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FINAL RULE
Fiscal Year 2020 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Final Rule
SUMMARY

On August 2, 2019, the Centers for Medicare & Medicaid Services (CMS) released its final 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 final rule will be published in the *Federal Register* on August 16, 2019.

The payment rates and policies described in the IPPS/LTCH final rule (CMS-1716-F) affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in long-term care hospitals paid under their respective prospective payment systems. The final rule also sets forth rate-of-increase limits for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals, and religious nonmedical health care institutions, which are paid based on reasonable costs.

CMS makes many data files available to support analysis of the final rule. These data files are generally available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-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-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending.

TABLE OF CONTENTS

TABLE OF CONTENTS	

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

CMS estimates that policies and rates in the final rule would increase combined operating and capital payments to approximately 3,300 acute care hospitals paid under the IPPS by about $3.9 billion in FY 2020 compared to FY 2019. The rule indicates that the increase results from an

additional $3.5 billion in IPPS operating and uncompensated care payments and $0.4 billion in IPPS capital and new technology add-on payments.

A. Inpatient Hospital Operating Update

The final rule would increase IPPS operating payment *rates* by 3.1 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 3.1 percent rate increase is the net result of a market basket update of 3.0 percent less an annual multi-factor productivity (MFP) adjustment of 0.4 percentage points; and an adjustment of +0.5 percentage points required under section 414 of the MACRA. 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 2.6 percent increase rather than a 3.1 percent increase.

Factor	Percent Change
FY 2020 Market Basket	3.0
Multifactor productivity adjustment	-0.4
MACRA Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	3.1

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 3.0 percent equal to -0.75 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 2.25 percentage points.

CMS estimates that 41 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; 167 hospitals because they are not meaningful EHR users; and 30 hospitals are estimated to be subject to both reductions.

The final update for hospitals that have not successfully submitted quality data will be 1.85 percent for FY 2020. The reduction to the update is applied before application of the MACRA documentation and coding adjustment and equals the 2.6 percent market basket net of MFP less 0.75 percentage points.

Hospitals that do not qualify as meaningful EHR users will receive an update of 0.35 percent for FY 2020. This update is also applied before application of the MACRA documentation and coding adjustment and equals the 2.6 percent market basket net of MFP less 2.25 percentage points.

Hospitals that have neither successfully submitted quality data nor qualified as meaningful EHR users will receive an update of -0.4 percent or the 2.6 percent market basket net of MFP less 3.0 percentage points (the entire market basket).

B. Payment Impacts

CMS' impact table for IPPS operating costs shows final FY 2020 payments increasing 2.9 percent. Not all policy changes are reflected in this total. For example, the total does not include increases in uncompensated care payments. The factors that are included in this total are:

Contributing Factor	National Percentage Change
FY 2020 increase in payment rates	+3.0[1]
Frontier hospital wage index floor and out-migration wage adjustment	+0.1[2]
Outliers	-0.13[3]
Residual	-0.14[4]
Total	+2.9[4]

[1]Weighted average of hospital-specific rate update of 2.6 and 3.1 percent for all other hospitals.
[2]The frontier hospital wage index floor increases payments about $64 million to 44 hospitals and the out-migration adjustment increases payments about $44 million to 176 providers.
[3] CMS has no actual FY 2019 claims data upon which to make an estimate of its FY 2019 outlier payments.
[4]CMS explains the residual and the total may be explained by "interactive effects among various factors" that CMS cannot isolate.

Table I Impact Analysis

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

Hospital Type	All Final Rule Changes
All Hospitals	2.9%
Large Urban	2.8%
Other Urban	3%
Rural	2.8%
Major Teaching	2.9%
Puerto Rico	14.8%

To the extent a given hospital category impact deviates from the national average of 2.9 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 policy that is budget neutral. The redistributive payment changes are reasonably modest in impact with two exceptions. Reclassification tends to favor rural areas (although other factors may offset that benefit). Most of the redistributive impact appears to be from CMS' policy to raise wage indexes below the 25th percentile by ½ of the difference between the hospital's own wage index and the 25th percentile wage index. This policy explains why hospitals in Puerto

Rico are seeing a much larger increase than the average for all hospitals nationwide. Puerto Rico hospitals have long since had lower wage indexes that hospitals in the United States.

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 is approving 9 of 13 applications for NTAP (3 applicants withdrew their applications prior to the issuance of the final rule and one did not receive FDA approval for its technology by the July 1 deadline) and continuing NTAP for an additional 9 technologies approved in prior years. Further, CMS is raising the marginal cost factor from 50 to 65 percent (75 percent for qualified infectious disease products (QDIP)) of the lower of: 1) the cost of the new technology; or 2) the amount by which the costs of the case exceed the standard MS-DRG payment for the case.

For the 18 technologies receiving NTAP payment in FY 2020, CMS estimates that changing the marginal cost factor will increase spending by $94 million. The total spending for NTAPs in FY 2020 is estimated at just under $400 million.

CMS is also adopting a policy that new technologies will meet the newness and substantial clinical improvement criteria if a device is part of the FDA's Breakthrough Devices and a medical product is designated by the FDA as a QIDP and receives FDA market authorization. This policy will not begin until FY 2021 and has no FY 2020 costs.

Low Volume Hospitals. CMS estimates a decrease of $7 million associated with the low-volume hospital policy. This estimate is based on 594 providers receiving approximately $442 million in FY 2020 compared to 60 providers receiving approximately $449 million in FY 2019.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to increase by 0.94 percent or just under $80 million. More detail on these calculations is in section IV. F.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is reduce FY 2020 payments to an estimated 2,583 hospitals or 85 percent of all hospitals. The readmissions penalty is estimated to affect 0.69 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. CMS includes an unnumbered table that illustrates the average net percentage payment adjustment by category of hospital (e.g. Large Urban, Other Urban, Rural, etc.) in FY 2020.

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 792 of 3,169 non-Maryland hospitals with a HAC score.

Rural Community Hospital Demonstration Program. CMS expects that the Rural Community Hospital Demonstration Program will have a net cost of $25.7 million in FY 2020 (a total cost in FY 2020 of $61 million less about $35 million to account for adjustments for updated estimates from prior years). CMS is applying a budget neutrality adjustment to the standardized amounts for this cost.

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] = 2.6 percent
- Hospital did NOT submit quality data and is a meaningful EHR user (applicable percentage increase = 1.85 percent)
- Hospital submitted quality data and is NOT a meaningful EHR user (applicable percentage increase = 0.35 percent)
- Hospital did NOT submit quality data and is NOT a meaningful EHR user (applicable percentage increase = -0.4 percent)

The applicable percentage changes listed above are prior to budget neutrality factors applied to the standardized amount and other non-budget neutral adjustments pertaining to documentation and coding. The updated standardized amounts for the final rule were calculated 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, 0.997649 (a decrease of 0.24 percent);
- Wage index, 1.001573 (an increase of 0.16 percent);
- Geographic reclassification, 0.985425 (a reduction of 1.46 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.997987 or -0.20 percent;
- Budget neutrality for a 5 percent cap on reductions to wage indexes of 0.998838; and
- The outlier offset factor is 0.949.

The net increase in the operating standardized amounts from FY 2019 to FY 2020 is 2.75 percent including the IPPS update of 2.6 percent, the MACRA documentation and coding adjustment of +0.5 percent and the miscellaneous adjustments described above that bring the total increase down to 2.75 percent. Of the adjustments above, MS-DRG recalibration and wage index is maintained on the standardized amount from year-to-year. The prior year geographic reclassification and outlier adjustments are removed from the FY 2019 standardized amount before the FY 2020 adjustment is applied (outlier is always 0.949). The budget neutrality adjustments for increase in wage indexes below the 25th percentile and the 5 percent cap on reductions to the wage index are new for FY 2020.

