). Multiplying this figure by 0.034 (3.4 percent) yields 0.0238 which is subtracted from 1.7351 to produce a reduced wage index of 1.7113.

hospitals located in rural areas of that state. Section 3141 of the Affordable Care Act also requires that a national budget neutrality adjustment be applied in implementing the rural floor.

In its November 2018 report, "Significant Vulnerabilities Exist in the Hospital Wage Index System for Medicare Payment" (A-01-17-00500) the Office of the Inspector General (OIG) quotes MedPAC stating that

[MedPAC] it is not aware of any empirical support for [the rural floor] policy, and that the policy is built on the false assumption that hospital wage rates in all urban labor markets in a State are always higher than the average hospital wage rate in rural areas of that State.

CMS indicates that in FY 2018, 366 urban hospitals benefited from the rural floor at the expense of a nationwide decrease in all hospitals' wage indexes of approximately 0.67 percent. In Massachusetts, 36 urban hospitals received a wage index based on hospital wages in Nantucket, an island that is home to the only rural hospital contributing to the state's rural floor wage index. The increased payments were offset by decreased payments to hospitals nationwide not based on actual local wage rates but on the rural floor calculation. CMS further describes a situation where all hospitals in a state receive a wage index higher than that of the single highest wage index urban hospital in the state.

The proposed rule further states wage index disparities associated with the rural floor significantly increased in FY 2019 with the urban to rural reclassifications of hospitals in Arizona, Connecticut and Massachusetts. CMS states the rural floor policy was meant to address anomalies of some urban hospitals being paid less than the average rural hospital in their states, not to raise the payments of many hospitals to the high wage level of a geographically urban hospital within the state.

The urban Massachusetts hospital that reclassified as rural has an approved MGCRB reclassification back to its geographic location, and, therefore is not considered rural for wage index purposes in the proposed rule. However, under the current wage index policy, the hospital would be able to influence the Massachusetts rural floor by withdrawing or terminating its MGCRB reclassification for FY 2020 or subsequent years. Such an urban to rural reclassification does not result in urban wage indexes being raised to the average of rural hospitals in their state. Rather, it raises the wage index of the urban hospitals to the relatively high level of one or more geographically urban hospitals reclassified as rural.

The stated legislative intent of the rural floor was to correct the "anomaly" of "some urban hospitals being paid less than the average rural hospital in their States." (Report 105-149 of the Committee on the Budget, House of Representatives, to Accompany H.R. 2015, June 24, 1997, section 10205, page 1305.) However, CMS believes that urban to rural reclassifications have stretched the rural floor provision beyond a policy designed to address such anomalies and goes beyond the general criticisms of the rural floor policy by MedPAC, CMS, OIG, and many stakeholders. Therefore, CMS is proposing to remove urban to rural reclassifications from the calculation of the rural floor beginning in FY 2020.

CMS indicates that its proposed calculation methodology is permissible under section 1886(d)(8)(E) of the Act and section 4410 of the BBA 1997 as neither of these provisions state how the rural floor wage index is to be calculated or what data are to be included in the calculation. Under CMS' proposal, in the case of Massachusetts, for example, the geographically rural hospital in Nantucket would still be included in the calculation of the rural floor for Massachusetts but a geographically urban hospital reclassified as rural would not.

CMS further cites section 1886(d)(8)(C)(iii) of the Act that indicates Lugar and MGCRB reclassifications may not reduce any county's wage index below the wage index for rural areas in the state. The proposed rule states that CMS' proposal will help ensure no urban hospitals not reclassified as rural, including those hospitals with no reclassification as well as Lugar and MGCRB reclassified hospitals will have their payments raised to the relatively high level of one or more geographically urban hospitals reclassified as rural.

CMS considered but rejected creating a national rural floor rather than a state-by-state rural floor. The proposed rule argues that a national labor floor would mitigate incentives to manipulate the wage index. However, CMS noted that the establishment of a national rural wage index area would have a negative impact on hospitals in the rural areas in states with current rural wage index values above the national rural wage index value.

Transitioning Wage Index Reductions and Transition Budget Neutrality

Following past practice when large changes to wage indexes have been transitioned, CMS is proposing a transition to mitigate any significant decreases in the wage index values of hospitals compared to their final wage indexes for FY 2019. For FY 2020 only, CMS proposes to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in FY 2019 but it is seeking public comments on alternative levels for the cap and accompanying rationale.

Following past practice, CMS invokes section 1886(d)(5)(I) of the Act to propose making the 5 percent cap on wage index reductions budget neutral. CMS proposes to apply a budget neutrality adjustment to ensure that estimated aggregate payments under the proposed transition for hospitals negatively impacted by proposed wage index policies would equal what estimated aggregate payments would otherwise have been absent the transition policy. The proposed budget neutrality adjustment is 0.998349 (-0.17 percent) to the FY 2020 standardized amount.

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, a hospice or home with written plan for home health services from a home health agency and those services begin within 3 days of 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 care 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 2020

CMS is proposing to make changes to a number of MS-DRGs effective for FY 2020 and reviewed the new and revised MS-DRGs for application of the post-acute care transfer policy and special payment methodology. As a result of its review, CMS proposes to remove MS-DRGs 273 and 274 from the list of MS-DRGs subject to the post-acute care transfer policy and the special payment methodology. It is not subjecting any additional MS-DRGs to the post-acute care transfer policy. For the FY 2020 final rule, CMS will update its analysis using the most recent available data at that time.

B. Inpatient Hospital Updates

The inpatient hospital update for FY 2020 is calculated by determining the rate of increase in the hospital market basket for IPPS hospitals in all areas, subject to the following reductions (in the order presented):

For hospitals that fail to submit quality information, the FY 2020 inpatient hospital update will be reduced by one quarter of the applicable percentage increase.
For a hospital that is not a meaningful EHR user (and to which no exemption applies), the FY 2020 inpatient hospital update will be reduced by three-quarters of the market basket update.
For all hospitals, the FY 2020 inpatient hospital update is subject to a 0.5 percentage point reduction for the 10-year moving average of economy-wide multifactor productivity.

The IHS Global Insight, Inc. (IGI) fourth quarter 2018 forecast (with historical data through the third quarter of 2018) for the hospital market basket is 2.7 percent. Using IGI's fourth quarter 2018 forecast, CMS proposes an MFP adjustment of -0.5 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 2020	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	3.2	3.2	3.2	3.2
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.8	-0.8
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.4	0.0	-2.4
MFP Adjustment	-0.5	-0.5	-0.5	-0.5
Applicable Percentage Increase	**2.7**	**0.3**	**1.9**	**-0.5**

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.

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

RRCs are rural hospitals that meet case-mix, discharge and other criteria that may geographically reclassify under special rules. CMS annually proposes revised case mix index (CMI) and discharge criteria to qualify for RRC status. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2019, CMS proposes that a rural hospital with fewer than 275 beds available for use must meet specific geographic criteria and:

Have a CMI value for FY 2018 that is at least—

- 1.6855 (national—all urban), or
- The median CMI value (not transfer adjusted) for urban hospitals (excluding hospitals with approved teaching programs) for the census region in which the hospital is located (see table on page 857 of the display copy of the rule for the regional CMIs).

Have at least 5,000 discharges (3,000 for an osteopathic hospital) for its cost reporting period that began during FY 2017. The median number of discharges for urban hospitals in each census

region is greater than the national standard of 5,000. Therefore, the minimum number of discharges a non-osteopathic hospital must have to qualify is 5,000 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 reflect the updated FY 2017 MedPAR file containing data from additional bills received through March 2019. 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 for FYs 2011 to 2022 changed the distance and discharge criteria as well as the maximum number of discharges to receive a 25 percent adjustment. Above this maximum number, CMS is required to provide a declining linear adjustment up to a cut-off number of discharges. Beginning with FY 2023, the criteria revert to the original standards. See the following table for the distance and discharge criteria and the payment methodology specified in statute and regulations:

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

2. FY 2019 – FY 2022

Application 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 October 1, 2019**. 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 a determination.

A hospital receiving the low-volume hospital payment adjustment for FY 2019 may continue to receive a low-volume hospital payment adjustment in FY 2020 by providing its MAC with a verification statement that it continues to meet the mileage criterion and provide information for the discharge criterion from its most recently submitted cost report.

Distance Criterion. 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 contact the hospital to obtain additional necessary information to process its application.

Discharge Criterion. For FY 2020 and subsequent fiscal years, the discharge determination is made using the hospital's most recently submitted cost report.

Payment Methodology. CMS provides the following payment formula to determine the low volume hospital adjustment (LVHA) from FYs 2019 through 2022:

LVHA = 0.25 – [0.25/3300] x (number of total discharges - 500) = (95/330) - (number of total discharges/13,200).

3. Indian Health Service and Tribal Hospitals

In the FY 2018 IPPS/LTCH PPS final rule, CMS adopted a regulatory provision specifying that for discharges occurring in FY 2018 and subsequent years, only the distance between Indian Health Service (IHS) and Tribal hospitals (collectively referred to as "IHS hospitals") will be considered when assessing whether an IHS hospital meets the mileage criterion. Similarly, only the distance between non-IHS hospitals would be considered when assessing whether a non-IHS hospital meets the mileage criterion.

Section 429 of the Consolidated Appropriations Act, 2018 enacted on March 23, 2018 requires the special treatment with respect to the proximities between IHS and non-IHS hospitals to apply to low-volume hospital payment adjustments for FYs 2011 through 2017. CMS proposes to make conforming changes to its regulations consistent with this statutory enactment.

E. Indirect Medical Education Payment Adjustment

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.

F. Disproportionate Share and Uncompensated Care

1. Background

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

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

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

The statute precludes administrative or judicial review of the Secretary's estimates of the factors used to determine and distribute UCP. UCP payments are only made to hospitals eligible to receive DSH payments that are paid using the national standardized amount (SCHs paid on the basis of hospital specific rates, hospitals not paid under the IPPS and hospitals in Maryland paid under a waiver are ineligible to receive DSH and, therefore, UCP payments).

2. Proposed FY 2020 Factor 1

CMS estimates this figure based on the most recent data available. It is not later adjusted based on actual data. CMS used the Office of the Actuary's (OACT) December 2018 Medicare DSH estimates, which were based on the September 2018 update of the HCRIS and the FY 2019 IPPS final rule impact file. Starting with these data sources, OACT applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

OACT's December 2018 Medicare estimates of DSH is $16.857 billion. **The proposed Factor 1 amount is seventy-five percent of this amount or $12.643 billion.** The proposed Factor 1 for 2020 is about $389 million more than the final Factor 1 for FY 2019.

OACT's estimates for FY 2020 began with a baseline of $15.093 billion in Medicare DSH expenditures for FY 2017. The table below shows the factors applied to update this baseline to the current proposed estimate for FY 2020.

Factors Applied for FY 2017 through FY 2020 to Estimate Medicare DSH Expenditures Using 2017 Baseline

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2017	1.0015	0.9986	1.004	1.0751	1.0795	15.093
2018	1.018088	0.9819	1.018	1.0345	1.0528	15.889
2019	1.0185	0.9791	1.005	1.02206	1.0243	16.275
2020	1.032	1.0055	1.005	0.9932	1.0358	16.857

- 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

The table below shows the factors that are included in the "update" column of the "Increases from 2017" table. All numbers are based on projections from the President's FY 2020 Budget.

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Multifactor Productivity Adjustment	Documentation and Coding	Total Update Percentage
2017	2.7	-0.75	-0.3	-1.5	0.15
2018	2.7	-0.75	-0.6	0.4588	1.8088
2019	2.9	-0.75	-0.8	0.5	1.885
2020	3.2	0	-0.5	0.5	3.2

3. Proposed FY 2020 Factor 2

Factor 2 adjusts Factor 1 based on the percent change in the uninsured since implementation of the ACA. For FYs 2014-2017, the statute required CMS to use CBO's estimate of the uninsured rate in the under 65 population from before enactment of the ACA for FY 2013. For FY 2018 and subsequent years, the statute requires Factor 2 to equal the percent change in the number of individuals who are uninsured from 2013 until the most recent period for which data are available minus 0.2 percentage points for each of fiscal years 2018 and 2019. In 2018, CMS began using uninsured estimates from the National Health Expenditure Accounts (NHEA) in place of CBO data as the source of change in the uninsured population.[23]

[23]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

For FY 2020, CMS estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2019 and 2020 is 9.4 percent. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates the proposed Factor 2 for FY 2020 (weighting the portion of calendar years 2019 and 2020 included in FY 2020) as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2019: 9.4 percent.
- Percent of individuals without insurance for CY 2020: 9.4 percent.
- Percent of individuals without insurance for FY 2020 (0.25 times 0.094) +(0.75 times 0.094): 9.4 percent

Proposed Factor 2 = 1-|((0.094-0.14)/0.14)| = 1- 0.3286 = 0.6714 (67.14 percent)

CMS calculated Factor 2 for the FY 2020 proposed rule to be 0.6714 or 67.14 percent, and the uncompensated care amount for FY 2020 to be $12.643 billion x 0.6714 = $8.489 billion, which is about $216 million more than the FY 2019 UCP total of about $8.273 billion; the percentage increase is 2.6 percent. The below tables show the Factor 1 and Factor 2 estimates for FY 2019 and the proposed factors for FY 2020:

FY 2020 Change in UCP
($ in Billions)

	FY 2019	FY 2020	$Change	% Change
Factor 1	$12.254	$12.643	$0.389	3.2%
Factor 2	0.6751	0.6714	-	-0.5%
UCP	$8.273	$8.489	$0.216	2.6%

4. Proposed Factor 3 for FY 2020

a. Background & 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

publicly available on the CMS website at: https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/index.html

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.

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

In the FY 2017 IPPS proposed rule, CMS stated that many of its concerns would no longer be relevant as hospitals were on notice as of FY 2014 that Worksheet S-10 could eventually become the data source to calculate UCP. MedPAC has also indicated that Worksheet S-10 data is a better data source for uncompensated care than low income patient days. In addition, CMS has undertaken extensive analysis of the Worksheet S-10 data, benchmarking Worksheet S-10 data against the data on uncompensated care costs reported to the Internal Revenue Service (IRS) on Form 990 by not-for-profit hospitals.[24] Key findings that CMS cites includes high correlation between uncompensated care costs reported on IRS Form 990 and Worksheet S-10 and the correlation coefficient has increased over time from 0.71 in 2010 to 0.80 in 2012.

CMS has issued several transmittals to improve instructions for the Worksheet S-10 data. In November 2016, CMS issued Transmittal 10 which made a number of changes to the Worksheet S-10, including the instructions regarding the reporting of charity care charges. Transmittal 11 issued in September, 2017 clarified that hospitals may include discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period. Transmittal 11 also clarified the definitions and instructions for uncompensated care, non-Medicare bad debt, non-reimbursed Medicare bad debt, and charity care.[25] In addition, this transmittal clarified that full or partial discounts given to uninsured patients who meet the hospital's charity care policy or financial assistance policy/uninsured discount policy may be included on Line 20, Column 1 of Worksheet S-10. These clarifications apply to cost reporting periods beginning on or after October 1, 2013. CMS also modified the application of the CCR.[26]

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

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

[26] Specifically, the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt. The CCR will be applied to the charges for uninsured patients approved for charity care or an uninsured discount, non-Medicare bad debt, and charges for noncovered days exceeding a length of stay limit imposed on patients covered by Medicaid or other indigent care programs.

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

b. Proposal to Use Audited FY 2015 Data

CMS notes that based on feedback from commenters emphasizing the importance of audits to ensure accurate and consistent data reported on Worksheet S-10 data, CMS began auditing FY 2015 data in the fall of 2018. However, CMS expresses concern over using 3 years of data in the calculation of Factor 3 for FY 2020 stating that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result – counter to its original goal in using 3 years of data. CMS notes that by using three years of data this could introduce unnecessary variability into its calculations; its analysis indicates that about 10 percent of audited hospitals have more than a $20 million difference between their audited FY 2015 data and their unaudited FY 2016 data.

CMS proposes to use a single year of Worksheet S-10 data from FY 2015 cost reports to calculate Factor 3 in the FY 2020 methodology. CMS notes that audited hospitals account for about half of the proposed total uncompensated care payments for FY 2020. CMS uses the most recent available HCRIS extract available – updated through February 15, 2019, but plans to update these data using the March 2019 HCRIS file for the final rule.

c. Alternative Considered to Use FY 2017 Data

CMS acknowledges that some hospitals have raised concerns regarding some of the adjustments made to the FY 2015 cost reports following the audits of these reports. Likewise, hospitals have contended that some of these adjustments would not have been made given revisions to instructions that were effective for cost reporting periods beginning on or after October 1, 2016. CMS made important changes to lines 20-22 of Worksheet S-10 regarding reporting charity care charges that are effective for cost reporting periods beginning on or after October 1, 2016.

CMS seeks public comment on whether the changes in the reporting instructions between the FY 2015 cost reports and the FY 2017 cost reports have resulted in a better understanding among hospitals of how to report uncompensated care costs and improved relative consistency and accuracy across hospitals in reporting these costs. CMS also seeks comments on whether, due to the changes in the reporting instructions, it should use a single year of uncompensated care cost data from the FY 2017 reports, instead of the FY 2015 reports, to calculate Factor 3 for FY 2020.

CMS notes that if it were to adopt a final policy that used Worksheet S-10 data from the FY 2017 cost reports to determine Factor 3 for FY 2020, it would also use the March 2019 update of HCRIS for the final rule. It notes that the proposed methodology for Factor 3 would be unchanged

regardless of whether FY 2017 or FY 2015 cost report data were used. In the payment impacts section of the rule, CMS shows the distribution of uncompensated care payments both using FY 2015 Worksheet S-10 data and FY 2017 Worksheet S-10 data. On the CMS website, CMS shows each hospital's Factor 3 amount under the proposal using FY 2015 data and the alternative using FY 2017 data.[27]

d. Proposed 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."

e. Methodological Considerations for Calculating Factor 3

Hospital Mergers

In the case of hospital mergers, 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.[28]

New Hospitals

CMS proposes to modify the policy for new hospitals that do not have data for the cost reporting period(s) used in the proposed Factor 3 calculation. For FY 2020, CMS proposes that new hospitals that are eligible for Medicare DSH would receive interim empirically justified DSH payments. CMS notes, for example, that there are some new hospitals (hospitals with CCNs established after October 1, 2015) that have a preliminary projection of being eligible for DSH payments. CMS proposes that the MAC would make a final determination on DSH eligibility at cost report settlement based on its FY 2020 cost report. If the hospital is ultimately determined to be eligible, the hospital would receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care payment amount reported on Worksheet S-10 of the hospital's FY 2020 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S-10 of the FY 2015 cost reports for all DSH eligible hospitals. The new hospital would not receive interim uncompensated care payments before cost report settlement because CMS does not have any FY 2015 uncompensated care data on which to

[27] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/FY2020-NPRM-Table-18.zip

[28] Comments on the list of mergers can be submitted to the CMS inbox at Section3133DSH@cms.hhs.gov.

determine interim payments. If CMS decided on the alternative policy of using FY 2017 data, it would modify the new hospitals policy to apply to hospitals with a CCN established on or after October 1, 2017.