The capital rate increases by 0.7 percent from $459.41 to $462.61. The combined increase in the operating standardized amount and the capital rate will be 2.6 percent for 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 =2.6 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$3,962.17	$1,838.96	$3,875.28	$1,798.63	$3,933.21	$1,825.52	$3,846.32	$1,785.19

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 =2.6 Percent)		Hospital Submitted Quality Data and is a NOT a Meaningful EHR User (Update = 0.35 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update =1.85 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.4 Percent)	
Labor	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**	**Labor**	**Nonlabor**
$3,596.70	$2,204.43	$3,517.82	$2,156.09	$3,570.41	$2,188.32	$3,491.54	$2,139.97

TABLE 1D. CAPITAL STANDARD FEDERAL PAYMENT RATE	
	Rate
National	$462.61

Note that the standardized amounts do not include the 2 percent Medicare sequester reduction that began in 2013 and will continue until at least 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.

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 (90 percent for patients in the burn DRGs).

FY 2020 outlier threshold. CMS is adopting an outlier threshold for FY 2020 of $26,473. 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 5.42 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.946112 to the capital federal rate to fund operating and capital outlier payments respectively.

FY 2020 outlier threshold methodology. CMS is following past practice targeting 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 final 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 adjusted for 2 years of inflation; from FY 2018 to FY 2020.

Charges. Commenters on prior proposed rules expressed concern about being unable to replicate the charge inflation factor used to update two-year old charge data to set the threshold. In response to this concern, CMS proposed to use older fiscal year data rather than more recent calendar year data to estimate the charge inflation factor because: 1) the data can be made publicly available so commenters can replicate CMS' charge inflation factor; and 2) the data includes more claims run-off after the end of the fiscal period and is more complete.

Comment/Response: Commenters supported CMS' proposal.

Final Decision: Finalize as proposed. For the FY 2020 final rule, CMS is using publicly available MedPAR files from March 2019 for the FY 2018 charge data. As these data are publicly available, CMS is no longer providing a table of quarterly charges that it used to determine the charge inflation factors. Nor is it providing a separate public use file of the monthly charge data which was also done in the past.

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 $58,422.22 ($565,500,080,304/9,679,538) for FY 2017 to the average covered charge per case of $61,579.19 ($586,179,656,482/9,519,120) for FY 2018. This rate-of-change is 5.4 percent (1.054371) or 11.1 percent (1.110994) over 2 years.

CCRs. CMS is using hospital CCRs from the March 2019 update to the Provider-Specific File (PSF) – the most recent data available for the final rule – and to apply an adjustment factor to the CCRs to account for cost and charge inflation. The adjustment methodology compares the national average case-weighted operating and capital CCRs from the most recent (March 2019) update of the PSF to the national average case-weighted operating and capital CCRs from the same period of the prior year (March 2018 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 March 2018 operating national average case-weighted CCR of 0.260798, a March 2019 operating national average case-weighted CCR of 0.254578. The percentage change between these two figures is -2.4 percent or 0.976150. This figure is the final rule national operating CCR adjustment factor. The same methodology applied to the capital CCRs produces a March 2018 capital national average case-weighted CCR of 0.021618 and March 2019 capital national average case-weighted CCR of 0.020794. The percentage change between these two figures is -3.8 percent or 0.961884.

For estimating the outlier threshold for FY 2020, CMS's calculation will reflect application of the floor on the wage index of eligible hospitals in frontier states and adjustments to the wage index for outmigration as well as new policies to: 1) increase the wage index for hospitals with a wage index below the 25th percentile wage index value across all hospitals, and (2) apply a 5 percent cap for FY 2020 on any decrease in a hospital's final rule wage index from its FY 2019 wage index.

Reconciliation. Unlike in past years, CMS will reflect the potential for outlier reconciliation in the determination of the FY 2020 outlier threshold. 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 proposed 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 indicated 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 final rule, CMS is using the March 2019 extract of the Hospital Cost Report Information System (HCRIS).

CMS proposed to determine reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2014 for FY 2020). It then proposed 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. In the proposed rule, CMS estimated that reconciliation in FY 2014 resulted in 16 hospitals being owed $24.3 million or -0.03 percent of total operating IPPS payments. In the final rule, CMS indicates that it used 22 cost reports for estimating operating reconciliation payments and the figure is now -0.04 percent.

As reconciliation resulted in CMS owing hospitals money rather than hospitals owing CMS money, CMS is adding this 0.04 percentage points to 5.1 percent to target outliers as 5.14 percent of total IPPS operating payments. CMS believes targeting outlier payments at 5.14 percent with reconciled outlier payments equaling -0.04 percent of total IPPS operating payment will result in an estimated 5.1 percent of total IPPS operating payments being paid as outliers. CMS is continuing its practice of reducing the standardized amounts by 5.1 percent (0.949) to fund the outlier pool.

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 proposed 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 -0.08 percent (a change from -0.05 percent in the proposed rule) based $6.2 in reconciled capital outlier payments for 19 hospitals.

Comment/Response: CMS indicates that comments on the methodology for projecting the estimate of capital outlier reconciliation payments were similar to those for operating that were earlier summarized but appear to be missing from the final rule. The response to the capital outlier comments suggests that commenters believe data for the reconciliation adjustment should be drawn from a year earlier than FY 2014. CMS refers readers to its missing earlier response on outlier reconciliation.

Final Decision: Despite the missing the earlier language, the rule is clear that CMS is continuing to use FY 2014 cost report for the FY 2020 outlier reconciliation adjustment.

FY 2018 Outlier Payments. CMS' current estimate, using available FY 2018 claims data, is that actual outlier payments for FY 2018 were approximately 4.98 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. While CMS says in this section that FY 2019 claims data are unavailable to estimate the percentage of total payments made as outliers in FY 2019, the impact section says that 2019 outliers are approximately 5.23 percent of total payments based on FY 2018 data.

II. MS-DRG Classifications and Relative Weights

A. Adoption of the MS-DRGs and the 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 implementing a positive 0.5 percentage point adjustment to the standardized amount.

Comment/Response: There has been a continuing disagreement between public commenters and CMS regarding an additional 0.7 percentage point adjustment CMS made in FY 2017. Commenters believe that CMS is required to restore this adjustment to the standardized amount as it was intended to be a one-time temporary adjustment to recoup increased spending due to documentation and coding improvements. CMS disagrees and believes that Congress specified the precise adjustments to be restored to the standardized amount and did not include this additional 0.7 percentage point adjustment.

Final Decision: No change. It seems likely this issue will be resolved through litigation.

B. Recalibration of the 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, CMS uses two data sources:

- FY 2018 MedPAR data: Bills received through March 31, 2019 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) are excluded. CMS used data from approximately 9,514,788 million Medicare discharges regrouped using the FY 2020 MS-DRG classifications.
- FY 2017 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2017 cost reporting periods, using the March 31, 2019 update of the FY 2017 HCRIS.

Comment/Response: Several commenters expressed concern about a 29 percent reduction to relative weight for MS-DRG 215 (Other Heart Assist System Implant) proposed for FY 2020.

Including the proposed FY 2020 reduction, commenters stated the MS-DRG relative weight would be reduced by 43 percent since FY 2017. Commenters stated that the proposed reduction in the relative weight resulted from several coding changes, a new FDA indication for Impella®, an implantable device for the treatment of cardiomyopathy with cardiogenic shock and a high percentage of claims that do not include a charge for the device. Commenters requested that CMS maintain the relative weight at the FY 2018 relative weight.

CMS responded that it does not believe that it is normally appropriate to address relative weight fluctuations that appear to be driven by changes in the underlying data but acknowledges that this situation is an outlier with successive reductions in each of the 3 years since CMS began using the ICD–10 data in calculating the relative weights.

Final Decision: For FY 2020 only, CMS is maintaining an MS-DRG's relative weight at its FY 2018 value if:

- The FY 2018 relative weight declined more than 20 percent from its FY 2017 value; and
- The FY 2019 relative weight would decline by more than 20 percent in FY 2020 and the FY 2019 relative weight was maintained at its FY 2018 value.

CMS calculates the IPPS relative weights by reducing hospital charges to cost using CCRs for 19 distinct cost centers. For FY 2020, CMS not making any changes to its methodology and will calculate MS-DRG weights using national averages for the 19 CCRs. Accompanying the final 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-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

Select file #4 (FY 2020 Final Rule: HCRIS Data File).

The FY 2020 CCRs are shown in the following table.

Group	FY 2019 CCR	FY 2020 CCR
Routine Days	0.442	0.432
Intensive Days	0.368	0.358
Drugs	0.191	0.189
Supplies & Equipment	0.299	0.299
Implantable Devices	0.309	0.299
Therapy Services	0.304	0.297
Laboratory	0.113	0.109
Operating Room	0.179	0.173
Cardiology	0.103	0.098
Cardiac Catheterization	0.110	0.106
Radiology	0.145	0.140
MRIs	0.074	0.072
CT Scans	0.035	0.034
Emergency Room	0.159	0.152

Group	FY 2019 CCR	FY 2020 CCR
Blood and Blood Products	0.296	0.283
Other Services	0.345	0.346
Labor & Delivery	0.382	0.373
Inhalation Therapy	0.156	0.150
Anesthesia	0.078	0.077

The final cost-based relative weights were normalized by an adjustment factor of 1.789031 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.

For very low volume MS-DRGs (generally those for newborns), CMS maintains the prior year relative weight and adjusts it by the average change in the relative weight for all MS-DRGs.

C. 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. For the proposed rule, CMS' MS-DRG analysis was 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. For the final rule, CMS generally did not perform any further MS-DRG analysis of claims data.

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

CMS uses the criteria established in FY 2008 (72 *FR* 47169) to determine if the creation of a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS-DRG is warranted. In order to warrant the creation of a CC or MCC subgroup within a base MS-DRG, the subgroup must meet all five of the following criteria:

- A reduction in variance of costs of at least 3 percent;
- At least 5 percent of the patients in the MS-DRG fall within the CC or MCC subgroup;

- At least 500 cases are in the CC or MCC subgroup;
- There is at least a 20-percent difference in average costs between subgroups; and
- There is a $2,000 difference in average costs between subgroups.

The FY 2020 ICD-10 MS-DRG GROUPER and Medicare Code Editor (MCE) Software Version 37, the ICD-10 MS-DRG Definitions Manual files Version 37 and the Definitions of MCE Manual Version 37 are available on the CMS website.[1]
Highlights of CMS' discussions are summarized below; the reader is referred to the final 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 the 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. In the proposed rule, 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 noted that although it does not yet have Medicare claims data to evaluate the new peripheral ECMO procedure codes, review of limited registry data indicated that the costs for peripheral ECMO appear to be similar to costs for central ECMO. CMS proposed reassignment of the two ICD-10-PCS procedure codes for peripheral ECMO to Pre-MDC MS-DRG 003.

[1] This information is available at https://www.cms.gov/Medicare/MEdicare-Fee=for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html.

Several commenters agreed with the proposal. CMS disagrees with a few commenters' recommendations of alternative assignments to MS-DRG 215 instead of MS-DRG 003 until claims data was available for analysis. In response to comments that peripheral ECMO procedures should be O.R. procedures, CMS states it will continue to monitor cases to determine if adjustments are warranted to account for changes in resource consumption.

CMS **finalizes** its proposal to reassign procedure codes describing peripheral ECMO procedures from their current MS-DRGs to MS-DRG 003 and to maintain peripheral ECMO procedures as non-O.R. procedures. CMS also finalizes title changes to MS-DRGs 207,291, 296, and 870 to no longer reflect the "or Peripheral ECMO' terminology.

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 did not propose splitting 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 noted 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 noted that instructions (Pub. No. 100-04, Transmittal 3571, Change Request 9674, effective January 1, 2017) state the appropriate revenue code for allogeneic stem cell acquisition/donor is revenue code 0815. CMS will consider 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 proposed 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 and final rule.[2] CMS proposed to delete these 128 clinically invalid codes from the transfusion table.

Commenters agreed with CMS' proposals. CMS **finalizes** its proposal to (1) reassign the four ICD-10-PCS codes for HCT procedures specifying autologous cord blood as the donor source from MS-DRG 014 to MS-DRGs 016 and 017; and delete the 128 clinically invalid codes from the transfusion table in the ICD-10-PCS Classification and listed in Table 6P.1a associated with this rule.

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

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 proposed 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.

Several commenters supported the proposal and agreed that CMS should wait for more clinical and cost data. MedPAC also stated that incorporating new technologies into the Medicare program by using an existing MS-DRG combined with a new technology add-on payment and outlier payment created incentives for efficiency and risk-sharing between providers and Medicare. Several commenters encouraged CMS to develop a new MS-DRG for FY 2020 to adequately cover the costs of treatment and not dis-incentivize hospitals from providing CAR-T cell therapies due to inadequate reimbursement. CMS continues to believe it does not have the comprehensive data needed to create a new MS-DRG.

After consideration of comments, CMS **finalizes** its proposal not to modify the MS-DRG assignment for cases reporting CAR-T cell therapies for FY 2020.
In the proposed rule, CMS requested specific comments related to the potential creation of a new MS-DRG for CAR T-cell therapy procedures:

- What is the most appropriate way to develop the relative weight of a new MS-DRG?
- Would it be appropriate to geographically adjust payment under a new MS-DRG?
- What, if any, adjustments should be made for IME and DSH payments for cases assigned to a new MS-DRG?

Relative Weight. CMS received many comments on the most appropriate way to develop the relative weight and modify rate setting trims for a new MS-DRG. Suggestions included different

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

ways to determine the cost of the CAR T-cell therapy and technical comments on claims inclusion and exclusion criteria related to clinical trials.

Geographic Adjustment. Some commenters thought that CMS should include adjustments for the wage index in a future MS-DRG for CAR T-cell therapies and they did not think CMS had the statutory flexibility to selectively apply the wage index. Many other commenters thought CMS should not apply the wage index to the cost of the drug and agreed that the drug cost does not vary by location.

IME and DSH Adjustments. Several commenters thought CMS should include adjustments for DSH and IME in a future MS-DRG for CAR T-cell therapy and discussed the financial burdens of new, higher cost services provided at teaching hospitals. Some commenters did not think CMS had the statutory flexibility to selectively apply these adjustments. Many commenters did not think CMS should apply the DSH and IME adjustment to the entire MS-DRG payment for CAR T-cell therapy as this would result in a higher than appropriate payment.

In the proposed rule, CMS also requested broad comments on payment alternatives for CAR T-cell therapies. CMS requested comments about establishing a specific CCR for reporting procedures involving the use of CAR T-cell therapies. For example, stakeholders had 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 also requested 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 equals the maximum add-on payment.

CMS discusses the wide range of comments related to payment for CAR-T cell therapy products. Recommendations included paying based on the average sales price (ASP); Wholesale Acquisition Cost (WAC) plus six percent; and reasonable cost. Some commenters indicated that CMS should require providers to report value code 86 (the actual invoice/acquisition cost) on their claims and include the actual product acquisition cost of the claim for payment purposes. Many commenters requested a new technology add-on payment percent of up to 100 percent for CAR T-cell therapy products.

CMS also requested comments about establishing a specific CCR for reporting procedures involving the use of CAR T-cell therapies. Several commenters suggested a CCR of 1.0 for CAR T-cell products for all payment purposes, including new technology add-on payments, outlier payments, and payments to IPPS-excluded cancer hospitals. MedPAC expressed concern about using a CCR of 1.0 because it would presume hospitals charged their actual costs and recommended the use of a lagged ASP based payment. One commenter cautioned CMS from using a CCR of 1.0 because it was a radical departure from previous payment methods. Some commenters suggested that CMS consider alternative payment models for CAR T-cell therapy based on outcome and value.