CMS makes additional clarifications and proposals regarding the new hospital policy for new Puerto Rico hospitals. In FYs 2018 and 2019, Factor 3 for all Puerto Rico hospitals, including new ones, was based on the low-income insured proxy data from FYs 2012 and 2013. For FY 2020, CMS proposes that Puerto Rico hospitals that do not have a FY 2013 cost report would be considered new hospitals and would be subject to the proposed new hospital policy, as detailed above. CMS believes the uncompensated care costs reported on FY 2020 Worksheet S-10 are the best available and appropriate data to calculate Factor 3 for new Puerto Rico hospitals. This would also make CMS' policy for new hospitals uniform.

Indian Health Service (IHS) and Tribal Hospitals and Subsection(d) Puerto Rico hospitals that have a FY 2013 cost report.

CMS proposes to adapt the policy first adopted for the FY 2018 rulemaking regarding FY 2013 low-income insured days when determining Factor 3 for IHS and tribal hospitals and subsection(d) Puerto Rico hospitals that have a FY 2013 cost report. CMS proposes to determine Factor 3 based on Medicaid days from FY 2013 and the most recent update of SSI days. CMS also proposes to continue its policy to use a proxy for SSI days for Puerto Rico hospitals, consisting of 14 percent of a hospital's Medicaid days, as finalized in the 2017 IPPS/LTCH PPS final rule.

All-inclusive Rate Providers

CMS believes it is no longer necessary to propose specific Factor 3 policies for all-inclusive providers, as it did in the FY 2019 IPPS/LTCH PPS final rule. CMS states that it has examined the CCRs from the FY 2015 cost reports and believe the risk that the data is aberrant is mitigated by the its proposal to apply trim methodologies for potentially aberrant uncompensated care costs for all hospitals.

Scaling factor

CMS is also not proposing a scaling factor to the Factor 3 of all DSH eligible hospitals to account for the averaging effect of using 3 years of data in the calculation. This is not necessary because CMS is proposing to use 1-year of cost report data as the basis for determining Factor 3.

Providers with multiple cost reports

CMS proposes to continue its policy on providers with multiple cost reports by annualizing Medicaid days data and uncompensated care cost data reported on the Worksheet S-10 if a hospital's cost report did not equal 12 months. CMS also proposes in the rare case where a provider has multiple cost reports beginning in the same year, but one report also spans the entirety of the following fiscal year, that it would use data from the cost report that spanned both fiscal years if the hospital had no cost report beginning in a fiscal year.

Application of Statistical Trim Methodologies

CMS proposes to continue its policies on applying statistical trim methodologies to potentially aberrant CCRs and uncompensated care costs reported on the Worksheet S-10. Thus, if a hospital's uncompensated care costs for FY 2015 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 from another available cost report. It would then apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs. CMS states that it would use FY 2016 cost report data if FY 2015 cost report data were aberrant. If 2017 data were used to calculate Factor 3, CMS states, in the case of aberrant data, that it would use data from the providers FY 2015 cost report in order to determine Factor 3. CMS also notes that while it expects all providers will have FY 2017 cost report in HCRIS by the time any data would be used for the final rule, if such data are not available for a given hospital, CMS would substitute the Worksheet S-10 data from the FY 2015 cost report.

Proposed Steps to Trim CCRs

Similar to the FYs 2018 and 2019 process, CMS proposes the following steps for trimming CCRs in FY 2020. There is a discrepancy in the proposed rule about how CMS plans to treat all-inclusive rate providers. CMS proposes to include all-inclusive rate providers and not remove them in the proposal described above – it plans to use the trimming process to capture any outliers. In the methodology steps detailed in the proposed rule, however, CMS suggests that all-inclusive rate providers would be removed and a statewide CCR would be assigned. We believe that CMS made an error in their description of their steps (kept the same language from last year) and thus we have removed that language from the methodology steps for trimming CCRs. This seems likely because only a small number of hospitals (less than 15) had their CCRs replaced with the statewide average CCR – there are over one hundred all-inclusive rate providers. For providers that did not report a CCR, CMS would assign them the statewide average CCR.

Methodology for Trimming CCRs	
Step 1	Remove Maryland hospitals.
Step 2	For FY 2015 cost reports, 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. 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 8 hospitals that have a CCR above the calculated ceiling of 0.925 for FY 2015. Under the alternative policy considered, the trim would remove 13 hospitals that have a CCR above the calculated ceiling of 0.942 for FY 2017).
Step 3	Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for 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"). Under the proposed rule, the statewide average CCR would therefore by applied to 8 hospitals, 13 hospitals under the alternative policy.

5. Request for Public Comments on Ways to Reduce Provider Reimbursement Review Board (PRRB) Appeals Related to a Hospital's Medicaid Fraction Used in the DSH Payment Adjustment Calculation

CMS states that as part of its ongoing efforts to reduce regulatory burden on providers, CMS is examining the backlog of appeals cases at the Provider Reimbursement Review Board (PRRB). A large number of appeals before the PRRB relate to the calculation of a hospital's disproportionate patient percentage (DPP) used in the calculation of the DSH payment adjustment. According to CMS, many hospitals annually appeal their cost reports to the PRRB in an effort to try and use updated State Medicaid eligibility data to calculate the Medicaid fraction.

CMS explores a couple of options that may prevent the need for such appeals, and thus reduce the backlog of PRRB appeals. One solution CMS suggests is to develop regulations governing the timing of the data for determining Medicaid eligibility, similar to its existing policy on entitlement to SSI benefits, which is determined at a specific time. Under this solution, a provider would submit a cost report with Medicaid days based on the best available Medicaid eligibility data at the time of the filing and could request a "reopening" when the cost report is settled without filing an appeal. CMS would issue directives to MACs requiring them to open these cost reports for this issue at a specific time and set a realistic time period during which the provider could submit updated data. Another option CMS is exploring is allowing hospitals, for a one-time per cost reporting period option, to resubmit a cost report with updated Medicaid eligibility information. This would be similar to its existing DSH policy allowing hospitals a one-time option to have their SSI ratios calculated based on their cost reporting period rather than the Federal fiscal year.

CMS seeks comments concerning the viability of these options, as well as any alternative approaches, that could help reduce the number of DSH-related appeals and inform its future rulemaking efforts. In particular, with respect to the reopening option, CMS is interested in the optimal time for review of data to occur balancing accurate payment and CMS' and the MACs' desire to settle cost reports in a timely manner (e.g. 2 years after cost report submission).

6. Impact Analysis

The regulatory impact analysis presented in Appendix A of the proposed rule includes the estimated effects of the changes to UCP for FY 2020 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,430 hospitals that are projected to be eligible for DSH in FY 2020. CMS presents estimates based on its proposal to use one-year of FY 2015 data and its alternative approach to use FY 2017 Worksheet S-10 data instead of FY 2015 Worksheet S-10 data to determine Factor 3.

Changes in FY 2020 UCP compared to FY 2019 are accounted for by a proposed increase in Factor 1 and a proposed decrease in Factor 2 as well as by a decrease in the number of hospitals eligible to receive DSH in FY 2020. Factor 1 is proposed to increase from $12.254 billion to $12.643 billion while Factor 2 is proposed to decrease 67.51 percent to 67.14 percent. As a result, the total amount of UCP is estimated at $8.489 billion, a 2.61 percent increase from FY 2019 UCP (about $216 million). The payment increase for any individual hospital will vary as payment impacts solely from Factor 3 are redistributive. A percent change in UCP payments of less than 2.61 percent indicates that hospitals within that category are projected to experience a smaller increase compared to the average for all hospitals, and a percent change of more than 2.61 percent indicates the category of hospitals is receiving a higher increase in UCP than the average for all hospitals. The table below shows impacts for selected categories of hospitals under the proposed and alternative approaches.

Hospital Type	Proposed Approach (FY 2015 data)	Alternative Approach (FY 2017 data)
All Hospitals	2.61%	2.61%
Urban	1.39%	2.04%
Large Urban	6.51%	6.37%
Other Urban	-5.11%	-3.45%
Rural	22.9%	12.04%
Beds: 0-99 (Urban)	25.79%	28.14%
Beds: 250+ (Urban)	-1.65%	0.61%
New England (Urban)	-6.92%	-8.32%
Middle Atlantic (Urban)	4.64%	-0.05%
West South Central (Urban)	22.52%	18.56%
Pacific (Urban)	-23.45%	-19.03%
Major Teaching	2.48%	0.91%
Non-Teaching	7.37%	5.03%
Voluntary	-5.11%	-2.81%
Proprietary	3.12%	0.23%
Government	20.26%	16.65%

Under its proposal, rural hospitals are projected to receive a larger percentage increase in uncompensated care payments (22.9%) than urban hospitals (1.39%) in FY 2020 compared to FY 2019. Urban hospitals in the Pacific region (California, Oregon, and Washington) are the most negatively affected, with these hospitals projected to receive a -23.45 percent decrease. In contrast, urban hospitals in the West South Central region (Arkansas, Louisiana, Oklahoma, and Texas) are projected to receive a 22.52 percent increase. Government hospitals are projected to receive a larger than average payment increase of 20.26 percent. Proprietary hospitals are projected to receive a slightly larger average payment increase of 3.12%, whereas voluntary hospitals are projected to receive a payment decrease of -5.11%. The impact analysis using the alternative approach (FY 2017) data were similar – though the effects were smaller for some categories of hospitals. For example, the projected increases for government hospitals were

lower at 16.65% compared with 20.26% for the proposed, and the proposed decreases in payments for Pacific region were smaller under the alternative approach (-19.03% compared to 23.45%).

G. Hospital Readmissions Reduction Program

1. Background

The Hospital Readmissions Reduction Program (HRRP) reduces payments to Medicare PPS hospitals having readmissions exceeding an expected level. The list of conditions to which the HRRP applies in FY 2019 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)[29].

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. Beginning with FY 2019, hospitals are assigned to one of five peer groups based on the proportion of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligibles[30] and the HRRP formula compares a hospital's performance to the median for its peer group.

Several changes to HRRP policies are proposed for FY 2020 in this rule. The proposals would establish factors for removal of HRRP measures; update the definition of dual eligible used for creating peer groups; create a subregulatory process for making nonsubstantive changes to the HRRP adjustment factor components; and make changes to regulatory text regarding these proposals and to codify other parts of the HRRP.

2. Removal of HRRP Measures

CMS proposes a set of factors it would use to determine whether a measure should be removed from the HRRP; no measures are proposed for removal at this time. The proposed factors are the same as those adopted for the Inpatient Quality Reporting (IQR) Program, the Hospital VBP Program, and other hospital quality reporting programs. As is the case in these other programs, the factors would not be used for automatic removal of measures but would be applied on a case-by-case basis. The proposed eight measure removal factors are:
Factor 1. Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped-out" measures);

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[29] Additional resources on HRRP are on the QualityNet.org website under the inpatient hospital tab at https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776124964.

[30] 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.

Factor 2. Measure does not align with current clinical guidelines or practice;
Factor 3. Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic;
Factor 4. Measure performance or improvement does not result in better patient outcomes;
Factor 5. Measure can be replaced by a measure that is more strongly associated with desired patient outcomes for the particular topic;
Factor 6. Measure collection or public reporting leads to negative unintended consequences other than patient harm;
Factor 7. Measure is not feasible to implement as specified; and
Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

3. Definition of Dual Eligible Beneficiary

CMS proposes to modify the definition of dual eligible in order to avoid undercounting the dual eligible status of beneficiaries who die in the month of a hospital discharge. For these beneficiaries, a 1-month lookback period would be used. CMS reports that this change would affect a small number of beneficiaries and would not have a "substantive impact," yet believes it should use the most accurate information available in counting dual eligibles for purposes of the HRRP adjustment. The proposal would take effect beginning in FY 2021; CMS notes that it does not have a policy that would allow it to make this change outside the normal rulemaking schedule. (Such a policy is proposed below.) The proposed new definition of dual eligible (with proposed new language *in italics*) is:

"Dual-eligible is a patient beneficiary who has been identified as having full benefit status in both the Medicare and Medicaid programs in the State Medicare Modernization Act (MMA) files for the month the beneficiary was discharged from the hospital*, except for those patient beneficiaries who die in the month of discharge, who will be identified using the previous month's data sourced from the State MMA files.*"

4. Subregulatory Process for Changes to Payment Adjustment Factor Components

Currently, a subregulatory process exists for making nonsubstantive modifications to HRRP measures. This allows CMS to update measures to reflect National Quality Forum (NQF) requirements without the delays associated with notice and comment rulemaking.

A similar process is proposed for nonsubstantive modifications to other components of the HRRP adjustment in order to provide for rapid adoption of minor changes. Substantive changes would continue to go through notice and comment rulemaking and would be those where the impact of the change to the payment adjustment factor component is so significant that it could no longer be considered to be the same as the previously finalized component. By contrast, examples of nonsubstantive changes would include updated naming or locations of data files and/or other minor discrepancies that do not change the intent of the policy. An example offered

is the proposed change immediately above that would modify the way dual eligible status is determined for beneficiaries who die in the same month as a hospital discharge.

5. Applicable Period for FY 2022

Consistent with current policies, CMS proposes that for FY 2022 the applicable period from which data would be collected for calculating the readmission payment adjustment factor would be the three-year period from July 1, 2017 through June 30, 2020. 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) are based on claims data from the applicable period. Previously finalized periods are shown with this proposal below.

Previously Finalized and *Proposed* HRRP "Applicable Periods"	
Payment Year	**Discharge Dates**
FY 2019	July 1, 2014-June 30, 2017
FY 2020	July 1, 2015-June 30, 2018
FY 2021	July 1, 2016-June 30, 2019
FY 2022	*July 1, 2017 – June 30, 2020*

6. Payment Adjustment for FY 2020

No changes are proposed to the methodology for calculating the HRRP payment adjustment for FY 2020. Using MedPAR data for the 3-year applicable period from July 1, 2015 through June 30, 2018 hospitals will be grouped by quintiles (five peer groups) based on the proportion of dual-eligible patients. The March update of the MedPAR file is used for each year (e.g., March 2016 update of the FY 2015 MedPAR file to identify FY 2015 claims with discharge dates on or after July 1, 2015; March 2017 update of the FY 2016 MedPAR file to identify claims within FY 2016 and so forth). 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)[31] 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)[32] that is the same across all hospitals and all conditions.

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

[31] 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.

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

Once hospitals have had a chance to review and correct their HRRP calculations for FY 2020, CMS will display the FY 2020 readmissions payment adjustment factors in Table 15 on its website. It expects this to occur in the fall of 2019.

7. Confidential Reporting of Stratified Readmissions Data

As early as the spring of 2020 it will include in the confidential hospital-specific reports data on the six readmissions measures stratified by patient dual eligible status. Results will be provided using two disparity methodologies: the within-hospital disparity method compares readmissions rates for dual eligibles and other beneficiaries, and the dual eligible outcome measure compares performance in care for dual eligibles across hospitals. These methods differ from the HRRP stratification and will not be used for any payment calculations. CMS is providing the data because it believes that it allows for a more meaningful comparison and will provide additional perspectives on health care equity.

8. Revisions to Regulatory Text

A series of revisions to the regulatory text involving the HRRP are proposed. One relates to the proposed change discussed in IV.G.2 above regarding the definition of dual eligible. Two other proposals also involve modifying definitions. First, "aggregate payments for excess readmissions" would be modified to reflect the peer grouping methodology now in use. Second, the definition of "base operating DRG payment amount" would be modified to reflect changes in MDH policy. These changes would be made to §412.152.

Additionally, CMS proposes to add the neutrality modifier and the proportion of dual eligibles to the list of specific items for which no administrative and judicial review is permitted (§412.154(d)). The current list prohibits this review for (1) the determination of base operating DRG payment amounts; (2) the methodology for determining the HRRP adjustment factor, including the excess readmissions ratio, aggregate payments for excess readmissions, and aggregate payments for all discharges; (3) the applicable period; and (4) the applicable conditions.

9. Impact Analysis

In the regulatory impact analysis section of the proposed rule CMS reiterates the analysis included in the FY 2019 IPPS/LTCH final rule which estimated that 2,599 hospitals, or 85 percent of those potentially penalized, will be penalized under the HRRP in FY 2019. A table shows the distribution of HRRP penalties as a percent of payments by type of hospital.

H. Hospital Value-Based Purchasing Program

Only one administrative change is proposed to policies under the Hospital Value-Based Purchasing (VBP) Program, involving the specific data used in the program for the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) measures. That proposal is described in IV.H.2 below. The

previously adopted measures; domain weights (25 percent each across the four domains); case minimums; baseline and performance periods (through FY 2025); and performance standards will continue. In this rule, CMS provides tables with updated performance standards for FYs 2022 through 2025. A historical table with the previously adopted measures appears at the end of this section.

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.

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 2018 update of the FY 2018 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 2020 IPPS proposed rule web page a Table 16 which includes proxy hospital-specific value-based incentive payment adjustment factors for FY 2020. These proxies are based on hospitals' TPSs from the FY 2019 Hospital VBP Program. They will be updated as Table 16A in the final rule to reflect the March 2019 update of the FY 2018 MedPAR file. Once hospitals have been able to review and correct their actual TPSs for FY 2020, CMS will post a Table 16B to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2020 program year. CMS expects to post Table 16B in the fall of 2019.

2. NHSN HAI Measure Data

To date, the NHSN HAI measure data used for the VBP Program has been the same data used to calculate these measures for the IQR Program. Because the FY 2019 IPPS/LTCH final rule removed these measures from the IQR Program, CMS proposes in this rule to use the same data to calculate the NHSN HAI measures for the VBP Program that it uses to calculate these measures for the Hospital Acquired Condition (HAC) Reduction Program. The proposal would begin with data collection on January 1, 2020 for the FY 2022 VBP Program performance period, which is the effective date of the removal of these measures from the IQR Program and the beginning of reporting of these measures for the HAC Reduction Program. The review and correction and data validation processes adopted for these data for the HAC Reduction Program (previously used for the IQR Program) would also apply. CMS believes this proposal would provide for a seamless shift from the use of IQR Program data for the VBP Program.

3. Impact Analysis

In the regulatory impact analysis section of the proposed rule CMS uses FY 2019 TPSs to estimate FY 2020 VBP Program adjustments; the distributional effects by type of hospital are shown.

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

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

I. Hospital-Acquired Condition Reduction Program

Several changes to HAC Reduction Program policies are proposed for FY 2020, although the program measures, data collection processes, scoring methodology, and the policies for review and correction of program data would remain unchanged. Under the proposals described below, CMS would establish factors for removal of program measures, establish the data collection period for the FY 2022 program year, and clarify certain data validation and data collection policies finalized in the FY 2019 IPPS/LTCH final rule. CMS also proposes changes to regulatory text which it says are needed to update references to domains which were previously removed from the scoring calculation effective with the FY 2020 payment year.

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 at the end of this section, which also shows historical program measures.

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 is 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. Removal of HAC Reduction Program Measures

In a proposal parallel to the one for the HRRP described in IV.G.2 above, CMS proposes a set of eight factors it would use to determine whether a measure should be removed from the HAC Reduction Program; no measures are proposed for removal at this time. The proposed factors are the same as those already adopted for the IQR Program, the Hospital VBP Program, and other hospital quality reporting programs. As is the case in these other programs, the factors would not be used for automatic removal of measures but would be applied on a case-by-case basis. The proposed eight measure removal factors are listed in item IV.G.2 above.

3. HAC Reduction Program Data Validation

In the FY 2019 IPPS/LTCH final rule, CMS adopted a HAC Reduction Program data validation process to replace the one used for the IQR Program. (This was necessitated by removal of HAC Reduction Program measures from the IQR Program.) Under the policy, the five chart-abstracted NHSN measures will be subject to validation under the HAC Reduction Program beginning with Q3 2020 discharges for FY 2023 payment. This reflects the timing of adoption of the data collection requirements for the NHSN measures to the HAC Reduction Program. All subsection (d) hospitals are eligible for random selection for the data validation sample because they are all subject to the HAC Reduction Program. Sample sizes were continued from the IQR Program: 400 randomly selected hospitals and 200 hospitals selected using targeting criteria. 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.

In this rule, CMS proposes to modify the number of hospitals targeted from exactly 200 hospitals to "up to 200 hospitals," which it says will provide flexibility to avoid selection of hospitals simply to meet the 200 number.

Further, CMS clarifies its provider selection process for the purpose of reducing the likelihood that hospitals could be selected for validation under the IQR Program and the HAC Reduction Program during the same reporting period. Specifically, CMS clarifies that it will randomly select one pool of 400 subsection (d) hospitals for validation of chart-abstracted measures in both programs. All the hospitals will be included for the HAC Reduction Program, whereas for the IQR Program, CMS will remove any hospitals without an active notice of participation in that program. The process will begin with the Q3 2020 infectious events, which is the beginning of the HAC Reduction Program validation process. After the random selection of 400 hospitals, CMS will select the targeted sample of up to 200 hospitals for validation under both programs.

No change is proposed to the previously finalized policy of selecting 40 cases annually from each hospital selected for validation.

In addition, CMS proposes to use a filtering method to better target "true events," or those that meet NHSN HAI criteria. It has found that many candidate cases selected for validation have positive cultures collected on the first or second day of a hospital stay and would be considered community onset events for CLABSI and CAUTI. The proposed filtering method would eliminate cases from the validation pool for which the positive cultures were collected on the first or second day following admission. CMS believes that this approach will increase the number of true events for validation without having to increase the sample size. Its analysis has shown that by using filtering the ratio of the number of true CDC NHSN HAI events to the total sample size of candidate events ("yield rate") would increase from 13 percent to 24 percent for CLABSI and from 9 percent to 17 percent for CAUTI. CMS believes that this would help it better understand the overreporting and underreporting of such events and that by improving the the power of the validation methodology CMS could potentially select fewer cases for validation and reduce hospital burden. CMS is considering a similar filtering approach to apply to the SSI measures, which also have a low yield rate. For the MRSA and CSI measures, CMS notes that the validator agreement rates for these measures have been lower than for CLABSI and CAUTI, and that these events are over-reported due to missing laboratory record information. CMS will provide additional training to hospitals with the hope of improving hospital validation performance on these measures.

4. Performance Period for FY 2022 Program Year

Consistent with previous policies, CMS proposes that the HAC Reduction Program "applicable period", or performance period, for FY 2022 will be the 24-month period from July 1, 2018 through June 30, 2020 for the PSI-90 measure and January 1, 2019 through December 31, 2020 for the NHSN measures.

5. 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 2020 by hospital characteristic using data from the FY 2019 final rule impact file. While by definition, 25 percent of hospitals overall would be in the worst quartile and subject to the penalty (795 hospitals total), this proportion varies from about 18 percent for rural hospitals with 200 or more beds to 49 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.

Summary Table: HAC Reduction Program Measures and Performance Periods						
	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): ◦ Following Colon Surgery ◦ Following Abdominal Hysterectomy		X	X	X	X	X
Methicillin-resistant staphylococcus aureus (MRSA)			X	X	X	X
Clostridium difficile (CDI)			X	X	X	X
Applicable Time Period (Performance Period)	1/1/12-12/31/13	1/1/13-12/31/14	1/1/14-12/31/15	1/1/15-12/31/16	1/1/16-12/31/17	1/1/17-12/31/18
Domain 2 weight	65%	75%	85%	85%	*	*
* Domains replaced with equal weighting of HAC Reduction Program measures.						
Note: PSI-90 is a composite of eight measures: PSI-3 (pressure ulcer rate), PSI-6 (iatrogenic pneumothorax rate), PSI-7 (central venous catheter related blood stream infections rate), PSI-8 (postoperative hip fracture rate), PSI-12 (postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT rate), PSI-13 (postoperative sepsis rate), PSI-14 (wound dehiscence rate), and PSI-15 (accidental puncture or laceration rate). The Patient Safety and Adverse Events composite "modified PSI-90" removed PS-07; added PSI-9 (postoperative hemorrhage or hematoma rate), PSI-10 (physiologic and metabolic derangement rate), and PSI-11 (postoperative respiratory failure rate); re-specified the PSI-12 and PSI-15 rates; and changed the weighting of component indicators.						

J. Payments for Indirect and Direct Graduate Medical Education Costs

Background

Teaching hospitals receive payments from Medicare to compensate them for their indirect medical education (IME) and direct graduate medical education (DGME) costs. These payments are based on the number of full-time equivalent (FTE) residents trained by the hospital subject to a cap based on the number of residents the hospital claimed for IME and DGME payment in 1996. For both IME and DGME, hospitals can count residents that train in non-provider sites if they incur the costs of the resident's salary and fringe benefits and the resident is providing patient care. A non-provider site does not include a critical access hospital (CAH).

Counting Residents in CAHs

Under current policy, CAHs that train residents in approved residency training programs are paid 101 percent of their reasonable costs for training. CMS has heard concerns CAHs may be too small to support residency training programs or may not be in a financial position to incur the

costs associated with residency training programs. In light of these concerns, CMS reexamined the statutory language associated with its policy that CAHs cannot be considered a "non-provider site" and is proposing to modify its policy, such that a hospital could include residents training in a CAH in its FTE count as long as it is meeting the requirements for counting residents in non-provider sites.

Historically, CMS used the terms "non-provider" and "non-hospital" interchangeably. While a CAH is defined as a "provider of services" under section 1861(u) of the Act, it does not meet the definition of a hospital under section 1861(e) of the Act. Up until FY 2014, CMS allowed a CAH the option to either function as a non-hospital site or to incur costs for training residents in an approved program and be paid 101 percent of the reasonable costs. However, CMS changed this policy effective in FY 2014 because the Affordable Care Act amended the IME and DGME statutory provisions to address time spent by residents training outside of the hospital setting by using the term "non-provider." As a CAH is a "provider of services," CMS no longer allowed resident time training in CAHs to be counted by a hospital for IME and DGME as training in a non-provider site.

CMS indicates that the Affordable Care Act changes were intended to promote the training of residents at sites outside of the IPPS hospital setting—many of which provide access to care for patients in rural and underserved areas—and reduce burden on hospitals for counting those residents. Therefore, CMS believes that it is important to support residency training in rural and underserved areas, including residency training at CAHs. Effective for portions of cost reporting periods beginning October 1, 2019, CMS proposes that a hospital may include FTE residents training at a CAH in its FTE count provided it meets the requirements for including a resident training in a non-provider setting in its IME and DGME FTE counts.

The proposed rule indicates that CMS' policy is permissible because the statute does not explicitly define "non-provider" and the term "hospital" does not include, unless the context otherwise requires, a critical access hospital. CMS further notes that the statute defines a non-provider setting as one in which the primary activity is the care and treatment of patients. As a CAH is a facility primarily engaged in patient care, CMS believes that it has the flexibility within the current statutory language to consider a CAH as a "non-provider" setting for direct GME and IME payment purposes.

If this proposal is finalized, CMS will work closely with the Health Resources and Services Administration and the Federal Office of Rural Health Policy to communicate the increased regulatory flexibility to CAHs as well as existing residency programs and the options it affords for increasing rural residency training.

3. Teaching Hospital Closure: Application Process for Resident Slots

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency slots after closure of a hospital that trained residents in an approved medical residency program. CMS is notifying the public of the closure of Good Samaritan Hospital, located in Dayton, OH (CCN 360052):

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
360052	Good Samaritan Hospital	Dayton, OH	19380	July 23, 2018	62.60	62.03

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. Therefore, hospitals must submit an application form to the CMS Central Office **no later than July 22, 2019** to be eligible to receive slots from this closed hospital. 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 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 policies 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.

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 14 due to the closure of Good Samaritan Hospital in Dayton, Ohio. 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.

K. Rural Community Hospital Demonstration Program

1. Background

The Rural Community Hospital Demonstration program allows up to 30 rural community hospitals to receive reasonable cost payment for covered inpatient hospital services furnished to Medicare beneficiaries. The program has been in place since January 1, 2005 with a statutory expiration date that has been extended twice. The latest extension opened the program to newly participating hospitals. Expiration of the program for individual hospitals will vary based on the hospital's cost reporting period and when it began participating in the program but will generally last 5 years from when it was last extended or the hospital first began participating. By FY 2023, the program will have expired for all participants unless extended again by statute.

The statute requires CMS to make the demonstration program budget neutral by applying an adjustment to IPPS rates that affects all hospitals rather than demonstration program participants. CMS describes the budget neutrality calculation in detail. In summary, CMS compares reasonable cost payments to what IPPS payments would have been in the absence of the demonstration. IPPS rates are adjusted for the difference. Interim reasonable cost payments from as submitted cost reports are initially used and then later reconciled as cost reports become final.

2. FY 2020 Budget Neutrality Adjustment

CMS identifies 29 hospitals participating in the program in FY 2020. For three of these hospitals, the 5-year participation or extension period will end in FY 2020 so CMS will prorate the reasonable cost amounts for these hospitals for the portion of their cost reporting periods in the demonstration that are within FY 2020. CMS estimates that the program will cost $61,970,567 in FY 2020. CMS will subtract $14,932,060 from this amount for reconciled FY 2014 cost reports. The total budget neutrality adjustment will be based on $47,038,507 or a proposed adjustment to the IPPS standardized amounts of 0.99958 (-0.04 percent). CMS will update these figures for the final rule.

V. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2020. For FY 2019, CMS established a national capital Federal rate of $459.41. CMS proposes a national capital federal rate of $463.81 for FY 2020.

Update Factor:

For FY 2020, CMS proposes to increase the national capital Federal rate by 1.5 percent based on the capital input price index (CIPI) of 1.5 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 2018 reclassification and recalibration or forecast error correction.

Table 1

PROPOSED CMS FY 2020 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE	
Capital Input Price Index (FY 2014-based CPI)	1.5
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	1.5
Effect of FY 2018 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Proposed Update	1.5

Other Adjustments:

The geographic adjustment factor (GAF) is a function of the hospital wage index. As CMS is proposing changes to the hospital wage index, the proposed rule explains that CMS determined the MS-DRG/GAF adjustment in two steps. In the first step, CMS calculated the level of the MS-DRG/GAF adjustment required for annual changes to MS-DRGs, the wage data, geographic reclassification and the rural floor no longer including urban to rural hospital reclassifications in the calculation of the rural floor wage index. In the second step, CMS accounts for its proposed change to narrow wage index variation and cap any reduction in the wage index at 5 percent.

CMS estimates that step 1 of this process produces an adjustment of 0.9999 while step 2 produces an adjustment of 0.9977. Taken together, the total adjustment is 0.9976 (0.9999 X 0.9977). The proposed FY 2020 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 GAFs is 0.9976; this adjustment in FY 2019 was 0.9969.

For FY 2020, CMS is taking outlier reconciliation into account in determining the outlier adjustment (see section I. D. for a full explanation of CMS' methodology). CMS estimates that capital outlier payments will be 5.39 percent of total capital payments. Taking into account outlier reconciliation, CMS is subtracting 0.05 percentage points for amounts refunded to hospitals. This makes capital outlier payments 5.34 percent of total capital payments. Therefore, the proposed FY 2020 outlier adjustment factor is 0.9466 (-5.34 percent), compared to 0.9494 in FY 2019. The net change is -0.29 percent (0.9466/0.9494). Thus, the outlier adjustment decreases the proposed FY 2020 capital federal rate by 0.29 percent.

Final Calculation:

The proposed rule includes the following chart to show how each of the proposed factors and adjustments affect the computation of the proposed for FY 2020 national capital Federal rate in comparison to the FY 2019 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2019 Capital Federal Rate and Proposed FY 2020 Capital Federal Rate

	FY 2019	Proposed FY 2020	Proposed Change	Percentage Change
Update Factor*	1.0140	1.0150	1.015	1.50
GAF/DRG Adjustment Factor*	0.9969	0.9976	0.9976	-0.24
Outlier Adjustment Factor**	0.9494	0.9466	0.9971	-0.29
Capital Federal Rate	$459.41	$463.81	1.0096	0.96

* 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 2019 to FY 2020 resulting from the application of the proposed 0.9976 GAF/DRG budget neutrality adjustment factor for FY 2020 is a net change of 0.9976 (or -0.24 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 0.9466/0.9494, or 0.9971 (or -0.29 percent).

Considering the update factor and the budget neutrality adjustments, CMS proposes a national capital Federal rate for FY 2020 equal to $463.81, representing a 0.96 percent increase over the FY 2019 rate of $459.41.

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

Most hospitals are paid under prospective payment systems. However, some hospitals continue to be paid based on reasonable costs subject to a per discharge limit updated annually under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. Hospitals that continue to be paid reasonable cost subject to a limit include 11 cancer hospitals, children's hospitals, and hospitals located in the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

The annual update to the TEFRA limit is based on based on IGI's 2017 fourth quarter forecast of the hospital market basket. CMS proposes to set a 3.2 percent rate-of-increase for FY 2020 to the annual per discharge limit for hospitals subject to the TEFRA methodology.

B. Request for Public Comments: Rate of Increase Ceiling for IPPS Excluded Hospitals.

As indicated above, TEFRA establishes a ceiling on the allowable rate of increase in hospital inpatient operating costs per discharge for IPPS excluded hospitals paid under the TEFRA methodology. If a hospital's inpatient operating costs exceed its ceiling, hospitals paid under TEFRA may request a payment adjustment for costs above the ceiling. An adjustment is intended to account for certain factors such as a significant change in services or patient population. Section 3004 of the Provider Reimbursement Manual (PRM) provides extensive examples of noncomparability of cost between cost reporting periods due to direct patient care changes such as increases in average length of stay, changes in the intensity of care, as well as additions/deletions of services. These examples were developed many years ago to assist providers in filing an adjustment request and to provide guidance to MACs when reviewing and evaluating a provider's adjustment request. The delivery of direct patient care services, as well as the cost report form and instructions, have evolved since the guidance and examples in section 3004 of the PRM were originally developed. For this reason, CMS is soliciting public comments, suggestions, and recommendations regarding the methodologies and examples provided in section 3004 of the PRM.

A hospital paid under TEFRA may also request a new base year (a permanent revised TEFRA target amount per discharge for determining the ceiling). A new base year is meant to account for substantial and permanent changes in furnishing patient care services since the base period, and, as such, the requirements are stringent. Historically, CMS has rarely authorized assignment of a new base year period because the adjustment mechanism is meant to address most situations where there is distortion in costs between the base year and the current period. Providers seldom meet the criteria for a new base period.

CMS is requesting public comments, suggestions, and recommendations on the possible criteria and circumstances needed to warrant a new base period, and, importantly, the documentation that would be required to qualify, particularly relative to and differentiating it from an adjustment. In addition, CMS invites comments, suggestions, and recommendations for regulatory and other policy changes to the TEFRA adjustment process. CMS is interested in feedback on whether or not there should be standardization in the supporting documentation (such as electronic workbooks) as part of TEFRA adjustment requests and, if so, CMS invites commenters to provide specific examples.

C. Critical Access Hospitals

<u>Proposed Change to CAH Payment for Ambulance Services</u>

A CAH can be paid 101 percent of reasonable costs for ambulance services if it is the only provider or supplier of ambulance services that is located within a 35-mile drive of the CAH. The CAH can be paid 101 percent of reasonable costs for ambulance services even if its ambulance company is more than a 35-mile drive from the CAH as long as it is the closest provider or supplier of ambulance services to the CAH. Otherwise, the CAH is paid for its ambulance services using the Ambulance Fee Schedule (AFS).

CMS has been advised of a situation where a non-CAH owned ambulance service is within a 35-mile drive of the CAH, but is not legally authorized to transport individuals to or from the CAH because it is in another state. Under this scenario, the CAH is paid for its ambulance services using the AFS even though there is no ambulance other than the CAH's own available to transport patients. CMS does not believe this result is consistent with the intent of the CAH program to provide access to care to individuals living in remote and rural areas, particularly in emergency situations and when individuals have no other mode of transportation due to hazardous traveling conditions.

Therefore, CMS is proposing to exclude consideration of ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals either to or from the CAH in applying the 35-mile distance criterion. CMS believes its proposed policy is reasonable under the statute because it retains the requirement that the CAH be the only provider or supplier of ambulance services within (or beyond a 35-mile drive of the CAH as long as there is no closer ambulance service) that is available to transport individuals either to or from the CAH.

The Frontier Community Health Integration Project (FCHIP) Demonstration[33]

The FCHIP Demonstration is designed to develop and test new models of care by CAHs by permitting enhanced reimbursement for telemedicine, nursing facility, ambulance, and home health services. Ten CAHs in Montana, Nevada, and North Dakota participate in the 3-year 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. According to the proposed rule, "this policy will likely have no impact for any national payment system for FY 2020."

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

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

A. Background

Since FY 2016, LTCHs have been paid under a dual-rate payment structure. An LTCH case is either paid at the "LTCH PPS standard federal payment" when the criteria for site neutral payment rate exclusion are met or a "site neutral payment rate" 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 2020:

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).
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 be paid the LTCH PPS standard federal payment, 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. For FY 2016 and FY 2017, the site neutral payment rate was a blend of the LTCH PPS standard federal rate and the IPPS comparable amount. Section 51005 of the BBA 2018 extended the transitional blended payment rate (50 percent LTCH standard federal payment and 50 percent IPPS comparable amount) for site neutral payment cases for an additional 2 years. The FY 2019 IPPS proposed rule made conforming changes to the regulations to implement the extended transitional blended payment.

Summary of Proposed Changes to LTCH PPS Rates for FY 2020*	
Standard Federal Rate, FY 2020	$41,558.68
Proposed Rule Update factors	
Update as required by Section 1886(m)(3)(C) of the Act	+2.7%
Penalty for hospitals not reporting quality data	-2.0%
Net update, LTCHs reporting quality data	+2.7% (1.027)
Net update LTCHs not reporting quality data	0.7% (1.007)
Proposed Rule Adjustments	
Proposed average wage index budget neutrality adjustment	1.0064747
Proposed budget neutrality adjustment to eliminate the 25-percent threshold policy	0.999856
Proposed Standard Federal Rate, FY 2020	
LTCHs reporting quality data ($41,558.68∗1.027∗1.0064747*0.999856)	$42,950.91
LTCHs not reporting quality data ($41,558.68*1.007*1.0064747*0.999856)	$42,114.47
Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$29,997

Summary of Proposed Changes to LTCH PPS Rates for FY 2020*	
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$26,994
Impact of Proposed Policy Changes on LTCH Payments in 2020	
Total estimated impact	0.9% ($37 million)
LTCH standard federal payment rate cases (71% of LTCH cases)	+2.3% (+$79 million)
Site neutral payment rate cases (29% of LTCH cases)**	-4.9% (-$41 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 2020" (see page 1,784 in display copy). Table IV does not include the impact of site neutral payment rate cases. ** LTCH site neutral payment rate cases are paid a rate that is based on the lower of the IPPS comparable per diem amount or 100 percent of the estimated cost of the case.	