CMS appreciates the comments it received. CMS continues to believe it would be premature to adopt structural changes to its existing payment mechanisms for CAR T-cell therapy. CMS will

consider all the comments in any future rulemaking related to the MS-DRG assignment for CAR-T cell therapy.

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

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 were not properly assigned. Based on analysis from the FY 2018 MedPAR file and input from CMS' clinical advisors, CMS proposed to remove these procedure codes from MS-DRGs 034, 035, and 036 (Carotid Artery Stent Procedures). CMS also identified 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 were 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". CMS proposed to delete procedure codes with the term "bifurcation". CMS proposes to remove the remaining valid procedure codes from MS-DRGs 037, 038, and 038. Several commenters supported these proposals. In response to a comment disagreeing with the proposal to delete the qualifier term "bifurcation" from procedure codes, CMS notes that the term bifurcation describes diagnosis related information which is generally not including in the ICD-10-PCS procedure classification.

After consideration of comments, CMS **finalizes** these proposals. It finalizes removing the procedure codes listed in the final rule from MS-DRGs 034, 035, and 036 that describe procedures which (1) do not include an intraluminal device; (2) describe procedures performed on arteries other than a carotid; and (3) describe procedures performed on a vein. A complete list of procedure codes removed from MS-DRGs 037, 038, and 039 is available in Table 6P.1b. associated with this final rule.

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). Commenters agreed and CMS **finalizes** its proposal to reassign cases reporting diagnosis code 126.01, 126.02, or 126.09 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 were substantial clinical and resource differences between the TMVR procedure and other procedures grouping to MS-DRGs 228 and 229 and that procedure code 02UGJZ was the only endovascular valve intervention with implant that maps to MS-DRGs 228 and 229. The requestor also noted 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.

Based on analysis of claims data and input from its clinical advisors, CMS proposed 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 proposed 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 proposed 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).

Several commenters agreed with the CMS' proposals. A few commenters recommended CMS delay the proposed reassignment of non-supplement transcatheter cardiac valve procedures to proposed new MS-DRGs 319 and 320 until more data is available. They thought CMS should give additional consideration given to clinical coherence. CMS does not agree with the need to delay the proposed reassignment of non-supplement transcatheter cardiac valve procedures. CMS' clinical advisors and several commenters supported grouping these other cardiac valve

[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).

procedures together because the procedure codes describe cardiac valve procedures with a percutaneous (transcatheter/endovascular) approach can be performed in a cardiac catherization laboratory, require special additional training and skills, and often require additional ancillary procedures and equipment. CMS presents updated analysis supporting the reassignment of these procedures to the MS-DRGs 319 and 320.

After consideration of comments, CMS **finalizes** its proposals. CMS notes that consistent with its annual process of reviewing the MS-DRGs, it will continue to monitor cases to determine if any additional modifications are needed.

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.

Commenters agreed and CMS **finalizes** its proposal 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.

Based on analysis of claims data and input from its clinical advisors, CMS proposed to add only ICD-CM diagnosis code M00.9 to the list of principal diagnosis codes for MS-DRGs 485, 486, and 487. Commenters did not support CMS' proposal not to add ICD-CM diagnosis code A54.42 to the list of codes for these MS-DRGs. CMS' clinical advisors reviewed this issue and agree with the commenters.

After consideration of comments, CMS **finalizes** the assignment of both ICD-10-CM diagnosis codes M00.9 and A54.42 to the list of principal diagnosis 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. CMS proposed 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.

Many commenters agreed with CMS' proposal. CMS disagrees with a commenter who did not support the proposal. CMS **finalizes** its proposal to remove the eight diagnosis codes listed in the final rule from MS-DRGs 485, 486, and 487 and maintain the assignment of these codes to 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 proposed to add these ten diagnosis codes to MS-DRGs 485, 486, and 487.

Commenters agreed and CMS **finalizes** its proposal to add the ten diagnosis codes listed in the final rule 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).
Based on analysis of claims data and input from its clinical advisors, CMS proposed 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.
Commenters agreed and CMS **finalizes** its proposal.

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 proposed 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 proposed to remove these ICD-10-CM diagnosis codes involving the cervical region from MS-DRGs 456, 457, and 458.

Commenters agreed and CMS **finalizes** both of the above proposals.

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 would 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 was 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 currently 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. Based on CMS' analysis and input from its clinical advisors, CMS did not propose to add diagnosis codes N13.6 and T83.192A to the list of principal diagnosis codes for MS-DRGs 691 and 692. Commenters agreed and CMS **finalizes** its proposal.

CMS' clinical advisors recommended evaluation of the frequency that ESWL is reported across all the MS-DRGs. Based on CMS' analysis and input from its clinical advisors, CMS proposed 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).

Commenters agreed and CMS **finalizes** its proposal.

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 proposed to reassign these diagnosis codes to MS-DRGs 729 and 730 (Other Male Reproductive System Diagnoses).
Commenters agreed and CMS **finalizes** its proposal

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.
Based on CMS' analysis and input from its clinical advisors, CMS proposed 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. Commenters agreed and CMS **finalizes** its proposal.

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.

Based on CMS' analysis and input from its clinical advisors, CMS proposed to maintain the assignment of these procedure codes.

Commenters did not agree with CMS' proposal to maintain the assignment of these procedure codes. In response to these comments, the clinical advisors reviewed the claims data in the September 2018 update of the FY 2018 MedPAR file. The clinical advisors continue to believe these codes should be maintained within the current structure of MS-DRGs 927, 928, and 929. Therefore, CMS **finalizes** its proposal. It notes that as additional claims data becomes available, it can look at the assignment of these procedure codes in future rulemaking.

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 proposed to reassign diagnosis code R93.89 to MDC 23 in MS-DRGs 947 and 948 (Signs and Symptoms).
Commenters agreed and CMS **finalizes** its proposal.

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 proposed 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 proposed 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).

Commenters agreed and CMS **finalizes** its proposal.

(2) Peritoneal Dialysis Catheter Complications. CMS proposed 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.

Commenters agreed and CMS **finalizes** its proposal.

(3) Bone Excision with Pressure Ulcers. CMS proposed 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.

CMS disagrees with comments that it was not appropriate for procedures performed on muscles to be grouped to MS-DRGs for skin and subcutaneous tissues. It notes that all pressure ulcers,

including those that extend to the muscle or bone are assigned to MDC 9. CMS' clinical advisors do not agree with the comment that these procedures should be assigned to MDC 8.
After consideration of comments, CMS **finalizes** its proposal to add ICD-10-PCS procedure codes describing excision of the sacrum, pelvic bones and coccyx to MDC 9 in MS-DRGs 579, 580, and 581.

(4) Lower Extremity Muscle and Tendon Excision. CMS proposed 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).
A commenter supported this proposal; other commenters did not because they thought that muscle and tendon procedures are more resource intensive than skin procedures. CMS' clinical advisors continue to believe that these procedures are clearly related to the principal diagnoses assigned to MDC 10 with which they are most frequently reported.
After consideration of comments, CMS **finalizes** its proposal.

(5) Kidney Transplantation Procedures. CMS proposed 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.

Commenters opposed CMS' proposal and raised concerns the proposal would reduce the reimbursement for kidney transplantation of recipients with serious cardiac conditions by 33 percent. Commenters stated that cases involving both chronic kidney disease and heart failure should not be paid less that cases involving patients without serious comorbid conditions. In response to comments, CMS believes it would be appropriate to take addition time to review the concerns raised by comments.

After consideration of comments, CMS **does not finalize** its proposal. Cases reporting a principal diagnosis in MDC 5 with a procedure describing kidney transplantation will continue to group to MS-DRGs 981 through 983.