B. LTCH PPS MS-DRGs and Relative Weights

Background

Similar to FY 2019, the annual recalibration of the MS-LTC-DRG relative weights for FY 2020 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.

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 2020 since the two systems share an identical base. Proposed MS-DRG changes are described elsewhere in this summary and details can be found in section II.F. of the preamble.

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

In developing the FY 2020 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 (described in more detail below).

Relative Weights Source Data

FY 2020 proposed relative weights are derived from the December 2018 update of the FY 2018 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 37 of the GROUPER to calculate the FY 2020 MS-LTC-DRG proposed relative weights.

Hospital-Specific Relative-Value Methodology (HSRV)

CMS proposes to continue to use its HSRV methodology in FY 2020, unchanged from FY 2019, 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 182 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 259 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 320 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 an 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 2020, CMS is using the FY 2015 relative weights for these MS-LTC-DRGs (as was done for FYs 2016- 2019).

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 2020 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 2020 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 (1.271 proposed for FY 2020). Second, a budget neutrality factor is applied to each normalized relative weight (0.9971599 proposed for FY 2020).

Extensive discussion of the entire 7-step process to determine MS-LTC-DRG relative weights is provided in the proposed rule (pages 1,076 to 1,094 of the display copy).

C. Payment Adjustment for LTCHs with Site Neutral Payments above a Threshold Percent

An LTCH's "discharge payment percentage" is the ratio of its Medicare discharges paid at the LTCH PPS standard federal payment rate to the total number of Medicare FFS discharges paid under the LTCH PPS during the cost reporting period. CMS is required inform an LTCH if its discharge payment percentage is not at least 50 percent beginning with FY 2016 cost reporting periods. For cost reporting periods beginning on or after October 1, 2019, CMS must notify the LTCH it will be paid at IPPS comparable amounts for all discharges in subsequent years subject to the LTCH's compliance with a reinstatement process.

CMS implemented this requirement in the FY 2016 IPPS/LTCH PPS final rule and established sub-regulatory policies and timeframes by which it calculates and informs LTCHs of their discharge payment percentage. In the FY 2020 IPPS proposed rule, CMS provides guidance for how it would implement the requirement to pay the IPPS comparable amount when the LTCH's discharge payment percentage exceeds 50 percent.

CMS would determine the discharge payment percentage six months after the end of the LTCH's cost reporting period. If the discharge payment percentage is less than 50 percent, CMS would notify the LTCH it will be paid for all of its discharges at IPPS comparable amounts in its next cost reporting period. For example, CMS would calculate the discharge payment percentage for a cost reporting period beginning on January 1, 2020 and ending on December 31, 2020 in July, 2021. If the discharge payment percentage is less than 50 percent, CMS would inform the LTCH it will be paid at IPPS comparable amounts for all of its discharges beginning with its January 1,

2022 cost reporting period. CMS proposes to codify implementation of this policy in new § 412.522(d)(3).

The statute also requires that CMS establish a reinstatement process. CMS proposes that an LTCH can be reinstated to receiving payment at the LTCH standard federal rate when the discharge payment percentage goes back above 50 percent for a subsequent cost reporting period. Following the above example, if the hospital's discharge payment percentage exceeded 50 percent in its January 1, 2021 to December 31, 2021 cost reporting period, the LTCH would be reinstated to receiving payments based on the LTCH standard federal rates and site neutral rates for its January 1, 2023 to December 31, 2023 cost reporting period. CMS proposes to codify the reinstatement process for LTCHs in new § 412.522(d)(5).

Although CMS believes the reinstatement process proposed would satisfy the statutory requirement without further modification, CMS is concerned that hospitals may be able to manipulate discharges or delay billing in such a way as to artificially inflate their discharge payment percentage if it did not create a special reinstatement process that is probationary. For this reason, CMS is also a proposing a special probationary cure process to recognize that there may be unusual circumstances that result in a discharge payment percentage that may not be fully reflective of an LTCH's typical mix of site neutral and LTCH PPS standard Federal payment rate discharges (for example, patients require a shorter period of ventilation than was expected on admission). Under this process, CMS is proposing a probationary cure period of six months. During the cure period, payment based on the IPPS comparable amount would be delayed for six months if for at least 5 consecutive months of the 6-month period immediately preceding the beginning of the cost reporting period during which the adjustment would apply, the discharge payment percentage is at least 50 percent. Under such circumstances, the LTCH would not ultimately be subject to the payment adjustment for the cost reporting period during which the adjustment would apply—provided the discharge payment percentage for that cost reporting period is at least 50 percent. If the discharge payment percentage for that cost reporting period is not at least 50 percent, the adjustment will be applied to the cost reporting period at settlement.

Following the above example, an LTCH would be informed of a discharge payment percentage of less than 50 percent for its calendar year 2020 cost reporting period in July of 2021. The probationary cure period would be July 1, 2021 through December 31, 2021. If the LTCH maintained a discharge payment percentage of 50 percent for 5 consecutive months between July 1, 2021 and December 31, 2021, application of the payment adjustment would be delayed for its 2022 cost reporting period. However, if the discharge payment percentage for the 2022 cost reporting period is not at least 50 percent, the payment adjustment delay would be lifted, and the 2022 cost report settlement would be made using an IPPS-comparable amount for all discharges.

CMS proposes to codify the special probationary reinstatement process at § 412.522(d)(6). It further expects to issue sub-regulatory guidance to describe the specific procedures for implementing the proposed probationary cure period if the policy is finalized. CMS specifically invites public comments on whether the probationary reinstatement process should mirror the existing process used by LTCHs for the greater than 25-day average length-of-stay requirements.

The proposed rule notes that the IPPS-comparable amount is the IPPS-comparable *per diem* amount also used to calculate payments under the SSO policy and site neutral payment rate payments.

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 2019, site neutral payment rate cases are proposed to be paid in FY 2020 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 2.7 percent. The update is equal to the 2013-based LTCH market basket of 3.2 percent less 0.5 percentage points (PP) for multifactor productivity. For LTCHs failing to submit data to the LTCH Quality Reporting Program (QRP), the annual update would be further reduced by 2.0 percentage points. The proposed LTCH update for FY 2020 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	3.2%	3.2%
Multifactor Productivity	-0.5 PP	-0.5 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	2.7%	0.70%

Area Wage Levels and Wage-Index

CMS sets out a proposed labor-related share of 66.0 percent for FY 2020 based on IGI's fourth quarter 2018 forecast of the 2013-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (61.9%) and capital costs (4.1%). 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 1.0064747.

4. Proposed LTCH Standard Federal Payment Rate Calculation

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

FY 2020 payment rate = $41,558.68 (FY 2019 payment rate) * 1.027 (statutory update factor) * 1.0064747 (area wage budget neutrality factor) * 0.999856 (25% threshold budget neutrality factor) = $42,950.91

For LTCHs not reporting data to the LTCH QRP: FY 2020 payment rate = $41,558.68 (FY 2019 payment rate) * 1.007 (statutory update factor less quality adjustment) * 1.0064747 (area wage budget neutrality factor) * 0.999856 (25% threshold budget neutrality factor) = $42,114.47

5. Elimination of the 25 percent Rule

In the FY 2019 IPPS rule, CMS adopted a policy to eliminate the 25 percent rule. This rule would have paid LTCHs at an IPPS comparable amount for all discharges not meeting the criteria to be paid the LTCH standard rate above 25 percent of the LTCH's total discharges. CMS adopted a policy to make elimination of this policy budget neutral through two temporary one-time adjustments to the LTCH standardized amount: 0.990884 for FY 2019 and 0.990741 for FY 2020 and one permanent one-time adjustment to the LTCH standardized amount of 0.991249 in FY 2021. A one-time temporary adjustment means the adjustment is removed for the following year while a one-time permanent adjustment stays on the rate and is not removed. For FY 2020, the net of removing the 0.990884 adjustment and adding the 0.990741 adjustment is 0.999856.

6. 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. Shown below are the FY 2020 COLAs.

Proposed Cost-of-Living Adjustment Factors for Alaska and Hawaii Under the LTCH PPS for FY 2020	
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

7. 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 HCOs. 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 $29,997 which CMS estimates will result in 7.9795 of LTCH standard federal payment rate cases being paid as HCOs. 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 2020 fixed-loss amount of $29,997 that applies to LTCH standard federal payment rate cases is significantly higher than the FY 2018 fixed-loss amount of $27,121. CMS states that the current FY 2019 HCO threshold of $27,121 results in estimated HCO payments for LTCH PPS standard Federal payment rate cases that exceed the 7.975 percent target by 0.265 percentage points. CMS believes this increase is largely attributable to an increase in the Medicare allowable charges in addition to updates to CCRs from the March to December 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 2020, CMS proposes a fixed-loss amount for site neutral payment rate cases of $26,994.

CMS also proposes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2020. Consistent with the policy adopted in FY 2019, 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.

8. 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 2020, the DSH/uncompensated care amount equals 75.36 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. Impact of Payment Rate and Policy Changes to LTCH PPS Payments

CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the payment rate and policy changes, for all LTCHs from FY 2019 to FY 2020, will result in an increase of 0.9 percent or $37 million in aggregate payments (from $4.274 billion to $4.311 billion). This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard federal payment rate cases of approximately 2.3 percent ($79 million) and the projected decrease in payments to site neutral payment rate cases of approximately 4.9 percent (-$41 million estimated). CMS modeling assumes that approximately 71 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 29 percent of LTCH cases would be paid the site neutral payment rate (calculated using FY 2018 LTCH claims data). The increase in LTCH PPS standard federal payment rates cases results from the 2.7 percent update and a -0.1 percent one-time permanent budget neutrality adjustment for the proposed elimination of the 25-percent threshold policy as well as estimated payments for SSO cases, a portion of which are not affected by the annual update to the LTCH PPS standard federal payment rate.

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 2020" 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 2020 relative to FY 2019 of approximately $79 million or 2.3 percent. CMS reports that regional differences in impacts are largely due to updates to the wage index.

The impacts below do not account for the potential that an LTCH's discharge payment percentage will exceed 50 percent and it will be paid at an IPPS comparable amount in a subsequent cost reporting period. As this policy will not affect any LTCHs until FY 2022, the policy will not have any impact in FY 2020. CMS estimates the policy will reduce Medicare spending under the LTCH PPS by $60 million in FY 2022. The proposed rule details how CMS came up with this estimate on pages 1,775 to 1,776 of the display copy of the rule.

Summary of Impact of Proposed Changes to LTCH PPS for Standard Federal Payment Rate Cases for FY 2020*		
LTCH Classification	**Number of LTCHs**	**Estimated percent change in payments per discharge**
All LTCH providers	384	2.3%
By Location:		
Rural	19	2.2%
Urban	365	2.3%
By Ownership Type:		
Voluntary	75	2.5%
Proprietary	295	2.3%
Government	14	2.5%
By Region		
New England	10	2.2%
Middle Atlantic	25	2.2%
South Atlantic	63	2.5%
East North Central	25	2.4%
East South Central	64	2.2%
West North Central	32	2.3%
West South Central	111	2.3%
Mountain	30	2.2%
Pacific	24	2.3%
*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 1,784 of display copy).		

Tables

The complete set of tables providing detail on the proposed LTCH PPS for FY 2020 is accessible at:

https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/LTCHPPS-Regulations-and-Notices-Items/LTCH-PPS-CMS-1716-P.html?DLPage=1&DLEntries=10&DLSort=3&DLSortDir=descending

The information at that link comprises the following:

Table 11: MS-LTC-DRGs, relative weights, geometric average length of stay, SSO threshold, and IPPS comparable threshold for FY 2020,
Table 12A: LTCH PPS Wage Index for Urban Areas for FY 2020,
Table 12B: LTCH PPS Wage Index for Rural Areas for FY 2020,
Table 8C: LTCH PPS statewide Average Cost-to-Charge Ratios for FY 2020,
Table 13A: Composition of low-volume quintiles for MS-LTC-DRGs for FY 2020,
Table 13B: No volume MS-LTC-DRG crosswalk for FY 2020, and the
LTCH PPS FY 2020 Proposed Impact File

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the rule, 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, changes are proposed to the Medicare and Medicaid Promoting Interoperability Programs.

A. Hospital Inpatient Quality Reporting (IQR) Program

CMS proposes three new IQR Program measures all of which involve electronically reported data submission. Two new opioid-related electronic clinical quality measures (eCQMs) would be added to the program beginning with the FY 2021 reporting period/FY 2023 payment determination. In addition, the Hybrid Hospital-Wide Readmission measure which had a 6-month voluntary reporting period in 2018 would be expanded with two additional 1-year voluntary data collection periods followed by mandatory reporting to begin with the FY 2026 payment determination. The existing claims-based hospital-wide readmission measure would be removed at that time. All other current IQR Program measures would be retained. A table at the end of this section shows previous and proposed IQR Program measures for FYs 2019 through 2023.

1. Proposed New Opioid-Related eCQMs

Two new eCQMs related to opioids would be added to the IQR Program measure set beginning with the FY 2023 payment determination; reporting would begin in 2021. CMS believes these measures would address the Meaningful Measures priorities regarding prevention and treatment of chronic disease and reducing harm caused in the delivery of care. These two eCQMs are also proposed for addition to the Medicare and Medicaid Promoting Interoperability Program, as discussed in VIII.D.6 below.

For each measure, CMS discusses the measure calculation; related background and clinical literature; history of stakeholder participation in measure development and measure testing; and status with the National Quality Forum and Measure Applications Partnership. Both measures are eCQMs for which data to determine performance would be collected entirely through electronic health records.

- Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e). This measure calculates the proportion of patients age 18 and older who are prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter (inpatient, observation stays, emergency department). Exclusions include patients with an active diagnosis of cancer or order for palliative care during the encounter. These exclusions align with the *2016 CDC Guidelines for Prescribing Opioids for Chronic Pain*. CMS does not expect the measure rate to be zero, but states the goal of the measure is to help systems identify and monitor patients at risk. Testing of the measure found the measure to be feasible, valid and reliable, with agreement between electronically- and manually-extracted data elements. Concurrent prescribing rates of 18.2 percent for inpatients and 6.1 percent in ED

settings are consistent with rates in the clinical literature. The measure is NQF endorsed. Refinements were made from previous specifications to address some concerns raised by the MAP. One exception regards the potential exclusion of patients for whom concurrent prescribing may be medically necessary. CMS explored the possibility of single-condition exclusions and found that there were few instances and no evidence-based guidelines to support such an exclusion. For the measure specifications CMS refers readers to the NQF fall 2017 final technical report on patient safety issued in July 2018 available at file:///C:/Users/lisa/Downloads/patient_safety_final_report_fall_2017.pdf.

Beginning with the 2022 reporting period/FY 2024 payment determination, CMS proposes that all hospitals participating in the IQR Program be required to report this eCQM. That is, for that year, hospitals would have to report this eCQM and 3 other eCQMs of their choosing. (See VIII.A.6 for more on proposed eCQM data submission requirements.)

- Hospital Harm—Opioid Related Adverse Events eCQM. This measure assesses the proportion of an acute care hospital's patients with an opioid-related adverse event during an admission as indicated by the administration of naloxone. The denominator is the number of patients age 18 or older who were discharged during the measurement period and had an admission that was initiated in the ED or in observational status. The numerator is the number of patients who received naloxone outside the operating room after 24 hours from hospital arrival OR during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to naloxone administration. This construct is intended to exclude patients who receive naloxone within 24 hours of arrival due to an opioid overdose that occurred in the community prior to hospital arrival. CMS expects this measure will capture rare events. The measure was submitted for NQF endorsement in spring 2019; refinements were made to previous specifications and further testing conducted in response to concerns raised by the MAP. Testing results and measure specifications are available at https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/measure-methodology.html. In light of earlier stakeholder concerns, **comments are specifically sought on the potential for this measure to disincentivize the appropriate use of naloxone in the hospital setting or withholding opioids when they are medically necessary in patients requiring palliative care or at end of life.**

2. Adoption of Hybrid Hospital-Wide Readmission Measure (NQF #2879)

The NQF-endorsed Hybrid Hospital-Wide Readmission (HWR) measure of a hospital's risk standardized unplanned readmission rate is identical to the claims-only HWR measure currently used in the IQR Program, except that in addition to the claims data used to measure readmissions and adjust for patient risk, the hybrid version of the measure also uses a set of core clinical data elements drawn from hospital electronic health records (EHRs) for purposes of patient risk adjustment and hospital service adjustment. The 13 data elements include lab test results and vital signs. Measure specifications and other information on the measure can be found on the QualityNet.org website at

https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228776337082.

In the FY 2018 IPPS/LTCH final rule CMS adopted a 6-month limited voluntary reporting period for the EHR-derived data elements used in the Hybrid Hospital-Wide Readmission measure. About 80 hospitals submitted the EHR data and will receive a confidential hospital-specific report in early summer 2019 that includes Hybrid HWR measure results of merging the submitted electronic data with claims data for the same set of index admissions.

In this rule, CMS proposes a step-wise movement to making this Hybrid HWR measure mandatory and using it to replace the existing claims-based HWR measure. Two new expanded voluntary data collection periods would be established: July 1, 2021 through June 30, 2022 and July 1, 2022 through June 30, 2023. The hybrid measure would become mandatory for FY 2026 payment determination, with the first year of mandatory reporting running from July 1, 2023 through June 30, 2024.

To report this measure, hospitals would use Quality Reporting Data Architecture (QRDA) Category I files to report the core clinical data elements for each Medicare FFS beneficiary who is 65 years and older during the annual measurement period. (QRDA I is the current reporting standard used for eCQMs in the IQR Program.) In addition, hospitals would be required to submit six linking variables that would allow CMS to merge the EHR core clinical data elements with claims data for the patient: CMS Certification Number; Health Insurance Claims Number or Medicare Beneficiary Identifier; Date of birth; Sex; Admission date, and Discharge date.

For CMS to reliably calculate the Hybrid HWR measure results, the hospital would have to report the core clinical data element vital signs for at least 90 percent of the Medicare FFS aged beneficiary discharges and the laboratory test results for at least 90 percent of non-surgical patients. (Lab results are not used in risk adjustment of the surgical cohort.)

CMS notes that the six linking variables required for linking EHR and claims data should be submitted for 100 percent of discharges in the measurement period, but hospitals would meet Hospital IQR Program requirements if they submit linking variables on 95 percent or more of discharges with a Medicare FFS claim for the same hospitalization during the measurement period.