(6) Insertion of Feeding Device. CMS proposed 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).

After consideration of comments, CMS **finalizes** its proposal to add ICD-10 procedure code 0DH60UZ to MDC 1 and MDC 10.

(7) Basilic Vein Reposition in Chronic Kidney Disease. CMS proposed 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).

Commenters agreed and CMS **finalizes** its proposal.

(8) Colon Resection with Fistula. CMS proposed 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).

After consideration of comments, CMS **finalizes** its proposal.

b. Reassignment of Procedures.

CMS **finalizes** its proposal 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 proposed 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).

A commenter supported this proposal; other commenters did not because they stated it was not appropriate for procedures performed on muscles to group to MS-DRGs for skin and subcutaneous tissue and transfer procedures were more resource intensive than grafts to the skin and subcutaneous tissue. CMS' clinical advisors agree that procedures performed on muscles would not generally be expected to group to MS-DRGs for skin and subcutaneous tissues. The clinical advisors, however, continue to believe that these cases involving hip muscle transfer represent a distinct, recognizable clinical group which is similar to those cases in MS-DRGs 573, 574, and 575, and that the procedures are clearly related to the principal diagnosis codes. After consideration of comments, CMS **finalizes** its proposal to add ICD-10-PCS procedure codes 0KXP0ZZ and 0KXN0ZZ to MDC 9.

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

(3) Finger Cellulitis. CMS proposed 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).
A commenter supported this proposal; other commenters did not because they thought it was not clinically appropriate for bone procedures to be grouped to skin and subcutaneous tissue MS-DGRs and that the small number of cases suggests there may be a coding issue. CMS' clinical advisors believe it is clinically appropriate for the procedures to group to the same MS-DRGs as the principal diagnoses and note that procedures describing excision of phalanx with the diagnostic qualifier "X" are assigned to these MS-DRGs.

After consideration of comments, CMS f**inalizes** its proposal to add procedure codes describing excision and resection of phalanx, listed in the final rule, to MS-DRGs 579, 580, and 581 in MDC 9.

(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 proposed 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).
Commenters agreed and CMS **finalizes** its proposal to add ICD-10-PCS procedure codes 0DW64CZ and 0DP64CZ to MDC 6 in MS-DRGs 326, 327, and 328.

(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 proposed 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.

CMS disagrees with a comment that this issue should be reevaluated and provides additional clarification about coding specific pelvic vein. CMS **finalizes** its proposal to add ICD-10-PCS procedure code 06LB3DZ to MDC 12 in MS-DRGs 715 through 718 and to MDC 13 in MS-DRGs 749 and 750.

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;

[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.

- 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 (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 proposed 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.

Some commenters agreed with this proposal; others disagreed because of the complexity of the procedure and thought CMS should not reassign any procedures until it has completed its comprehensive review. CMS **finalizes** its proposal.

(2) Percutaneous Drainage of Pelvic Cavity. CMS proposed 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.
Some commenters agreed with this proposal and a commenter thought CMS should not reassign any procedures until it has completed its comprehensive review. CMS **finalizes** its proposal.

(3) Percutaneous Removal of Drainage Device. CMS proposed 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.
Some commenters agreed with this proposal and a commenter thought CMS should not reassign any procedures until it has completed its comprehensive review. CMS **finalizes** its proposal.

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

(1) Percutaneous Occlusion of Gastric Artery. CMS proposed 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 noted 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.

Some commenters agreed with this proposal and a commenter thought CMS should not reassign any procedures until it has completed its comprehensive review. CMS **finalizes** its proposal.
(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 did not propose to change the current non-O.R. designation of the eight procedure codes describing endoscopic insertion of an endobronchial valve.

Commenters disagreed with the proposal for a variety of reasons including the skill level, anesthesia requirements, and the severity level of the patients. Commenters had several suggested reassignments for the eight procedures. In addition, commenters thought CMS should not reassign these procedures until it has completed its comprehensive review. CMS agrees that there may be a need to further refine surgical MS-DRGs 163 through 167 and evaluate procedures designated as O.R. and non-O.R. CMS's clinical advisors, however, continue to believe that the endoscopic insertion of an endobronchial valve should be designated as an O.R. procedure and they did not support reassigning these procedures to MS-DRGs 981, 982 and 983 as those MS-DRGs are defined by procedures designated as extensive O.R. procedures.
After consideration of comments, CMS **finalizes** the designation of the eight procedure codes listed in the final rule that describe endoscopic insertion of an endobronchial valve as non-O.R. affecting MS-DRGs 163, 164, and 165.

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

a. 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.

[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.

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 received many comments on these proposed changes, with the majority of commenters requesting that the adoption of the proposed changes be delayed providing additional time to evaluate the broad scope of this proposal. After consideration of comments, **CMS does not finalize its proposed changes with the exception of the proposed changes to the codes related to antimicrobial resistance**.

CMS agrees with comments expressing concerns related to the public health crisis from antimicrobial resistance. CMS believes it is appropriate to change the severity level designation from non-CC to CC for the ICD-10 diagnosis codes specifying antibiotic drug resistance. CMS **finalizes** a change to the severity level for all codes in category Z16 (Resistance to antimicrobial drugs) from non-CC to CC designation (see table in final rule).

b. Requested Changes to Severity Levels.

CMS received seven requests for changes to severity levels of ICD-10-CM diagnosis codes for FY 2020. These requests included (1) Acute right heart failure; (2) Chronic right hear failure; (3) Ascites in alcoholic liver disease and toxic liver disease; (4) Factitious disorder imposed on self; (5) Nonunion and malunion of physeal metatarsal fractures; (6) Other encephalopathy; and (7) Obstetrics chapter codes. Based on review of review of data and input from its clinical advisors, CMS did not propose any changes to the severity levels of any of the requested diagnosis codes.

Some commenters disagreed with CMS' proposal not to change any of the severity levels. As discussed above, CMS is not generally finalizing any of its proposed changes to the severity level designations. Similarly, CMS is **not finalizing any proposed changes** to the obstetric chapter diagnosis codes. CMS will consider the public comments it received on the external requests for changes to severity level designations as it reviews and considers the public comments on its comprehensive CC/MCC analysis.

d. Additions and Deletions to the Diagnosis Code Severity Levels.

The following tables identify the additions to the MCC severity list and the additions to the CC severity list for FY 2020:

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

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

e. 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. Since CMS is not finalizing the proposed changed to the severity level designations, the following tables identify the changes to the ICD-10 MS-DRGs Version 36 CC Exclusion List.

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 Number	Table Title
6A	New Diagnosis Codes
6B	New Procedure Codes
6C	Invalid Diagnosis Codes
6D	Invalid Procedure Codes
6E	Revised Diagnosis Code Titles
6F	Revised Procedure Code Titles
6G.1	Secondary Disorders Order Additions to the CC Exclusion List
6G.2	Principal Disorders Order Additions to the CC Exclusion List
6H.1	Secondary Disorders Order Deletions to the CC Exclusion List
6H.2	Principal Disorders Order Deletions to the CC Exclusion List
6I.1	Additions to the MCC List
6I.2	Deletions to the MCC List
6J.1	Additions to the CC List
6J.2	Deletions to the CC List

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

16. 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 final 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 finalized for MDC 5 (Diseases and Disorders of the Circulatory System) CMS **finalizes** 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. Information on ICD-10-CM diagnosis codes can be found on the CDC website at http://www.cdc.goc/nchs/icd/icd10.htm.

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 2020, CMS finalized its proposal 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 reassigned assignment to new MS-DRGs 319 and 320. CMS **finalizes** its proposal to add 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 revises 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 changes are reflected in the table below (reproduced from the final 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
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC
MDC 03	129	Major Head & Neck Procedures with CC/MCC or Major Device
MDC 03	130	Major Head & Neck Procedures without CC/MCC
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC

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

D. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(K) and (L) of the Act establishes 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, 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 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]

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 they become 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

[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.