During the voluntary data collection periods hospitals who fail to meet these requirements would not be penalized under the IQR Program, but once the Hybrid HWR measure becomes mandatory, failing to meet the data submission requirements would result in the hospital receiving the IQR Program update penalty.

Initial electronic specifications for the proposed voluntary data collection period would be provided in spring of 2020 as part of the 2021 annual update issued by the Electronic Clinical Quality Improvement (eCQI) Resource Center. Confidential feedback reports would be provided for the two proposed new voluntary reporting periods. The first would be delivered to hospitals

in the spring of 2023. No public reporting of the Hybrid HWR measure would occur during the voluntary reporting periods.

Public reporting on the *Hospital Compare* website of hospital performance on the Hybrid HWR measure would begin with the data collected for the first mandatory data collection period (July 1, 2023-June 30, 2024).

3. Removal of Claims-based Hospital-Wide Readmission Measure

Contingent on adoption of the Hybrid HWR measure effective with the FY 2026 payment determination, CMS proposes to remove from the IQR Program the claims-based HWR measure at that time. The proposal cites removal factor 3, reflecting a different measure that is more proximal in time to desired patient outcomes, because the measurement of the core clinical data elements starts with the beginning of the applicable inpatient stay, whereas the risk factors used for the current claims-based measure look at the year preceding admission.

4. Potential Future Hospital IQR Program Measures

CMS discusses in detail three potential future IQR Program measures, all of which are eCQMs also under consideration for future addition to the Promoting Interoperability Program. **CMS specifically requests comment on any potential unintended consequences that might result from future adoption of each of these measures.** In each case CMS reviews the relevant clinical literature supporting the need for the measure.

- Hospital Harm – Severe Hypoglycemia eCQM measures the proportion of patients who experienced a severe hypoglycemic event (low glucose test result of <40mg/dL) within 24 hours of the administration of an antihyperglycemic agent. This indicates harm to a patient and CMS discusses the clinical issues and gaps in measurement for how often these events occur in the inpatient setting. The proposed measure is a respecification of an NQF-endorsed measure. The new version has received support from the MAP conditioned on NQF review and re-endorsement. The measure was submitted to the NQF for review in the spring of 2019.
- Hospital Harm – Pressure Injury eCQM measures the rate at which new hospital-acquired pressure injuries occur during an acute care hospitalization. The numerator is the number of admissions where a patient has a newly-developed stage 2, 3 or 4 pressure injury, a deep tissue pressure injury, or an unstageable pressure injury that was not documented as present in the first 24 hours of hospital arrival. The denominator is all patients age 18 and older discharged during the measurement period. The MAP had several recommendations for modifying this measure which CMS says will be considered during the NQF review of the measure which is scheduled for June 2019.
- Cesarean Birth (PC-02) eCQM (NQF #0471e) assesses the rate of nulliparous women (those who have never given birth) with a term singleton baby in a vertex position delivered by cesarean birth. The Joint Commission is the measure steward and maintains the measure specifications. The MAP supported the measure conditional on NQF review and endorsement. `

5. Confidential Reporting of Stratified Data for Hospital Quality Measures

Confidential hospital-specific reports containing the results of the Pneumonia Readmission measure using two disparity methods were provided to hospitals in August 2018. The two methods are a within-hospital disparity method that compares readmission rates for dual eligibles and other beneficiaries within a hospital, and a dual eligible outcome measure which compares performance in care for dual eligibles across hospitals. CMS hosted a National Provider Call and used other methods to help hospitals understand this information. Updates of these data will be provided in the spring of 2019.

In addition, CMS plans to expand these reports to include five additional measures in the spring of 2020: AMI readmission measure; CABG readmission measure; COPD readmission measure; heart failure readmission measure; and THA/TKA readmission measure. **Comments are sought on CMS' plan to expand the disparity methods to five additional measures.** In the future, CMS will include hospitals' disparity results in the regular annual confidential hospital-specific reports on claims-based measures that are made available to hospitals each spring for download through the QualityNet security portal. CMS has not yet determined future plans for public reporting of the stratified data and intends to continue to engage with hospitals and other stakeholders on these issues.

6. Form, Manner and Timing of Quality Data Submission

CMS reviews procedural and data submission requirements for the Hospital IQR Program; no changes are proposed to most of these policies which involve procedural requirements, data submission for chart-abstracted measures, data submission deadlines, sampling and case thresholds, HCAHPS administration and submission requirements, data validation, data accuracy and completeness acknowledgement, public display of measures on *Hospital Compare*, reconsideration and appeals, and the extraordinary circumstances exception policy.

The proposed rule would establish eCQM reporting and submission requirements for the FY 2022 through FY 2024 payment determinations (2020 through 2022 reporting periods). For the FY 2022 and 2023 payment determinations, CMS proposes to continue to require that hospitals report one self-selected calendar quarter of data for four self-selected eCQMs. Beginning with the FY 2024 payment determination (2022 reporting period) this requirement would change. All hospitals would be required to report one self-selected calendar quarter of data for the proposed Safe Use of Opioids Concurrent Prescribing eCQM plus three additional self-selected eCQMs. CMS said it considered allowing hospitals to choose one of the two new proposed opioid measures, but that approach would be more complicated, and it believes that the concurrent prescribing measure is more closely related to combatting the current opioid epidemic.

CMS proposes to continue for the FY 2022 payment determination (2020 reporting period) and subsequent years the requirement that EHRs be certified to all available eCQMs used in the IQR Program. CMS believes this requirement supports hospital flexibility in choice of eCQMs and promotes health information technology (IT) vendor testing all available eCQMs. No changes

are made to previously adopted policies regarding use of the 2015 Edition Certification Criteria, eCQM file format requirements, and submission deadlines for eCQM data.

If the proposed voluntary and then mandatory reporting of the Hybrid HWR measure is finalized, updated implementation guidance, schematrons, and sample files would be made available on the eCQI Resource Center website. CMS proposes to apply the same zero-denominator declaration and case threshold exemption policies to hybrid measure reporting as apply to eCQM reporting.

If a hospital's EHR is capable of reporting hybrid measure data, but the hospital does not have patients that meet the measure's denominator criteria the hospital may submit a zero in the denominator and that would count as a successful submission for the hybrid measure. Similarly, hospitals that have five or fewer inpatient discharges per quarter or twenty or fewer inpatient discharges per year as defined by a hybrid measure's denominator population, would be exempted from reporting on that hybrid measure.

The deadline for submission of the Hybrid HWR core clinical data elements and linking variables would be three months following the end of the applicable reporting period. For example, for the first voluntary reporting period (July 1, 2021 through June 30, 2022) the deadline for submitting the core clinical data would be September 30, 2022.

8. Impact Analysis

In the Regulatory Impact Analysis section of the proposed rule, CMS estimates that for FY 2020 39 hospitals are estimated to not receive the full market basket rate of increase because they failed the IQR Program quality data submission process or chose not to participate in the program, but are meaningful users under the Medicare Promoting Interoperability Program. These hospitals would be subject to a payment reduction of 0.8 percentage points from the update factor they would otherwise receive. Another 32 hospitals are estimated to receive a combined payment reduction of 3.2 percentage points because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program.

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure *Proposed Measures in Italics*					
	2019	**2020**	**2021**	**2022**	**2023**
Chart-Abstracted Process of Care Measures					
STK-4 Thrombolytic therapy for acute ischemic stroke	Removed				
VTE-5 VTE discharge instructions	Removed				
VTE-6 Incidence of potentially preventable VTE	X	X	Removed		
Severe sepsis and septic shock: management bundle (NQF #500)	X	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	Removed		

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure *Proposed Measures in Italics*					
	2019	**2020**	**2021**	**2022**	**2023**
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	Removed	
IMM-2 Immunization for influenza (NQF #1659)	X	X	Removed		
PC-01 Elective delivery < 39 weeks gestation (NQF#0469)	X	X	X	X	X
Electronic Clinical Quality Measures					
AMI-8a Timing of Receipt of Primary Percutaneous Coronary Intervention (PCI) (NQF #0163) STK-2 Antithrombotic therapy for ischemic stroke (NQF #0435) STK-3 Anticoagulation therapy for Afib/flutter (NQF #0436) STK-5 Antithrombotic therapy by end of hospital day 2 (NQF #0438) STK-6 Discharged on statin (NQF #0439) STK-8 Stroke education STK-10 Assessed for rehabilitation services (NQF #0441) VTE-1 VTE prophylaxis (NQF #0371) VTE-2 ICU VTE prophylaxis (NQF #0372) ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital (NQF#0495) ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status (NQF #0497) PC-01 Elective delivery < 39 completed weeks gestation (NQF #0469) PC-05 Exclusive breast milk feeding (NQF #0480) Healthy term newborn EDHI-1a Hearing screening prior to hospital discharge CAC- 3 Children's asthma care – 3	Report 4 of the following 15 eCQMs: AMI-8a CAC-3 ED-1 ED-2 EHDI-1a PC-01 PC-05 STK-02 STK-03 STK-05 STK-06 STK-08 STK-10 VTE-1 VTE-2		Report 4 of the following 8 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2	Report 4 of the following *10* eCQMs ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2 ***Opioid-related Adverse Events*** ***Safe use of Opioids****
Healthcare-Associated Infection Measures					
Central Line Associated Bloodstream Infection (CLABSI)	X	X	X	Removed	
Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy	X	X	X	Removed	
Catheter-Associated Urinary Tract Infection (CAUTI)	X	X	X	Removed	
MRSA Bacteremia	X	X	X	Removed	
Clostridium Difficile (C. Diff)	X	X	X	Removed	
Healthcare Personnel Influenza Vaccination	X	X	X	X	X
Claims-Based Measures					
Mortality					
AMI 30-day mortality rate	X	Removed			

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure *Proposed Measures in Italics*					
	2019	**2020**	**2021**	**2022**	**2023**
Heart Failure (HF) 30-day mortality rate	X	Removed			
Pneumonia 30-day mortality rate	X	X	Removed		
Stroke 30-day mortality rate	X	X	X	X	X
COPD 30-day mortality rate	X	X	Removed		
CABG 30-day mortality rate	X	X	X	Remove	
Readmission/ Coordination of Care					
AMI 30-day risk standardized readmission	X	Removed			
Heart Failure 30-day risk standardized readmission	X	Removed			
Pneumonia 30-day risk standardized readmission	X	Removed			
TKA/THA 30-day risk standardized readmission	X	Removed			
Hospital-wide all-cause unplanned readmission	X	X	X	X	X**
Stroke 30-day risk standardized readmission	X	Removed			
COPD 30-day risk standardized readmission	X	Removed			
CABG 30-day risk standardized readmission	X	Removed			
Hybrid (claims+EHR) hospital-wide readmission		Voluntary			
Excess days in acute care after hospitalization for AMI	X	X	X	X	X
Excess days in acute care after hospitalization for HF	X	X	X	X	X
Excess days in acute care after hospitalization for PN	X	X	X	X	X
Patient Safety					
PSI-90 Patient safety composite (NQF #0531)	X	Removed			
PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351)	X	X	X	X	X
THA/TKA complications	X	X	X	X	Removed
Efficiency/Payment					
Medicare Spending per Beneficiary	X	Removed			
AMI payment per 30-day episode of care	X	X	X	X	X
Heart Failure payment per 30-day episode of care	X	X	X	X	X
Pneumonia payment per 30-day episode of care	X	X	X	X	X
THA/TKA payment per 30-day episode of care	X	X	X	X	X
Kidney/UTI clinical episode-based payment	X	Removed			
Cellulitis clinical episode-based payment	X	Removed			
Gastrointestinal hemorrhage clinical episode-based payment	X	Removed			
Aortic Aneurysm Procedure clinical episode-based payment	X	Removed			
Cholecystectomy/Common Duct Exploration episode-based payment	X	Removed			
Spinal Fusion clinical episode-based payment	X	Removed			
Patient Experience of Care					
HCAHPS survey + 3-item Care Transition Measure	X	X	X	X	X
Structural Measures					

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure *Proposed Measures in Italics*					
	2019	**2020**	**2021**	**2022**	**2023**
Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	Removed				
Participation in a Systematic Clinical Database Registry for General Surgery	Removed				
Safe Surgery Checklist Use	X	Removed			
Hospital Survey on Patient Safety Culture	X	Removed			
*As proposed, beginning with the FY 2024 payment determination, hospitals would be required to report this eCQM and 3 other self-selected eCQMs **As proposed, beginning with the FY 2026 payment determination, this measure would be replaced by the Hybrid HWR measure.					

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 removingmeasures and the procedures for hospital participation in the program. Currently, there are 11 PPS-exempt cancer hospitals.[34] No policy has been adopted on the consequences if a PCH fails to meet the quality reporting requirements; CMS has previously 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 15 measures were previously adopted for FY 2021. Technical specifications for PCHQR Program measures are available on the QualityNet.org website.

In this rule, CMS proposes to: (1) remove the pain management questions from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care measure effective October 1, 2019; (2) remove the measure External Beam Radiotherapy for Bone Metastases; and (3) add the measure Surgical Treatment Complications for Localized Prostate Cancer.

Removal of Pain Management Questions. The 3 HCAHPS pain management questions[35] proposed for removal have previously been removed from the HCAHPS survey for purposes of the IQR Program and the Inpatient VBP Program. The rationale for removal is concern among stakeholders that the questions might create incentives for providers to prescribe more opioids in order to achieve higher scores on the pain management dimension. CMS removed the questions out of an abundance of caution, in light of the national opioid epidemic. For the same reasons, and for alignment across programs, CMS proposes to remove these questions from the PCHQR

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

[35] The questions ask: (12) During this hospital stay, did you need medicine for pain? (Yes/No); (13) During this hospital stay, how often was your pain well controlled? (Never, Sometimes, Usually, Always); (14) During this hospital stay, how often did the hospital staff do everything they could to help you with your pain? (Never, Sometimes, Usually, Always)

Program beginning with FY 2022 payment. Under the proposal, data collected on these questions beginning with October 2018 discharges would not be publicly reported, but CMS would provide performance results to PCHs in confidential preview reports as early as July 2019.

Removal of External Beam Radiotherapy for Bone Metastases Measure. This measure is proposed for removal from the PCHQR Program beginning with FY 2022 payment based on previously adopted removal Factor 8: the costs associated with a measure outweigh the benefit of its continued use in the program. Specifically, the radiation delivery CPT codes used for the measure, which were part of a respecification after the measure was finalized, have required additional exclusions and proven burdensome on PCHs. In addition, CMS notes that the measure lost NQF endorsement in 2018 and is no longer being maintained by the measure steward.

Addition of Surgical Treatment Complications for Localized Prostate Cancer Measure. This measure uses claims data to calculate hospital-specific rates of urinary incontinence and erectile dysfunction among patients undergoing localized prostate cancer surgery. For the FY 2022 program year claims data for July 1, 2019 through June 30, 2020 would be used to calculate measure rates. Measure specifications are available from the Measure Applications Partnership "2018 Measures Under Consideration List" Excel file, at: http://www.qualityforum.org/map/.

Future Topics. **CMS seeks comments on future topics for PCHQR Program measures, and in particular is interested in comments related to pain management for cancer patients, given the issues with and proposed removal of the HCAHPS pain management questions**. It notes that in August 2018, the Alliance of Dedicated Cancer Centers convened a group of expert stakeholders to discuss and provide recommendations regarding best practices for the future of pain measurement among cancer patients, within the context of the national opioid crisis. The relatively high prevalence of pain symptoms in the cancer patient population, particularly those with advanced disease or metastatic cancer, underscores the need for feasible, valid, and reliable pain measures.

CMS believes that other cancer-specific, non-survey, patient experience assessment tools that evaluate cancer patient pain may be more appropriate than the HCAHPS survey pain questions proposed for removal. In particular, CMS believes there should be consideration given to a shifting focus toward Patient-Reported Outcome (PRO)-Performance Measures (PRO-PMs), as a growing body of research demonstrates the benefits of integration of PROs into oncology practice, including improved patient outcomes and survival. **CMS seeks comment on measurement concepts that could be further developed to assess appropriate pain management in the cancer patient population.** Specific topics could include measures that assess cancer patient safety, patient and family education, and patient experience and engagement (specifically PRO-PMs) in the context of cancer pain management. **In addition, CMS invites comment on the potential future adoption of measures that assess post-treatment addiction prevention for cancer patients, and on existing measures or measurement concepts that evaluate pain management for cancer patients, and do not involve opioid use.**

Public Display. Two changes are proposed with respect to public display of PCHQR Program measures. First, public display of performance on the Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy measure would begin in 2020. CMS has recently provided a first round of confidential reports to PCHs on this measure, and another round is planned before public display would be effective. Second, CMS previously deferred public display of the CDC NHSN infection measures. In this rule, it proposes that public display of the Methicillin-resistant Staphylococcus aureus (MRSA), Clostridium Difficile Infection (CDI), colon/abdominal hysterectomy surgical site infection measures and the influenza vaccine for healthcare personnel measure would begin with the October 2019 *Hospital Compare* release. Additional time is needed with respect to the updated risk-adjusted versions of the Central Line Associated Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measures. CMS expects that the earliest public display possible for these measures is 2022.

Confidential Reporting. To prepare PCHs for public reporting, CMS proposes to conduct two confidential reporting periods of measure results on five measures: the four end-of-life care measures and the Unplanned Readmissions for Cancer Patients measure. Confidential reporting is intended to educate PCHs and other stakeholders about the measures, allow PCHs to review their measure results prior to public reporting, test the reporting process and identify technical changes to measure specifications that might be needed. The data collection periods used for calculating the confidential reports are July 1, 2019 through June 30, 2020 for the end-of-life care measures and fiscal year 2020 for the readmissions measure.

PCHQR Program Measures for 2022 *Proposals in Italics*	
Measure	**Public Display**
Safety and Healthcare Associated Infection	
Colon/Abdominal Hysterectomy SSI (NQF #0753)	*Proposed 2019**
NHSN CDI (NQF #1717)	*Proposed 2019**
NHSN MRSA bacteremia (NQF #1716)	*Proposed 2019**
NHSN Influenza vaccination coverage among health care personnel (NQF #0431)	*Proposed 2019**
NHSN CLABSI (NQF #0139)**	*Deferred until 2022*
NHSN CAUTI (NQF #0138)**	*Deferred until 2022*
Clinical Process/Oncology Care	
Oncology: Plan of Care for Pain (NQF #0383)	2016
The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOLChemo) (NQF #0210)	
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215)	
Intermediate Clinical Outcomes	
The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216)	
The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL-ICU) (NQF #0213)	
Patient Experience of Care	
HCAHPS (NQF #0166)	2016
Clinical Effectiveness	

PCHQR Program Measures for 2022 *Proposals in Italics*	
Proposed for removal External Beam Radiotherapy for Bone Metastases	2017
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	*Proposed 2020*
30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188)	
Proposed: Surgical Treatment Complications for Localized Prostate Cancer	
*Public display, previously deferred, is proposed to begin with the October 2019 *Hospital Compare* update.	

C. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

The LTCH QRP was first implemented in FY 2014, as required under section 1886(m) of the Act. 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 must meet LTCH QRP patient assessment and quality data reporting requirements or be subject to a 2.0 percentage point update factor reduction. LTCHs submit data on the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) patient assessment instrument to CMS using the Quality Improvement Evaluation System Assessment Submission and Processing (QIES ASAP) system.

A table at the end of this section (item VIII.C.7) displays the 15 measures adopted for the LTCH QRP for FY 2021. This proposed rule would not change this measure list.

1. New Measures and Measure Update for FY 2022

CMS proposes the addition of two new process measures for the LTCH QRP beginning with FY 2022 for a new quality measure domain entitled "Transfer of Health Information." In addition, CMS proposes to update the specifications for the Discharge to Community PAC LTCH QRP measure in order to exclude baseline nursing facility (NF) residents from the measure. Specifications for the proposed measures are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Proposed-Specifications-for-LTCH-QRP-Quality-Measures-and-SPADE.pdf. Proposed data submission requirements for the two new measures are discussed in VIII.C.4 below.

- Transfer of Health Information to the Provider -- PAC Measure. This proposed measure would assess whether a current reconciled medication list is given to the subsequent provider when an individual transitions from a post-acute care (PAC) setting to another setting. Specifically, the measure would be calculated as the proportion of patient stays with a discharge assessment indicating that a current reconciled medication list was provided to the subsequent provider at discharge. The denominator would be the total number of LTCH patient stays ending in discharge to a subsequent provider (an acute care hospital, intermediate care, home under the care of a home health service organization or hospice, institutional hospice, skilled nursing facility (SNF), another LTCH, inpatient rehabilitation facility (IRF), inpatient psychiatric facility, or a CAH). The numerator would be the number

of LTCH patient stays with an LCDS discharge assessment indicating a current reconciled medication list was provided to the subsequent provider at discharge.

In discussing this proposed measure, CMS reviews the literature on care transitions and the need for transfer of medication lists. CMS measure development contractors convened a Technical Expert Panel (TEP) for this measure and comments were sought on the CMS measures management system blueprint website. A summary report on these comments is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/IMPACT_Medication-Profile-Transferred-Public-Comment-Summary-Report.pdf. A pilot test was conducted in 2018 involving 6 LTCHs and 18 other PAC providers. The pilot test summary is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Transfer-of-Health-Information-2018-Pilot-Test-Summary-Report_Final.pdf. The Measure Applications Partnership conditionally supported the measure pending endorsement by the National Quality Forum and suggested that the medication information transferred include information about supplements and opioids. CMS identified a related NQF-endorsed measure "Documentation of Current Medications in the Medical Record" (NQF #0419) but believes that the proposed measure better addresses the Transfer of Health Information domain because NQF #0419 does not address the transfer of medication information, only the documentation of it. In addition, the domain requires that at least some of the data used to calculate the measure be collected as standardized patient assessment data through the PAC assessment instruments.

- Transfer of Health Information to the Patient -- PAC Measure. This related proposed new measure would assess whether a current reconciled medication list was provided to the patient, family, or caregiver when a patient was discharged from a PAC setting to a private home/apartment, board or care home, assisted living, group home, transitional living, or home under care of a home health service organization or hospice. The same links provided for the proposed measure above include information on the public comments and pilot testing of this measure. The MAP also conditionally supported this measure. No similar NQF-endorsed measure was identified. The measure denominator would be the total number of LTCH patient stays ending in discharge to the locations listed above, and the numerator would be the number of LTCH patient stays with an LCDS discharge assessment indicating that a current reconciled medication list was provided to the patient, family, or caregiver at discharge.

- Update to the Discharge to Community PAC Measure. CMS proposes to update the specifications for this measure to remove baseline nursing facility residents. The measure reports an LTCH's risk-standardized rate of Medicare fee-for-service patients who are discharged to the community following an LTCH stay, who within the following 31 days remain alive and do not have an unplanned readmission to an acute care hospital or LTCH. Under the proposal, CMS would exclude baseline NF residents from the measure beginning with the FY 2020 LTCH QRP, with baseline NF residents defined as LTCH patients who had

a long-term NF stay in the 180 days preceding their hospitalization and LTCH stay, with no intervening community discharge between the NF stay and qualifying hospitalization.

Based on previous comments supporting this change, CMS analyzed the impact and found that after excluding baselined NF residents, 39 percent of LTCHs had an increase in their risk-standardized discharge to community rate that exceeded the national observed patient-level discharge to community rate.

2. Request for Information on LTCH QRP Quality Measures, Measure Concepts and Standardized Patient Assessment Data Elements under Consideration for Future Years

CMS seeks comment on the importance, relevance, appropriateness and applicability of the following measures, Standardized Patient Assessment Data Elements (SPADEs) and concepts under consideration for future years. CMS will not respond to these comments in the final rule, but they will be considered in future policy making.

- Quality Measures and Measure Concepts
  - Functional mobility outcomes
  - Sepsis
  - Opioid use and frequency
  - Exchange of electronic health information and interoperability
  - Nutritional status
- Standardized Patient Assessment Data Elements
  - Cognitive complexity, such as executive function and memory
  - Dementia
  - Bladder and bowel continence including appliance use and episodes of incontinence
  - Care preferences, advance care directives, and goals of care
  - Caregiver Status
  - Veteran Status
  - Health disparities and risk factors, including education, sex and gender identity, and sexual orientation

3. Standardized Patient Assessment Data Reporting Beginning with FY 2022

The IMPACT Act requires that, beginning in FY 2019, LTCHs must report SPADEs as required for at least the quality measures with respect to certain categories, summarized here as functional status; cognitive function; special services and interventions; medical conditions and comorbidities; impairments; and other categories deemed necessary and appropriate by the Secretary. The standardized patient assessment data must be reported under the LTCH QRP at least with respect to LTCH admissions and discharges, but the Secretary may require the data to be reported more frequently.

In the FY 2018 IPPS/LTCH proposed rule (82 FR 20100-20116), CMS proposed to require LTCHs to report 23 SPADEs, but only 2 were ultimately finalized. Commenters had raised a

general concern that CMS was moving too quickly given the other IMPACT Act requirements also being adopted at that time and had specific concerns that the proposed SPADEs needed further testing. The SPADEs that were finalized address two IMPACT Act categories (1) Functional status: Data elements currently reported by LTCHs to calculate the measure Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function and (2) Medical conditions and morbidities: data elements used to calculate the pressure ulcer measures.

In this rule, CMS proposes again to require LTCHs to report a new series of SPADEs, most of which are the same or modifications of the SPADEs that were previously proposed and not finalized. The list of proposed SPADEs, along with information on their current use in PAC patient assessment instruments and whether changes would be needed to the LCDS are summarized in a table below. Detailed specifications for the proposed SPADEs are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Proposed-Specifications-for-LTCH-QRP-Quality-Measures-and-SPADE.pdf. A change table and mockup of proposed LTCH QRP items are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html. These latter two documents also include the proposed data elements associated with the proposed new transfer of health information measures discussed above.

The required reporting would begin with the FY 2022 LTCH QRP. Under the proposal, for FY 2022 the data would be reported with respect to both admissions and discharges occurring between October 1, 2020 and December 31, 2020. For FY 2023 and later years, the data would be required for admissions and discharges that occur during a calendar year – 2021 for the FY 2023 LTCH QRP, 2022 for the FY 2024 LTCH QRP, etc.

For each proposed SPADE, CMS offers a rationale, discusses whether the element is currently used in any PAC patient assessment instruments, and describes past comments from stakeholders and pilot testing. The following are the proposed SPADEs that were not part of those proposed in FY 2018 rulemaking:

- Functional Status. Six mobility-related data elements that have been adopted for the other three PAC settings are proposed for addition to the LCDS. CMS notes that the statute requires that SPADEs apply to all four settings.
- High-Risk Drug Classes: Use and Indications. This proposed new data element would ask at admission and discharge whether the patient is taking any medications in 6 specific drug classes, and if so, whether there is an indication noted for all the medications in the drug class. The six drug classes are antipsychotics, anticoagulants, antibiotics, opioids, antiplatelets, and hypoglycemics (including insulin). In describing its proposal, CMS cites the literature on the potential adverse effects associated with these drugs and discusses comments it received from stakeholders during the development process.
- Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities). This proposed new data element would assess at admission and discharge the frequency with which pain effects a patient's sleep, ability to participate in therapy activities, and other day-to-day activities. In discussing

this proposal, CMS reviews changes in the practice of pain management and the literature on complications from opioid use in the elderly. It believes this proposal will support PAC clinicians in applying best practices in pain management consistent with current guidelines.

- Social Determinants of Health. This is a new category of SPADEs that would collect data on social determinants of health using existing PAC data collection mechanisms. CMS describes the requirements in the IMPACT Act for the Secretary to assess adjustments to quality and resource use measures to reflect social risk factors, including establishing new data sources. CMS believes that use of existing patient assessment instruments would be less burdensome on providers. Work by the Assistant Secretary for Planning and Evaluation and the National Academies of Sciences, Engineering and Medicine (NASEM) on social risk factors in response to the IMPACT Act requirements is reviewed.

  Seven SPADEs are proposed consistent with a 2016 NASEM report on identifying social risk factors:[36] race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social isolation. In the case of race and ethnicity and preferred language, the LCDS already collects this information on admission, but the current items would be revised. Data on all these proposed SPADEs would be collected at admission and discharge, but in the case of race and ethnicity, collection at admission would be deemed to meet both requirements because the information would be unlikely to change. Three of the proposed items under the social determinants of health categories are not currently used in any PAC patient assessment instrument. The health literacy item would ask how often the patient needs to have someone help read instructions, pamphlets or other written materials from the doctor or pharmacy. (The five responses are never, rarely, sometimes, often and always.) In discussing its proposal CMS reviews the testing of this question and compares it to other health literacy screening tools. The proposed transportation item comes from the Protocol for Responding to and Assessing Patients' Assets, Risks and Experiences (PROMISE) assessment tool and is currently part of the Accountable Health Communities (AHC) screening tool used by the CMS Innovation Center for the AHC program. It would ask the patient whether lack of transportation has kept them from medical appointments, meetings, work or from getting things needed for daily living. The three responses are: (1) Yes, it has kept me from medical appointments or getting medications, (2) Yes, it has kept me from non-medical meetings, appointments, work or getting things I need, and (3) No. Finally, the social isolation item is also part of the AHC screening tool. It comes from the Patient-Reported Outcomes Measurement Information System (PROMIS®) Item Bank on Emotional Distress. It would ask patients how often they feel lonely or isolated from those around them, with the same five possible responses as the health literacy question.

With respect to the proposed Hearing, Vision, Race, and Ethnicity SPADEs, CMS proposes that LTCHs submitting these SPADEs with respect to admission only would be deemed to have

[36] National Academies of Sciences, Engineering, and Medicine. 2016. *Accounting for social risk factors in Medicare payment: Identifying social risk factors*. Chapter 2. Washington, DC: The National Academies Press.

submitted them for both admission and discharge, because it is unlikely that assessment of these SPADEs would change during the LTCH stay.

In proposing the SPADEs, CMS says that it considered provider burden as well as overall clinical relevance; interoperable exchange to facilitate care coordination during transitions in care; ability to capture medical complexity and risk factors that can inform both payment and quality; and scientific reliability and validity and consensus agreement for its usability. The specific SPADEs proposed were identified through feedback from stakeholders, TEPs, and the results of a national beta test of candidate elements conducted by a CMS contractor. That test collected data from 3,121 patients and residents across LTCHs, SNFs, IRFs, and HHAs between November 2017 and August 2018. Information on the methods and results can be found at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/Downloads/Development-and-Evaluation-of-Candidate-SPADEs_National-Beta-Test-Background-and-Methods.pdf. Results from the PAC Payment Reform Demonstration (PAC PRD) of 2006 – 2012 were also considered. Summaries of the several TEPs that discussed these data elements and comments received in that process are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-Downloads-and-Videos.html.

In the collection of information requirements section of the proposed rule CMS estimates that the proposed changes to the LTCH QRP would require additional data collection efforts and annual costs would total about $5,500 per LTCH or $2.3 million across all LTCHs.

Proposed Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to LCDS**
Functional Status		
Mobility Data Elements: Car Transfer; Walking 10 feet on uneven surfaces; 1 step (curb); 4 steps; 12 steps; Picking up object	MDS IRF-PAI OASIS	New item
Cognitive Function and Mental Status		
Brief Interview for Mental Status (BIMS)	MDS IRF-PAI	New item
Confusion Assessment Method	LCDS (6 items) MDS (4 items)	Replace LCDS item
Patient Health Questionnaire-2 to 9 (depression screening)	MDS (PHQ-9) OASIS (PHQ-2)	New item
Special Services, Treatments, and Interventions		
Cancer Treatment: Chemotherapy (IV, Oral, Other)	MDS (single)	New item
Cancer Treatment: Radiation	MDS	New item
Respiratory Treatment: Oxygen Therapy (Intermittent, Continuous, High-concentration Oxygen Delivery)	MDS OASIS	New item

Proposed Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to LCDS**
	PAC PRD	
Respiratory Treatment: Suctioning (Scheduled, As needed)	MDS PAC PRD	New item
Respiratory Treatment: Tracheostomy Care	MDS	New item
Respiratory Treatment: Non-invasive Mechanical Ventilator (BiPAP, CPAP)	LCDS MDS	Replace LCDS item
Respiratory Treatment: Invasive Mechanical Ventilator	LCDS MDS	Replace LCDS item
Intravenous (IV) Medications (Antibiotics, Anticoagulation, Vasoactive Medications, Other)	LCDS MDS OASIS	Replace LCDS items
Transfusions	MDS PAC PRD	New item
Dialysis (Hemodialysis, Peritoneal dialysis)	LCDS MDS	Replace LCDS item
Other Treatment: Intravenous (IV) Access (Peripheral IV, Midline, Central line, Other)		New item
Nutritional Approach: Parenteral/IV Feeding	LCDS MDS IRF-PAI OASIS	Replace LCDS item
Nutritional Approach: Feeding Tube	MDS OASIS IRF-PAI PAC PRD	New item
Nutritional Approach: Mechanically Altered Diet	MDS OASIS IRF-PAI	New item
Nutritional Approach: Therapeutic Diet	MDS	New item
High-Risk Drug Classes: Use and Indications		New item
Medical Condition and Comorbidity Data		
Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities)	OASIS MDS	New item
Impairment		
Hearing	MDS	New item **
Vision	MDS OASIS	New item **
Social Determinants of Health		
Race	MDS LCDS IRF-PAI	Modify LCDS items**
Ethnicity		

Proposed Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to LCDS**
	OASIS	
Preferred Language and Interpreter Services	MDS LCDS	Modify LCDS item
Health Literacy		New item
Transportation	PREPARE/AHC screening tool	New item
Social Isolation	PROMISE/AHC screening tool	New item
*This column reflects whether the proposed rule indicates that the specific elements proposed, or similar or related elements, are included in the current PAC assessment instruments or tested in the PAC PRD. The PAC instruments referenced are: LCDS; SNF Minimum Data Set (MDS); Inpatient Rehabilitation Facility-Patient Assessment Instrument (IRF-PAI); Long-Term Care Hospital Continuity Assessment Record and Evaluation Data Set (LCDS); and OASIS for home health agencies. ** LTCHs submitting these SPADEs with respect to admission only would be deemed to have submitted them for both admission and discharge, because it is unlikely that assessment of these SPADEs would change during the LTCH stay.		

4. Form, Manner, and Timing of Data Submission

Reporting System Update

CMS reports that it is upgrading the Quality Improvement and Evaluation System (QIES) Assessment and Submission Processing (ASAP) system used by LTCHs to report LTCH QRP data to CMS. The new system will be called the internet QIES (iQIES) and CMS proposes changes to the regulatory text consistent with this change effective October 1, 2019. A general reference to use of a "CMS-designated data submission system" will replace the existing references to QIES ASAP.

Schedule for Reporting Requirement Updates

CMS proposes to move the implementation date of any new version of the LCDS from April to October, beginning October 1, 2020. This would align the LCDS with the MDS and IRF-PAI implementation dates and provide LTCHs an additional 6 months to prepare for any changes to the reporting requirements. In addition, for the first program year in which measures or SPADEs are adopted, LTCHs would only be required to report data on patients who are admitted and discharged during the last quarter (October 1 to December 31) of the calendar year that applies to the program year. Full calendar year reporting would apply in subsequent years. For new data elements to be reported in 2020 for the FY 2022 payment determination, the reporting deadline for the fourth quarter 2020 data would be May 15, 2021. The proposed rule includes a table displaying the reporting deadlines for data reported in 2021 for FY 2023 payment.

Schedule for Reporting Proposed Transfer of Health Information Quality Measures and SPADES

As summarized in section VIII.C.1 above, two new measures are proposed beginning with FY 2022 payment. CMS proposes that LTCHs would be required to collect data for these measures beginning with patients discharged on or after October 1, 2020. The initial reporting schedule described above would apply.

Similarly, with respect to reporting on the proposed new SPADEs as summarized in section VIII.C above, LTCHs would be required to collect data for all patients discharged on or after October 1, 2020 at both admission and discharge. As noted above, for some SPADEs collection by an LTCH at admission only would be deemed to meet this requirement. The initial reporting schedule described above would apply.

5. Remove of the List of Compliant LTCHs

CMS proposes to stop publishing a list of compliant LTCHs, (i.e., those meeting the LTCH QRP reporting requirements) on the LTCH QRP website, effective beginning with the FY 2020 payment determination. CMS agrees with feedback it has received from stakeholders that this listing does not provide new information to providers regarding their annual payment update status.

6. Public Display of Measure Data for the LTCH QRP

CMS proposes to add the LTCH QRP measure "Drug Regimen Review Conducted with Follow-Up for Identified Issues" to the *Long Term Care Hospital Compare* website at https://www.medicare.gov/longtermcarehospitalcompare/.

Display would begin with 2020 or as soon as technically feasible. The data display would be for a rolling four quarters of data, initially using data for discharges occurring during calendar year 2019. Data for LTCHs with fewer than 20 eligible cases in any four consecutive rolling quarters would not be publicly displayed. For those LTCHs, the website would indicate that the number of cases is too small to publicly report.

7. Table of LTCH QRP Measures

LTCH QRP Measures, by Year			
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139)	X	X	X
Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short-Stay) (NQF #0678)	X	Replaced	
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury		X	

LTCH QRP Measures, by Year			
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)	X	X	Removed
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	X	X	X
NHSN Facility-Wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)	X	X	Removed
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717)	X	X	X
All-Cause Unplanned Readmissions for 30 Days Post Discharge from LTCHs (NQF #2512)	Removed		
Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (Application of NQF #0674)	X	X	X
Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631)	X	X	X
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (NQF #2631)	X	X	X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632)	X	X	X
NHSN Ventilator Associated Event Outcome Measure	X	X	Removed
Medicare spending per beneficiary MSPB-PAC LTCH	X	X	X
Discharge to Community PAC LTCH	X	X	X
Potentially Preventable Readmissions 30 Days Post LTCH Discharge	X	X	X
Drug Regimen Review Conducted with Follow-up		X	X
Mechanical Ventilation Process Measure: Compliance with Spontaneous Breathing Test by Day 2 of the LTCH Stay		X	X
Mechanical Ventilation Outcome Measure: Ventilator Liberation Rate		X	X

D. Medicare and Medicaid Promoting Interoperability Program

A hospital that is not identified as a meaningful EHR user under the Medicare Promoting Interoperability Program is subject to a reduction of 2.4 percentage points in the update factor for FY 2020. In the impact analysis section of this proposed rule, 243 hospitals are estimated to not meet the meaningful use requirements for FY 2019 payment; 32 of these hospitals also fail to meet the Hospital IQR Program requirements and therefore be subject to a combined update factor reduction of 3.2 percentage points.