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.

3. ICD-10-PCS Section "X" Codes for Certain New Medical Services and Technologies

"X" codes 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. 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 latter half of the fiscal year.

For FY 2020, CMS **finalizes** its proposal to discontinue new technology add-on payments for:

- Defitelio® (Defibrotide),
- Ustekinumb (Stelara®), and
- Bezlotuxumab (ZINPLAVA™).

For FY 2020, CMS **finalizes** its proposal to continue nine new technology add-on payments for the new medical services and technologies listed below. As discussed in section II.H.9 of this summary, CMS finalizes its proposal to increase the maximum new technology add-on payment

[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.

to 65 percent, or 75 percent for certain antimicrobial products. This policy is reflected in the maximum add-on payments listed.

- KYMRIAH® (Tisagenleclucel) and YESCARTA® (Axicabtagene Ciloleucel) with the maximum new technology add-on payments at $242,450 For FY 2020. CMS estimates the FY 2020 add-on payments at approximately $93,585,700, based on 386 patients.
- VYXEOS™ (Cytarabine and Daunorubicin Liposome for Injection) with the maximum new technology add-on payments at $47,352.50 for FY 2020. CMS estimates the FY 2020 add-on payments at approximately $45,485,400, based on 960 patients.
- VABOMERE™ (meropenem-vaborbactam) with the maximum new technology add-on payments at $8,316 for FY 2020 (75 percent of the average cost of the technology). CMS also finalizes its proposal to identify cases involving VABOMERE™ with ICD-10-PCS codes XW033N5 or XW043N5 or NDCs 65-293-0009-01 or 70842-0120-01. CMS estimates the FY 2020 add-on payments at approximately $22,020,768, based on 2,648 patients.
- remedē® System with the maximum new technology add-on payments at $22,425 for FY 2020. CMS estimates the FY 2020 add-on payments at approximately $1,794,000, based on 80 patients.
- ZEMDRI™ Plazomicin with the maximum new technology add-on payments at $4,083.75 for FY 2020 (75 percent of the average cost of the technology). CMS estimates the FY 2020 add-on payments at approximately $10,209,375, based on 2,500 patients.
- Giapreza™ with the maximum new technology add-on payments at $4,083.75 for FY 2020. CMS estimates the FY 2020 add-on payments at approximately $11,173,500, based on 5,730 patients.
- Sentinel® Cerebral Protection System with the maximum new technology add-on payments at $1,820 for FY 2020. CMS estimates the FY 2020 add-on payments at approximately $11,830,000, based on 6,500 patients.
- AQUABEAM System with the maximum new technology add-on payments at $1,625 for FY 2020. CMS disagrees with comments that the beginning of the newness period should not be the date FDA granted the De Novo request for the therapy because Aquabeam therapy was assigned a CPT Category III code and was non-covered by the Medicare Administrative Contractors. CMS notes that Category III codes are not recognized on inpatient claims and maintains the newness period began December 21, 2017. CMS estimates the FY 2020 add-on payments at approximately $677,625, based on 417 patients.
- AndexXa™ (andexanet alfa) with the maximum new technology add-on payments at $18,281.25 for FY 2020. CMS estimates the FY 2020 add-on payments at approximately $98,755.313, based on 5,402 patients.

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

For FY 2020, CMS received 18 applications for new technology add-on payments. 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.

Three applicants withdrew their applications: AbbVie Pharmaceuticals (the applicant for VENCLEXTA®), Somahlution (the applicant for DuraGraft®), and Nabriva Therapeutics (the applicant for CONTEPO™). One applicant, Merck (the applicant for Imipeneum, Cilastatin, and Relabactam (IMI/REL) Injection) did not receive FDA approval for its technology by July 1, 2019 and is not eligible for consideration for new technology add-on payments for FY 2020. The summary below provides a high-level discussion of the remaining 13 applications. **CMS approves nine of these applications for new technology add-on payments for FY 2020:** AZEDRA® (Ulratace® iobenguane Iodine-131) Solution, CABLIVI® (caplacizumab-yhdp), ELZONRIS™ (tagraxofusp, SL-401), Balversa™ (Erdafitinib), ERLEADA™ (Apalutamide), SPRAVATO (Esketamine), XOSPATA® (gilteritinib), JAKAFI™ (Ruolitinib), and T2Bacteria® (T2 Bacteria Test Panel).

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[10]. 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 stated there are no curative treatment for these tumors and successful management of patients involves decreasing tumor burden, controlling endocrine activity, and treating debilitating symptoms.

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. Cases involving the use of AZEDRA® are identified by ICD-10-PCS codes XW033S5 and XW043S5.

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 stated 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.

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

After consideration of comments received supporting the applicant's assertion that AZEDRA® is not substantially similar to other current therapies, CMS agrees that that AZEDRA® utilizes a new mechanism of action, is not substantially similar to an existing technology and meet the criteria for newness.

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 number of cases under each MS-DRG was less than 11 in total), 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.

In response to CMS' concern about the limited number of cases for the analysis, the applicant stated that this is consistent with a product used to treat an ultra-rare disease. The applicant also noted that the cost information and analysis demonstrated that AZEDRA® will significantly exceed the relevant cost-threshold. After consideration of this comment, CMS believes that AZEDRA® meets the cost criterion.

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 acknowledged the challenges with constructing robust clinical studies due to the extremely rare occurrence of patients diagnosed with pheochromocytoma and paraganglioma tumors. CMS raised 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 received multiple comments in support of AZEDRA® and the applicant also provided additional information responding to CMS' concerns. In addition, the applicant highlighted AZEDRA®'s FDA Breakthrough Therapy, Fast Track, Priority Review, and Orphan Drug designations to demonstrate the meaningful efficacy and safety criteria that a product must meet to obtain these statuses.

After review of the comments, review of the additional information provided by the applicant, and review of the FDA Evaluation and Review of AZEDRA®, CMS believes the drug offers a treatment option for the FDA indicated approved population for whom no other FDA approved treatment is available. CMS discusses other related FDA documents it reviewed. CMS also discusses the FDA's postmarketing requirement (PMR) for the applicant to fully characterize the

risk of developing secondary malignancies. Risk management will also include product labeling and routine pharmacovigilance to ensure safe and effective use of ^{131}I-MIBG; CMS will also monitor any additional data as it becomes available.

CMS finalizes that AZEDRA® meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of AZEDRA® will be identified by ICD-10-PCS codes XW033S5 and XW043S5. The applicant estimated an average total cost per patient of approximately $151,000. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving AZEDRA® is $98,150. CMS estimates the FY 2020 add-on payments at approximately $39,269,000, based on 400 patients.

b. CABLIVI® (caplacizumab-yhdp)

The Sanofi Company submitted an application for CABLIVI®, a humanized bivalent nanobody[11] 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. CABLIVI® was granted approval for ICD-10-PCS procedure codes XW013W5, XW033W5, and XW043W5, effective October 1, 2019.

For the first criterion (same or similar mechanism of action), the applicant discussed 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 explained 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 noted there are no studies specifically comparing SOC treatment options and that these treatment options are not specifically approved for the treatment of aTTP.

[11] 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.

In response to CMS' concern that CABLIVI® does not treat a different type of disease or a different patient population than currently available treatment options, several commenters supported that CABLIVI® was a novel therapy and the applicant provided additional information about CABLIVI® mechanism of action.

After consideration of the comments and information submitted by the applicant in its application, CMS believes that although potential cases representing patients who may be eligible for CABLIVI® would be assigned to the same MS-DRGs as cases representing patients receiving SOC for aTTP, and that CABLIVI® is used to treat the same or similar disease and a similar patient population as current treatment options, CMS concludes that CABLIVI® does not use the same or similar mechanism of action as other aTTP treatment options. CMS concludes that CABLIVI® meets the newness criterion.

Cost. Based on the applicant's revised analysis, CMS concludes 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.

In the proposed rule, CMS acknowledged the challenges with constructing robust clinical studies due to the extremely rare occurrence of patients diagnosed with aTTP. CMS stated it was 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 was concerned that it may not have sufficient information to determine the extent to which the results are attributable to CABLIVI®. CMS was also concerned about the lack of long-term data. Another issue raised by CMS was that although both the studies included key secondary endpoints such as death or major thromboembolic events, it was concerned these endpoints were not clearly defined, and that other defined endpoints, such as heart attack, stroke and a bleeding episode, were not evaluated.

Several commenters provided comments in support of CABLIVI® including information demonstrating substantial clinical improvement. The applicant provided additional information to address CMS' concerns. CMS also notes that CABLIVI® is the only FDA-approved therapy for treating aTTP in conjunction with PE and immunosuppressive therapy. CMS believes that CABLIVI® meets the substantial clinical improvement criterion.

CMS finalizes that CABLIVI® meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of CABLIVI® will be identified by ICD-10-PCS codes XW013W5, XW033W5, and XW043W5. The average total cost of CABLIVI® per patient is $51,100. For 2020, using a maximum new technology add-on

payment of 65 percent, the add-on payment for a case involving CABLIVI® is $33,215. CMS estimates the FY 2020 add-on payments at approximately $4,351,165, based on 131 patients.

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. 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 stated the CivaSheet® configuration substantially reduces the dose delivered to neighboring radiosensitive structures. The applicant concluded 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 stated that clinical conditions that may require the use of CivaSheet® include treatment of the same patient population diagnosed with a variety of cancers.

After consideration of the applicant's comments, CMS believes CivaSheet® uses a mechanism of action unique from other brachytherapy technologies and meets the newness criterion.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes 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 was 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 was concerned that there are no comparisons to other current treatments, nor any long-term follow-up with comparisons to currently available therapies.

CMS discusses the comments it received, including information provided by the applicant which contained additional references and a summary of the clinical trials currently underway. CMS still believes the data remains limited and notes the clinical trials will not complete enrollment until 2020. CMS reiterates it's concerns with the supporting evidence and concludes it is unable to determine that CivaSheet® represents a substantial clinical improvement over existing technologies.

CMS finalizes that CivaSheet® does not meet the criteria for new technology add-on payments.

d. 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 stated 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 stated 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 stated 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 was 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.
The applicant provided additional information, including a comparison of the polymer matrix stent vs. the paclitaxel-coated stent. After consideration of the applicant's comments, CMS believes the device uses a unique mechanism of action and the Eluvia™ stent meets the newness criterion.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes the Eluvia™ stent 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 was concerned the IMPERIAL study, which showed significant differences in primary patency at 12 months, was designed for non-inferiority and not superiority.

CMS also discussed the results 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.[12] Although the Eluvia™ stent was not included in the meta-analysis, CMS invited comments on the implications of the meta-analysis results to a finding of substantial clinical improvement for the Eluvia™ stent.

The applicant provided additional information regarding CMS' concerns about the evidence submitted in support of substantial clinical improvement. The applicant does not believe the findings suggested in the meta-analysis should impact CMS determining the Eluvia™ stent meets the substantial clinical improvement criterion and stated that the Eluvia™ stent is different from the devices evaluated in the meta-analysis. In addition, several commenters supporting the Eluvia™ stent's application for new technology add-on payment. One comment expressed safety concerns with paclitaxel devices.

CMS discusses the information available from the FDA, including the June 19-20, 2019 Advisory Committee meeting of the Circulatory System Devices Panel[13]. CMS notes the FDA

[12] 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).
[13] Additional information is available at https://www.fda.gov/advisory-committees/advisory-committee-calendar/june-19-2019-circulatory-system-devices-panel-medical-devices-advisory-committee-meeting#event-materials.

continues to recommend that health care providers report any adverse events or suspected adverse experiences with the use of paclitaxel-coated devices. In addition, because the FDA believes alternative treatment options should generally be used for most patients while it continues to evaluate the increase long-mortality associated with paclitaxel-coated devices and the impact on the overall benefit-risk profile of these devices, CMS remains concerns it does not have enough information to determine that the Eluvia™ stent represents a substantial clinical improvement over existing technologies. CMS will monitor any new information or recommendations as they become available.

CMS finalizes that the Eluvia™ stent does not meet the criteria for new technology add-on payments.

e. 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 stated 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 stated 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. 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).

Based on the applicant's comments and information submitted in its application, CMS believes ELZONRIS™ has a unique mechanism of action that would treat a new patient population and meets the newness criterion.

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

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 raised 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 discusses the additional information the applicant presented to address CMS' concerns. The applicant noted that BPDCN is a very rare and highly aggressive hematologic malignancy, with an estimated incidence of 0.41/1,000,000 patient age-adjusted to the 2000 US standard population, corresponding to less than 100 new cases per year. After reviewing this information, CMS concludes that ELZONRIS™ is a substantial clinical improvement for a patient population unresponsive to, or ineligible, for currently available treatments.

CMS finalizes that ELZONRIS™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of ELZONRIS™ will be identified by ICD-10-PCS codes XW033Q5 and XW043Q5. CMS calculates the average total cost of ELZONRIS™ per patient is $192,997. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving ELZONRIS™ is $125,448.05. CMS estimates the FY 2020 add-on payments at approximately $30,985,668, based on 247 patients.

f. Balversa™ Erdafitinib

Johnson & Johnson (on behalf of Janssen Oncology, Inc) submitted an application for Balversa™ 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. Balversa™ is a pan-fibroblast FGFR inhibitor with potential antineoplastic activity.

Newness. Balversa™ 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 received accelerated FDA approval on April 12, 2019. Balversa™ was granted approval for the ICD-10-PCS code XW0DXL5 with an effective date of October 1, 2019.

For the first criterion (same or similar mechanism of action), the applicant asserted that Balversa™ 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 Balversa™ will be a specific subset of patients with FGFR genetic alterations.
Based on the information submitted in its application, CMS believes Balversa™ has a unique mechanism of action and meets the newness criterion.

Cost. Based on the information presented in the application (discussed in the proposed rule) and updated analysis submitted by the applicant, CMS concludes Balversa™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that Balversa™ provides a substantial clinical improvement for a select group of patients diagnosed with locally advanced or metastatic urothelial carcinoma who failed first-line treatment and have limited second-line treatment options by reducing mortality, decreasing pain and reducing recovery time. Balversa™ 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 Balversa™ 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 had several concerns with the information presented including there was no information comparing Balversa™ to existing therapies and the available data is based on a small sample size.

CMS discusses the additional information the applicant presented to address CMS' concerns. This includes information on data trends supporting an improved objective response rate (ORR) for Balversa™ when compared to other FDA approved medications for metastatic urothelial carcinoma. After reviewing this additional information, CMS concludes that Balversa™ meets the substantial clinical improvement criterion.

CMS finalizes that Balversa™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of ELZONRIS™ will be identified by ICD-10-PCS code XW03DXL5. CMS calculates the average total cost of Balversa™ per patient is $5,481.89. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving Balversa™ is $3,563.23. CMS estimates the FY 2020 add-on payments at approximately $178,1622, based on 50 patients.

g. 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. ERLEADA™ was granted approval for the ICD-10-PCS code XW0DXJ5 with an effective date of October 1, 2019.

For the first criterion (same or similar mechanism of action), the applicant maintained 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 stated 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.
Based on the information submitted in its application, CMS believes ERLEADA™ has a unique mechanism of action and meets the newness criterion.