1. Reporting Periods in 2019 and 2021

CMS previously adopted a continuous 90-day reporting period for the Medicare Promoting Interoperability Program for reporting during 2019 and 2020. The policies include a requirement

that for the FY 2020 payment adjustment year, an eligible hospital that had not demonstrated meaningful use in a prior year must use a continuous 90-day reporting period that ends before the October 1, 2019 deadline for registering and attesting to meaningful use.

In this rule CMS conditionally proposes to eliminate the October 1, 2019 reporting period deadline for hospitals that had not previously demonstrated meaningful use. These hospitals would then have all of 2019 to complete the reporting requirement for the FY 2020 payment adjustment. The condition to this proposal is that the proposal described below to modify the Query of Prescription Drug Monitoring Program (PDMP) measure from a numerator/denominator reporting to yes/no attestation is adopted in the final rule.

CMS proposes to also apply a continuous 90-day reporting period for returning participants during 2021 (for the FY 2023 payment adjustment). CMS believes that this is an appropriate length of time and that the proposal offers stability to the program. The proposed regulatory text would also require eligible hospitals that have not previously demonstrated meaningful use a continuous 90-day reporting period within 2021 that would apply for the FY 2022 and 2023 payment adjustment years, and for FY 2022 payment the self-selected reporting period would be required to end before the October 1, 2021 deadline for registering and attesting to meaningful use.

2. Medicaid Promoting Interoperability Program

The statute prohibits any Medicaid Promoting Interoperability Program payments to hospitals after December 31, 2021, other than for a successful appeal related to 2021 or an earlier year. Based on attestation data and information from states, CMS believes there will be no hospitals eligible to receive Medicaid Promoting Interoperability Program payments in 2021 because of the requirement that after 2016 payments may only be made to hospitals that received a payment in the prior year. In last year's rulemaking CMS asked whether this belief was accurate and received one comment in agreement. **CMS again invites comments on whether it is correct in thinking that no hospitals are able to receive Medicaid Promoting Interoperability Program payments in 2021. If this is not true, comments are sought on how to adjust reporting periods for Medicaid eligible hospitals in a manner that limits burden on hospitals and states.**

3. Actions Must Occur During Reporting Period

In response to queries, CMS has previously issued an FAQ (number 8231) indicating that when reporting a numerator value, the hospital is not constrained to the EHR reporting period unless it is expressly required in the measure's numerator statement. Currently, measures associated with the public health and clinical data exchange objective do not contain this limitation. In these cases, actions outside the EHR reporting period could be counted in the numerator if they occurred after the start of the reporting year and before the date of attestation.

CMS now proposes a different policy in light of the new scoring methodology adopted in the FY 2019 IPPS/LTCH final rule. Because hospitals may elect an EHR reporting period that is 90

consecutive days or up to an entire calendar year, CMS proposes that beginning with reporting periods in 2020, for hospitals and CAHs submitting attestations under the Medicare Promoting Interoperability Program both the numerators and denominators of measures would only increment based on actions that have occurred during the hospital's chosen EHR reporting period. This policy would be codified in regulatory text.

Under the proposal, an exception would apply to the Security Risk Analysis measure because actions included in that measure may occur at any time during the calendar year in which the EHR reporting period occurs. All other measures would be subject to the limitation.

The proposals would not apply to the Medicaid Promoting Interoperability Program because some measures that were removed from the Medicare Promoting Interoperability Program remain in that program (e.g., view, download and transmit; and secure messaging) and for those measures CMS believes it is appropriate to continue to allow hospitals to report actions in the numerators outside the EHR reporting period.

4. Changes to Measures

CMS proposes changes to the two opioid-related measures that it adopted in the FY 2019 IPPS/LTCH final rule. The changes are made in response to the many concerns raised by stakeholders, and also provisions of the Substance Use–Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018 (Pub. L. 115-271) which CMS believes will affect the maturation, requirements and use of PDMPs and state networks. As discussed further below, CMS includes several requests for information in this proposed rule intended to help it develop better measures in the future to support prevention and treatment of substance use disorder.

- Changes to Query of PDMP Measure. CMS proposes to modify this measure in three ways: (1) the measure would remain optional for 2020 reporting and eligible for 5 points, (2) beginning with 2019 reporting it would be changed to a yes/no measure instead of a numerator/denominator measure, and (3) as an optional measure the exclusion for this measure would be removed. As currently defined, the measure assesses the number of Schedule II opioid prescriptions for which certified electronic health record technology (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. Under the proposal, hospitals electing to report this optional measure would report "yes" if for at least one Schedule II opioid electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH used data from CEHRT to conduct a query of a PDMP for prescription drug history, except where prohibited and in accordance with applicable law.

  In discussing this proposal, CMS describes stakeholder concerns about the ongoing development of PDMPs, the lack of integration of PDMPs in the EHR workflow, and the costs and burdens if developers specify calculations for this measure that later need to be

changed. The current work of the ONC in assessing the policy and technical issues impacting PDMP integrations is noted, In addition, related provisions of the SUPPORT Act are discussed, including new requirements and federal funding for PDMP enhancement, integration, and interoperability, and requirements for mandatory use of PDMPs by certain Medicaid providers along with federal Medicaid funding for certain state expenditures related to PDMPs. CMS believes that its proposal would reduce burden on health IT developers and providers.

With respect to scoring this measure, CMS clarifies that for 2019 reporting this optional measure is worth 5 points, not "up to" five points as was stated in the FY 2019 final rule in some places. Under the proposal, a hospital that responds "yes" on this measure would receive 5 points.

CMS further proposes that if the changes to the Query of PDMP measure are finalized, the e-Prescribing measure would be worth up to 10 points for reporting in 2020 and subsequent years. The complete proposed scoring for 2020 reporting is discussed further below.

CMS welcomes comments on future timing for requiring a measure that includes EHR-PDMP integration and on the value of the measure for advancing the effective prevention and treatment of opioid use disorder, especially in relation to potential opportunities under the SUPPORT Act for the Medicare Promoting Interoperability Program to take into account states' Medicaid investments and requirements.

Finally, CMS notes that stakeholders have asked it to define a value set for controlled substances for the opioid-related measures, which it has defined as Schedule II controlled substances under 21 CFR 1308.12. CMS anticipates working closely with the DEA on future technical requirements that can better support measurement of adoption and use of electronic prescribing of controlled substances, which may include the definition of a value set related to such measures.

- Removal of Verify Opioid Treatment Measure. CMS proposes to remove this optional measure from the Medicare Promoting Interoperability Program beginning with 2020 reporting. The measure was finalized as an optional measure beginning with 2019 reporting. It assesses the percentage of patients for whom a Schedule II opioid was prescribed during the EHR reporting period and for whom the eligible hospital or CAH sought to identify a signed opioid treatment agreement and then incorporated any agreement found into CEHRT. The measure would apply to patients who received an opioid prescription for at least 30 cumulative days within a 6-month lookback period. In proposing to remove this measure, CMS cites ongoing concerns of stakeholders regarding the lack of defined data elements, structure, standards and criteria for the electronic exchange of opioid agreements; calculating the 30-day lookback period; the burden caused by lack of a definition for what constitutes an opioid treatment agreement. CMS also clarifies that for purposes of 2019 reporting, this measure is worth 5 points, not "up to" 5 points as was stated in some places in the FY 2019 final rule.

Clarification for Support Electronic Referral Loops by Receiving and Incorporating Health Information. CMS proposes to modify the regulatory text to match the measure to require that the electronic summary of care must be received using CEHRT and that clinical information reconciliation for medication, medication allergy, and current problem list must be conducted using CEHRT.

5. Scoring the Medicare Promoting Interoperability Program in 2020 Reporting Periods
As previously finalized, in order to be considered a meaningful user an eligible hospital or CAH must meet all of the following requirements:

- Report on all the required measures across all four objectives, unless an exclusion applies*
- Report "yes" on all required yes/no measures, unless an exclusion applies*
- Attest to completing the actions included in the Security Risk Analysis measure*
- Achieve a total score of at least 50 points

*Failure on this requirement results in a total score of zero.

With the proposed changes to measures described above, CMS proposes to modify the scoring for the 2020 reporting period. The table below compares the previously adopted measures and points with those proposed in this rule.

Current and Proposed Performance-Based Scoring Methodology for EHR Reporting Periods in 2020

Objectives	Measures	Maximum Points	
		Current	Proposed
e-Prescribing	e-Prescribing	5 points	10 points*
	Query of Prescription Drug Monitoring Program (PDMP)	5 points	5 points (bonus)
	Verify Opioid Treatment Agreement	5 points (bonus)	removed
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points	40 points
Public Health and Clinical Data Exchange	Choose any two of the following: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Public Health Registry Reporting Clinical Data Registry Reporting Electronic Reportable Laboratory Result Reporting	10 points	10 points
*This change in points is conditional on CMS finalizing the Query of PDMP measure as optional.			

6. 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 2020 reporting period, 8 eCQMs are available for reporting by eligible hospitals and CAHs. They must report on four of these 8 eCQMs 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. The 8 current eCQMs are:

- STK-2 Antithrombotic therapy for ischemic stroke (NQF #0435)
- STK-3 Anticoagulation therapy for Afib/flutter (NQF #0436)
- STK-5 Antithrombotic therapy by end of hospital day 2 (NQF #0438)
- STK-6 Discharged on statin (NQF #0439)
- VTE-1 VTE prophylaxis (NQF #0371)
- VTE-2 ICU VTE prophylaxis (NQF #0372)
- ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status (NQF #0497)
- PC-05 Exclusive breast milk feeding (NQF #0480) Healthy term newborn

CMS proposes to add two eCQMs to the list of those available for reporting beginning with the 2021 reporting period. The same proposal is being made for the IQR Program, as discussed above in section VIII.A.1.

- Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e). This measure calculates the proportion of patients age 18 and older who are prescribed two or more opioids or an opioid and benzodiazepine concurrently at discharge from a hospital-based encounter (inpatient, observation stays, emergency department). Exclusions include patients with an active diagnosis of cancer or order for palliative care during the encounter. Beginning with the 2022 reporting period this measure would be mandatory, and eligible hospitals and CAHs would select to report 3 out of the other available eCQMs.
- Hospital Harm—Opioid Related Adverse Events eCQM. This measure assesses the proportion of an acute care hospital's patients with an opioid-related adverse event during an admission as indicated by the administration of naloxone. The denominator is the number of patients age 18 or older who were discharged during the measurement period and had an admission that was initiated in the ED or in observational status. The numerator is the number of patients who received naloxone outside the operating room after 24 hours from hospital arrival OR during the first 24 hours after hospital arrival with evidence of hospital opioid administration prior to naloxone administration. Considering earlier stakeholder concerns, **comments are specifically sought on the potential for this measure to disincentivize the appropriate use of naloxone in the hospital setting or withholding opioids when they are medically necessary in patients requiring palliative care or at end of life.**

In addition, **CMS seeks comment on whether it should consider proposing to adopt the Hybrid HWR eCQM in future rulemaking for the Promoting Interoperability Program**. As described in section VIII.A.1 above, this measure is proposed for the IQR Program as a replacement for the claims-based hospital-wide readmission measure. It uses a set of 13 core clinical data elements drawn from hospital EHRs for purposes of patient risk adjustment and hospital service adjustment in combination with the claims data on readmissions.

For 2020 and 2021 reporting, CMS proposes to continue the same reporting rules in place for 2019 reporting, which is to report one self-selected calendar quarter of data on 4 self-selected eCQMs. Eligible hospitals and CAHs for which electronic reporting is not feasible would report for a full calendar year on all available eCQMs. The data submission period would end 2 months after the end of the reporting calendar year – e.g., February 28, 2021 for the 2020 reporting period. As stated above, for the 2022 reporting period, CMS proposes that the new Concurrent Prescribing eCQM would be mandatory, with hospitals and CAHs selecting 3 other eCQMs to report.

The previously adopted requirements that EHRs be certified to all CQMs adopted for the Promoting Interoperability Program would be extended for the 2020 reporting period and subsequent years. No changes are proposed to previously adopted policies regarding use of 2015 CEHRT and data submission using QRDA-1 and the QualityNet Portal. More information on the form and manner of reporting is available on the eCQI Resource Center web page at: https://ecqi.healthit.gov/.

Elimination of Attestation. Beginning with the 2023 reporting period, CMS proposes that all eligible hospitals and CAHs would be required to submit eCQM data electronically – attestation would be eliminated as a method of reporting for the Medicare Promoting Interoperability Program. CMS notes that attestation is currently only permitted where electronic reporting is not feasible, and it believes that the proposed timing would allow for an adequate transition period for hospitals and CAHs to move to electronic reporting.

7. RFI on Potential Future Opioid Measures

CMS seeks comment on potential new measures for opioid use disorder (OUD) prevention and treatment that could be included in future years of the Promoting Interoperability Program. Comments are specifically sought on measures with the following characteristics:

- Are applicable to all hospital settings (for example, rural, urban, small hospitals, large hospitals);
- Are represented by a measure description, numerator/denominator or "yes/no" attestation statement, and possible exclusions;
- Include evidence of positive impact on outcome-focused improvement activities, and the opioid crisis overall;
- Leverage the capabilities of CEHRT, including automatic calculation and reporting of numerator, denominator, exclusions and exceptions, and timing elements to reduce quality measurement and reporting burdens to the greatest extent possible;

- Are based on well-defined clinical concepts, measure logic and timing elements that can be captured by CEHRT in standard clinical workflow and/or routine business operations. Well-defined clinical concepts include those that can be discretely represented by available clinical and/or claims vocabularies such as SNOMED CT, LOINC, RxNorm, ICD-10 or CPT; and
- Align with clinical workflows in such a way that data used in the calculation of the measure is collected as part of a standard workflow and does not require any additional steps or actions by the health care provider.

8. RFI on National Quality Forum and CDC Opioid Quality Measures

CMS specifically seeks comments on the development of the Promoting Interoperability Program that are based on existing efforts to measure clinical and process improvements specifically related to the opioid epidemic, including the opioid quality measures endorsed by the NQF and the CDC Quality Improvement (QI) opioid measures discussed below. CMS welcomes public comment on the specific use cases for health IT implementation for the potential measure actions. Comments are sought on any modifications to the NQF and CDC measures that may be necessary to make the measures as applicable as possible to all participants of the Promoting Interoperability Program. In addition, comments are sought on whether there are ways in which the two sets of measures could be correlated for the Promoting Interoperability Program. Finally, comments are sought on which measures might best advance the implementation and use of interoperable health IT and encourage information exchange between care teams and with patients.

NQF Measures

- Use of Opioids at High Dosage in Persons Without Cancer (NQF #2940).
- Use of Opioids from Multiple Providers in Persons Without Cancer (NQF #2950).
- Use of Opioids from Multiple Providers and at High Dosage in Persons Without Cancer (NQF #2951).

More information on these measures is available through NQF's Quality Positioning System at: http://www.qualityforum.org/QPS/QPSTool.aspx.

CDC QI Measures

The CDC developed the 16 QI opioid measures listed below to align with the recommendations in the CDC Prescribing Guideline and to improve opioid prescribing. The Implementing the CDC Prescribing Guideline document also includes practice-level strategies to help organize and improve the management and coordination of long-term opioid therapy and the measures address treatment guidelines for both initial treatment practices and long-term treatment and outcomes. CMS seeks comment on which of the 16 CDC QI opioid measures have value for potential consideration for the Promoting Interoperability Program. Further, comments are sought on whether CMS should consider a different type of measurement concept for the OUD prevention and treatment measures, such as reporting on a set of cross cutting activities and measures (for

example, a set of one clinical decision support (CDS), the related CDC QI opioid measure, and a potentially relevant clinical quality measure).

Measure 1: Use immediate-release opioids
Measure 2: Check PDMP before prescribing opioids
Measure 3: Urine drug testing before prescribing opioids
Measure 4: Evaluate within four weeks of starting opioids
Measure 5: Three days' supply for acute pain
Measure 6: Dosage of ≥ 50 morphine milligram equivalents (MMEs)
Measure 7: Dosage of > 90 MMEs
Measure 8: Concurrent prescribing of opioids and benzodiazepines
Measure 9: Follow-up visit quarterly
Measure 10: Quarterly pain and functional assessments
Measure 11: Check PDMP quarterly
Measure 12: Counsel on risks and benefits annually
Measure 13: Annual urine drug test
Measure 14: Referral for nonpharmacological therapy
Measure 15: Naloxone counseling and prescribed or referred
Measure 16: Medication-assisted treatment (MAT)

The measures are described in Appendix B of the Implementing the CDC Prescribing Guidelines document https://www.cdc.gov/drugoverdose/pdf/prescribing/CDC-DUIPQualityImprovementAndCareCoordination-508.pdf.

9. Request for Information (RFI) on a Metric to Improve Efficiency of Providers within EHRs

CMS requests comments on the potential for a metric to assess provider efficiency using EHRs. It discusses the potential that adoption of EHRs has for eliminating time consuming paper-based processes, and the research and stakeholder experiences indicating that this potential has not been achieved. A related report issued by the ONC in November 2018 is cited, which discusses these issues and identifies best practices for design to improve efficiency in use of EHRs.[37]

Comments are sought on how implementation of efficient workflows and technologies can be effectively measured and how to measure and incentivize efficiency as it relates to the meaningful use of CEHRT and the furthering of interoperability. A 2017 NQF report[38] discussed measure concepts of productivity and efficiency related to health information exchange.

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[37] ONC. *Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs*. November 2018. https://www.healthit.gov/sites/default/files/page/2018-11/Draft%20Strategy%20on%20Reducing%20Regulatory%20and%20Administrative%20Burden%20Relating.pdf

[38] NQF. *A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy*. https://www.qualityforum.org/Projects/i-m/Interoperability_2016-2017/Key_Informant_Summary_Report.aspx

In commenting on a potential metric to evaluate health provider efficiency using EHRs, CMS specifically asks consideration of the following:

- What do stakeholders believe would be useful ways to measure the efficiency of health care processes due to the use of health IT? What are measurable outcomes demonstrating greater efficiency in costs or resource use that can be linked to the use of health IT-enabled processes? This includes measure description, numerator/denominator or "yes/no" reporting, and exclusions.
- What are specific technologies, capabilities, or system features (beyond those currently addressed in the Promoting Interoperability Program) that can increase the efficiency of health care provider interactions with technology systems, for instance, alternate authentication technologies that can simplify health care provider logon? How could CMS reward health care providers for adoption and use of these technologies?
- What are key administrative processes that could benefit from more efficient electronic workflows, for instance, conducting prior authorization requests? How could CMS measure and reward health care providers for uptake of more efficient electronic workflows?

10. Request for Information (RFI) on Including Medicare Promoting Interoperability Program Data on the *Hospital Compare* Website

CMS seeks comment on posting the performance of eligible hospitals and CAHs on Medicare Promoting Interoperability Program measures on *Hospital Compare.* Specifically, CMS asks the following questions.

- Of the six required measures and one bonus measure that would apply for an EHR reporting period in CY 2020, how many and which ones should CMS consider posting?
- What process should be in place to allow eligible hospitals and CAHs the opportunity to review the data prior to publication? This includes comment on how many days the preview period should be for eligible hospitals and CAHs to review data prior to publication and a correction process for those who may have identified an error in their data.

11. Request for Information (RFI) on the Provider to Patient Exchange Objective

CMS discusses its focus on improving electronic patient access to their health information and in particular the role of the Application Programming Interface (API) in allowing patients to use an application of their choice for this purpose. The recent ONC 21st Century Cures Act proposed rule would establish new standards for APIs to be made part of the 2015 Edition of CEHRT that providers are required to use under the Promoting Interoperability Program. The proposed standards would require the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard. As part of the proposal, health IT developers would have 24 months from the publication of the final rule to implement these changes to certified health IT products. CMS seeks comment on:

- whether eligible hospitals and CAHs should make patient health information available immediately through the open, standards-based API, no later than one business day after it is available to the eligible hospital or CAH in their CEHRT;
- the barriers to more immediate access to patient information; and
- if there are specific data elements that may be more or less feasible to share no later than one business day.

The existing Provide Patients Electronic Access to Their Health Information measure does not specify the overall operational expectations associated with enabling patients' access to their health information. For instance, the measure only specifies that access must be "timely." CMS requests public comment on:

- whether the measure should be made more specific with respect to the experience patients should have regarding their access (e.g., require that patients be provided routine access to their health information without needing to reauthorize their app and re-authenticate themselves); and
- whether, if ONC's proposal for a FHIR-based API certification criterion is finalized, stakeholders would support a possible bonus under the Promoting Interoperability Programs for early adoption of a certified FHIR-based API in the intermediate time before ONC's final rule's compliance date for implementation of a FHIR standard for certified APIs.

CMS also seeks comment on an alternative measure under the Provider to Patient Exchange objective that would require health care providers to use technology certified to the EHI criteria to provide the patient(s) their complete electronic health data contained within an EHR. Specifically, CMS asks the following questions:

- Do stakeholders believe that incorporating this alternative measure into the Provider to Patient Exchange objective will be effective in encouraging the availability of all data stored in health IT systems?
- In relation to the Provider to Patient Exchange objective as a whole, how should a measure focused on using the proposed total EHI export function in CEHRT be scored?
- If the ONC-proposed electronic health information export certification criterion is finalized and implemented, should a measure based on the criterion be established as a bonus measure? Should this measure be established as an attestation measure?
- In the long term, how do stakeholders believe such an alternative measure would impact burden?
- What data elements do stakeholders believe are of greatest clinical value or would be of most use to health care providers to share in a standardized electronic format if the complete record was not immediately available?

Additional general questions CMS asks are:

- Do stakeholders believe that CMS should consider including a health IT activity that promotes engagement in the health information exchange across the care continuum that would encourage bi-directional exchange of health information with community partners, such as post-acute care, long term care, behavioral health, and home and community based services to promote better care coordination for patients with chronic conditions

and complex care needs? If so, what criteria should CMS consider when implementing a health information exchange across the care continuum health IT activity in the Promoting Interoperability Program?

- What criteria should CMS employ, such as specific goals or areas of focus, to identify high priority health IT activities for the future of the program?
- Are there additional health IT activities CMS should consider recognizing in lieu of reporting on existing measures and objectives that would most effectively advance priorities for nationwide interoperability and spur innovation?
- For purposes of future policy development, what are ways for ONC and CMS to continue to facilitate private sector efforts on a workable and scalable patient matching strategy so that the lack of a specific unique patient identifier (UPI) does not impede the free flow of information? How might CMS leverage its program authority to provide support to those working to improve patient matching?

12. Request for Information (RFI) on Integration of Patient-Generated Health Data into EHRs Using CEHRT

Although in the FY 2019 IPPS/LTCH final rule CMS removed a previously finalized Promoting Interoperability Program measure related to patient-generated health data (PGHD), that decision was due to flaws in the measure and not the concept of capturing PGHD into EHRs. CMS believes that the bi-directional availability of data is critical, including patients being able to import their health data into their medical record and have it be available to health care providers. CMS notes work of the ONC on this topic,[39] which urges clinicians and care teams to identify priority use cases and PGHD types valuable to improving patient care and developing management strategies for shared responsibilities around collecting, verifying, and analyzing PGHD. Highlighted also is the important role that clinicians can play in helping patients understand how to share PGHD, the differences between solicited and unsolicited PGHD, and how PGHD are relevant for the patient's care.

CMS seeks comments on ways that the Promoting Interoperability Program could adopt new elements related to PGHD that represent clearly defined uses of health IT; are linked to positive patient outcomes; and advance the capture, use, and sharing of PGHD. CMS notes that program elements other than a traditional numerator/denominator measure are possible, such as an attestation approach. CMS asks these specific questions:

- What specific use cases for capture of PGHD as part of treatment and care coordination across clinical conditions and care settings are most promising for improving patient outcomes? (For instance, use of PGHD for capturing advanced directives and pre/post-operation instructions in surgery units.)
- Should the Promoting Interoperability Program explore ways to include bonus points for health care providers engaging in activities that pilot promising technical solutions or

[39] ONC. *Conceptualizing a Data Infrastructure for the Capture, Use, and Sharing of Patient-Generated Health data in Care Delivery and Research*. 2018. https://www.healthit.gov/sites/default/files/onc_pghd_final_white_paper.pdf

approaches for capturing PGHD and incorporating it into CEHRT using standards-based approaches?

- Should inpatient health care providers be expected to collect information from their patients outside of scheduled appointments or procedures? What are the benefits and concerns about doing so?
- Should the Promoting Interoperability Program explore ways to reward health care providers for implementing best practices associated with optimizing clinical workflows for obtaining, reviewing, and analyzing PGHD?

13. Request for Information (RFI) on Engaging in Activities that Promote the Safety of the EHR

CMS notes that although the benefits of widespread adoption of EHRs include improved availability of patient health information, supporting more informed clinical decision making, and reduced medical errors, many stakeholders have identified risks to patient safety as a potential unintended consequence. Specifically, disruption of established workflows and creating new challenges for clinicians may increase the incidence of certain errors, resulting in harm to patients.

Comments are sought on ways that the Promoting Interoperability Program may reward hospitals for engaging in activities that can help to reduce errors associated with EHR implementation. CMS in particular is interested in comments on whether to award points under the program for hospitals that attest to performance of an assessment based on one of the ONC SAFER Guides. The SAFER Guides (available at: https://www.healthit.gov/topic/safety/safer-guides) are designed to help healthcare organizations conduct self-assessments to optimize the safety and safe use of EHRs in nine different areas: High Priority Practices, Organizational Responsibilities, Contingency Planning, System Configuration, System Interfaces, Patient Identification, Computerized Provider Order Entry, Test Results Reporting and Follow-Up, and Clinician Communication. Some EHR developers use the SAFER Guides as part of their health care provider training modules.

Specifically, CMS says it might consider offering points towards the Promoting Interoperability Program score to hospitals that attest to conducting an assessment based on the High Priority Practices and/or the Organizational Responsibilities SAFER Guides, which cover many foundational concepts from across the guides. Alternatively, points might be awarded for review of all nine of the SAFER Guides. CMS also invites comments on alternatives to the SAFER Guides, including appropriate assessments related to patient safety.

CMS requests comments on these ideas and other approaches stakeholders believe CMS could take to reward activities that promote reduction of safety risks associated with EHR implementation.

IX. MedPAC Recommendations

CMS reports that it reviewed MedPAC's March 2019 "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 2020 in Appendix B of the proposed rule.

X. Other Required Information

This section includes a listing and a description of the 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.

XI. Provider Reimbursement Review Board Appeals

The Provider Reimbursement Review Board (PRRB) is the administrative adjudication body that handles Medicare Part A provider cost reimbursement appeals. Between 2015 and 2017, on average, 3,000 appeals were filed per year and approximately 2,200 were resolved. The appeals inventory is now over 10,000 (including approximately 5,000 group appeals). The proposed rule lists the following examples of initiatives to decrease the number of appeals submitted; decrease the number of appeals in inventory; reduce the time to resolution; and increase customer satisfaction:

- Develop standard formats and more structured data for submitting cost reports and supplemental and supporting documentation.
- Create more clear standards for documentation to be used in auditing of cost reports.
- Enhance the Medicare Cost Report Electronic Filing (MCReF) portal by creating more automation for letter notifications, increasing provider transparency during the cost report reconciliation process, and improving the ability for providers to see where they are in the process.
- Explore opportunities to improve the process for claiming DSH Medicaid eligible days as part of the annual Medicare cost report submission and settlement process.
- Utilize artificial intelligence (AI) design risk protocols based on historical audit outcomes and empirical data to drive the audit and desk review processes.
- Triage the current appeals inventory and expand the provider's utilization of PRRB rules 46 and 47.2.3 (that is, resolve appeal issues through the cost report reopening process).

In addition, the proposed rule requests public comments on PRRB appeals related to a hospital's Medicaid fraction in the DSH payment adjustment calculation which is discussed in more detail in section IV

TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES
FY 2020 OPERATING COSTS

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2020 MGCRB Reclassifications (4) [5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6) [7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7) [8]	All Proposed FY 2020 Changes (8) [9]
All Hospitals	3,242	3.1	0	0	0	0	0.1	0	3.5
By Geographic Location:									
Urban hospitals	2,476	3.1	0	0	-0.1	0	0.1	0	3.5
Large urban areas	1,268	3.1	-0.1	0	-0.7	-0.1	0.1	-0.2	3.4
Other urban areas	1,208	3.1	0	0	0.5	0.1	0.2	0.1	3.7
Rural hospitals	766	2.8	0.2	0.1	1	-0.1	0.1	0.4	3.6
Bed Size (Urban):									
0-99 beds	643	3	0.4	-0.1	-0.8	0	0.3	0	3.6
100-199 beds	759	3.1	0	0	-0.2	0.1	0.2	0	3.4
200-299 beds	431	3.2	0	0	0.1	0.1	0.1	0	3.4
300-499 beds	424	3.1	-0.1	0	0	0	0.1	-0.1	3.6
500 or more beds	219	3.1	-0.1	-0.1	-0.2	-0.1	0	0	3.6
Bed Size (Rural):									
0-49 beds	302	2.7	1.1	0	0.4	-0.1	0.2	0.7	4.9

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2020 MGCRB Reclassifications (4) [5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6) [7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7) [8]	All Proposed FY 2020 Changes (8) [9]
50-99 beds	272	2.8	0.3	0.1	0.5	0	0.2	0.5	3.6
100-149 beds	108	2.9	0.1	0	0.9	-0.1	-0.1	0.3	3.7
150-199 beds	45	3	-0.2	0.2	1.6	-0.1	0.2	0.4	3.2
200 or more beds	39	2.9	0	0.1	1.7	0	-0.1	0.3	3
Urban by Region:									
New England	112	3.2	0.3	-0.3	1.5	0.3	0.1	1.3	1.7
Middle Atlantic	307	3.2	-0.2	-0.1	0.3	-0.2	0.1	-0.4	3.1
South Atlantic	399	3.1	0	-0.2	-0.5	-0.1	0	0	3.5
East North Central	386	3.2	0	0	-0.4	-0.2	0	-0.1	3.6
East South Central	147	3.1	-0.1	-0.1	-0.4	-0.2	0	0.9	4.5
West North Central	157	3	0.2	0.4	-0.8	-0.1	0.6	-0.1	4.2
West South Central	375	3.2	-0.3	0.1	-0.7	-0.2	0	0.1	3.5
Mountain	169	3.1	0.2	0.2	0	0.2	0.3	0	3
Pacific	374	3.1	0	0.1	0.5	0.6	0.1	-0.7	4.1
Puerto Rico	50	3.2	-2.3	-0.5	-1	0.2	0.1	12.7	13.6

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2020 MGCRB Reclassifications (4) [5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6) [7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7) [8]	All Proposed FY 2020 Changes (8) [9]
Rural by Region:									
New England	20	3	0.5	-0.8	0.6	-0.1	0	0.2	2.3
Middle Atlantic	53	2.8	0.1	-0.2	0.9	-0.1	0	0	3.1
South Atlantic	120	2.9	0	0	1.4	-0.1	0	0.7	3.6
East North Central	114	2.8	0.3	0	0.9	-0.1	0	0.1	3.4
East South Central	150	3	0	0.4	1.8	-0.2	0.1	1.1	4.3
West North Central	93	2.5	0.3	0.2	0.1	0.1	0	0.1	3.3
West South Central	142	3	0.3	0	1.5	0	0.1	0.8	4.5
Mountain	50	2.6	0.6	0.3	0.1	-0.1	0.6	0	3.3
Pacific	24	2.8	0.7	0.1	1	-0.1	0	-0.2	3.6
By Payment Classification:									
Urban hospitals	2,188	3.1	0	0	-0.6	0	0.1	-0.1	3.5
Large urban areas	1,283	3.1	-0.1	0	-0.7	-0.1	0.1	-0.2	3.4

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2020 MGCRB Reclassifications (4) [5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6) [7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7) [8]	All Proposed FY 2020 Changes (8) [9]
Other urban areas	905	3.1	0.1	-0.1	-0.3	0.3	0.2	0.1	3.8
Rural areas	1,054	3	0	0.1	1.5	-0.1	0.1	0.2	3.5
Teaching Status:									
Nonteaching	2,127	3.1	0.1	0	0.1	0.1	0.1	0.1	3.6
Fewer than 100 residents	865	3.2	0	0	-0.1	0	0.2	0	3.5
100 or more residents	250	3.1	-0.1	0	0	-0.2	0	-0.1	3.5
Urban DSH:									
Non-DSH	538	3.1	0.3	0	-0.3	-0.2	0.2	0	3.7
100 or more beds	1,393	3.1	0	-0.1	-0.5	0.1	0.1	-0.1	3.5
Less than 100 beds	352	3.1	0.3	-0.1	-0.8	0.1	0.1	0	3.4
Rural DSH:									
SCH	256	2.6	0.1	0	-0.1	0	0	0.2	3
RRC	442	3.1	-0.1	0.2	1.8	-0.1	0.1	0.1	3.5
100 or more beds	31	3.2	0.1	-0.6	1.1	-0.2	0	0.3	2.9

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2020 MGCRB Reclassifications (4) [5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6) [7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7) [8]	All Proposed FY 2020 Changes (8) [9]
Less than 100 beds	230	2.9	0.9	-0.1	0.5	-0.1	0.2	1.3	5.1
Urban teaching and DSH:									
Both teaching and DSH	776	3.1	-0.1	-0.1	-0.7	0	0.1	-0.1	3.5
Teaching and no DSH	84	3.2	0.3	-0.1	-0.4	-0.2	0.1	-0.2	3.7
No teaching and DSH	969	3.2	0	-0.1	-0.3	0.3	0.1	0	3.5
No teaching and no DSH	359	3.1	0.3	0	-0.7	-0.1	0.2	-0.1	3.9
Special Hospital Types:									
RRC	380	3.2	0	0.1	2	-0.1	0.2	0.1	3.7
SCH	305	2.6	0.2	-0.1	-0.1	0	0	0.1	3.1
MDH	149	2.8	0.5	-0.1	0.6	-0.1	0.1	0.6	4
SCH and RRC	143	2.7	-0.1	0	0.3	0	0	0.1	2.9
MDH and RRC	17	2.9	-0.2	-0.1	0.4	-0.1	0	0.2	2.6
Type of Ownership:									

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2) [3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3) [4]	FY 2020 MGCRB Reclassifications (4) [5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5) [6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6) [7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7) [8]	All Proposed FY 2020 Changes (8) [9]
Voluntary	1,893	3.1	0	0	0	0	0.1	0	3.5
Proprietary	852	3.1	0.1	0	-0.1	0	0.1	0.2	3.6
Government	496	3	-0.1	-0.1	-0.1	0.1	0	0	3.6
Medicare Utilization as a Percent of Inpatient Days:									
0-25	596	3.1	-0.2	0.1	-0.3	0	0	-0.1	3.4
25-50	2,122	3.1	0	0	0	0	0.1	0	3.6
50-65	414	3	0.2	-0.1	0.4	0.2	0.1	0.1	3.2
Over 65	73	2.3	1.9	0.3	-0.7	-0.1	0.7	1.2	7.2
FY 2020 Reclassifications by the Medicare Geographic Classification Review Board:									
All Reclassified Hospitals	957	3.1	0	0.1	1.7	-0.1	0.1	0	3.4

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Frontier State Wage Index and Proposed Outmigration Adjustment (6)[7]	Application of Proposed Lowest Quartile and Highest Quartile Wage Index Policies and Proposed Transition (7)[8]	All Proposed FY 2020 Changes (8)[9]
Non-Reclassified Hospitals	2,285	3.1	0	0	-1	0.1	0.1	0	3.6
Urban Hospitals Reclassified	679	3.1	-0.1	0.1	1.7	-0.1	0.1	0	3.3
Urban Non-Reclassified Hospitals	1,753	3.1	0	0	-1.1	0.1	0.1	0	3.6
Rural Hospitals Reclassified Full Year	278	2.9	0	0.1	1.9	-0.1	0	0.3	3.4
Rural Non-Reclassified Hospitals Full Year	441	2.8	0.5	0	-0.4	0	0.1	0.7	4
All Section 401 Reclassified Hospitals	335	3.1	-0.1	0.2	1.7	-0.1	0.2	0.1	3.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	47	3.1	0.2	-0.1	1.6	-0.1	0	0.3	3.4

[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 2018, and hospital cost report data are from reporting periods beginning in FY 2017 and FY 2016.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 2.7 percent adjustment to the national standardized amount and the proposed hospital-specific rate (the estimated 3.2 percent market basket update reduced by 0.5 percentage point for the proposed multifactor productivity adjustment), and the 0.5 percentage point 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 37 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2018 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 0.998768 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 2016 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 1.000915.
[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). T he effects demonstrate the FY 2020 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2020. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.986451.
[6] This column displays the effects of the proposed rural floor. For FY 2020 and subsequent years, we are proposing to calculate the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103. The statute 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 0.996316.
[7] This column shows the combined impact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wage index no less than 1.0 and of section 1886(d)(13) of the Act, as added by section 505 of Pub. L. 108-173, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.
[8] This column displays the effect of the proposal to increase the wage index for hospitals with a wage index value below the 25th percentile wage index (that is, the proposed lowest quartile wage index adjustment), the associated budget neutrality decrease to the wage index for hospitals with a wage index value above the 75th percentile (that is, the proposed highest quartile wage index adjustment), and the proposed transition policy to place a 5-percent cap on any decrease in a hospital's wage index from its final wage index in FY 2019 (that is, the proposed 5-percent cap). This column reflects the proposed budget neutrality factor of 0.998349 for the proposed 5-percent cap.
[9] This column shows the estimated change in payments from FY 2019 to FY 2020.