Cost. Based on the information presented in the application (discussed in the proposed rule) and updated analysis submitted by the applicant, CMS concludes ERLEADA™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted 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 discussed several concerns with the information submitted including whether the SPARTAN trial results are generalizable to the US population and in particular, African-American patients. CMS discusses the additional information and analysis the applicant presented to address CMS' concerns. This included information on the treatment benefit evaluated by region and

subpopulations. After reviewing this additional information, CMS concludes Erdafitinib™ meets the substantial clinical improvement criterion.

CMS finalizes that Erdafitinib™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of ELZONRIS™ will be identified by ICD-10-PCS code XW03DXJ5. CMS calculates the average total cost of Erdafitinib™ per patient is $2,858.84. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving Erdafitinib™ is $1,858.25. CMS estimates the FY 2020 add-on payments at approximately $286,171, based on 154 patients.

h. 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 and CMS has not yet finalized a decision.

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 stated 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 asserted that patients receiving treatment with SPRAVATO will be a subset of patients receiving current anti-depressants.

After consideration of the applicant's comment and the information submitted in its application, CMS believes SPRAVATO has a unique mechanism of action and meets the newness criterion.

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 was 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 suggested that one-third of patients diagnosed with MDD often also have TRD, it was unclear which cases should be removed. It was 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 was also concerned that patients with TRD could account for the costliest of patients diagnosed with MDD.

The applicant provided additional information regarding CMS' concerns about the assumptions for the cost analysis and updated the analysis selecting the 1/3 of cases with the highest charges. This choice was made based on a study comparing Medicare beneficiaries with TRD and Medicare beneficiaries without TRD which found that the cost of the inpatient hospitalizations for the TRD cohort were higher. After consideration of the additional information and updated analysis, CMS concludes SPRAVATO meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted 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 summarized the information and discussed several concerns. CMS was 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 was 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, given SPRAVATO is comprised of the drug ketamine, CMS was 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 discusses the additional information the applicant submitted to address CMS' concerns. This included information about the FDA mandated Risk Evaluation and Mitigation Strategy (REMS) program and other procedures to mitigate potential risk for misuse and abuse in patients. The applicant stated that additional safeguards, such as safety surveillance and the restricted distribution of SPRAVATO to a limited number of wholesalers and distributers, are aimed at minimizing the risk of misuse. After reviewing this additional information, CMS concludes SPRAVATO meets the substantial clinical improvement criterion.

CMS finalizes that SPRAVATO meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of SPRAVATO will be identified by ICD-10-PCS code 3E097GC (Induction of Other Therapeutic Substance into Nose). The applicant estimates the average total cost of SPRAVATO per patient is $1,561.21. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving SPRAVATO is $1,014.79. CMS estimates the FY 2020 add-on payments at approximately $6,494,656, based on 6,400 patients.

i. 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 stated 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. XOSPATA® was granted approval for the ICD-10-PCS code XW0DXV5 with an effective date of October 1, 2019.
For the first criterion (same or similar mechanism of action), the applicant stated 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 indicated 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.
After consideration of the information submitted in its application, CMS believes XOSPATA® has a unique mechanism of action, treats a new patient population for which there are no other available treatments, and therefore meets the newness criterion.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes XOSPATA® 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 noted the applicant did not provide direct numbers for the comparator arm of the ADMIRAL study and was concerned that without this information, it may be difficult to determine XOSPATA®'s comparative effectiveness.

CMS discusses the additional information the applicant submitted to address CMS' concerns. This included updated information on the results of the Phase 3 ADMIRAL trial. After consideration of the additional data provided, CMS believes XOSPATA® meets the substantial clinical improvement criterion.

CMS finalizes that XOSPATA® meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of XOSPATA® will be identified by ICD-10-PCS code XW0DXV5. CMS estimates the average total cost of XOSPATA® per patient is $11,250. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving XOSPATA® is $7,312.50. CMS estimates the FY 2020 add-on payments at approximately $13,710,938, based on 1,875 patients.

j. 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.[14] 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 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 was concerned that the mechanism of action for GammaTile™ may be the same or similar to current forms of radiation or brachytherapy.

CMS received multiple comments supporting the claim that GammaTile™ is not substantially similar to existing technologies. The applicant also provided additional information about the mechanism of action and asserted that GammaTile™ should be disqualified because it is a type of radiation therapy. Based on the comments and information submitted in its application, CMS believes GammaTile™ has a unique mechanism of action that is different from current forms of radiation therapy and meets the newness criterion.

[14] 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.

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

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 was 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 noted a lack of analyses, meta-analyses or statistical tests that indicated seeded brachytherapy procedures represented a statistically significant improvement over alternative treatments.

Multiple commenters supported that GammaTile™ meets the substantial clinical improvement criterion. The applicant provided additional information to address several of CMS' concerns, including updated analysis of patient outcome data. CMS acknowledges the difficulty in establishing randomized control groups in studies involving brain tumors but it is still concerned that the data does not provide sufficient information for CMS to determine that GammaTile™ represents a substantial clinical improvement.

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

k. 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.

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 received FDA approval on May 24, 2019 for the treatment of patients with steroid-refractory aGVHD in adult and pediatric patients 12 years and older. JAKAFI™ was granted approval for the ICD-10-PCS code XW0DXT5 with an effective date of October 1, 2019.

For the first criterion (same or similar mechanism of action), the applicant asserted 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 stated 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 stated JAKAFI™ represents a new treatment option for a patient population without existing or alternative options. CMS noted that there were 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 also expected patient cases to be generally assigned to the same MS-DRGs as patients with steroid-resistant aGVHD receiving current treatment options.

The applicant provided additional information, including descriptions of JAKAFI™'s mechanism of action and how it differs from other treatments used for aGVHD. After consideration of the applicant's comment, the support of another commenter and the information submitted in its application, CMS believes JAKAFI™ has a unique mechanism of action and meets the newness criterion.

Cost. Based on the information presented in the application (discussed in the proposed rule) and updated analysis submitted by the applicant, CMS concludes JAKAFI™ meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted 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 had several concerns including the results provided do not include any data directly comparing JAKAFI™ to any second-line treatments. CMS stated 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 suggested 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 stated it may be difficult to directly assess whether JAKAFI™ provides a substantial clinical improvement compared to existing treatments. CMS was 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.

CMS discusses the additional information the applicant submitted to address CMS' concerns and a comment supporting JAKAFI™. This included updated information on the results of the Phase II REACH1 study demonstrating improved outcomes and subgroup analysis of comparing patients over and under 65 years of age. After consideration of the additional data provided, CMS believes JAKAFI™ meets the substantial clinical improvement criterion.

CMS finalizes that JAKAFI™ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of JAKAFI™ will be identified by ICD-10-PCS code XW0DXT5. CMS estimates the average total cost of JAKAFI™ per patient is $6,118.56. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving XOSPATA® is $3,977. CMS estimates the FY 2020 add-on payments at approximately $556,788 based on 140 patients.

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).[15] 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.

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 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 concluded 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.

After consideration of the information submitted in its application, CMS believes SSO_2 Therapy has a unique mechanism of action and therefore meets the newness criterion.

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

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes SSO_2 Therapy 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 summarized these studies and discussed several concerns. CMS noted 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 was 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 discussed 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.

Several commenters provided additional information about the studies submitted and stated SSO_2 Therapy meets the substantial clinical improvement criterion. CMS agrees that the results of many of the studies are promising but it remains uncertain if the clinical improvement in these studies is a result of the infarct size reduction after SSO_2 Therapy, or other developments in STEMI care delivery. CMS is concerned that the data does not provide sufficient information for CMS to determine that SSO_2 Therapy represents a substantial clinical improvement. **CMS finalizes that SSO_2 Therapy does not meet the criteria for new technology add-on payments**.

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 detects 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 believed 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 stated the T2Bacteria® Panel would be used as a diagnostic aid in the treatment of similar diseases and patient populations as blood cultures. CMS was 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.

The applicant and several commenters provided additional information about T2Bacteria® Panel's mechanism of action, including the fact that identification of any bloodstream pathogen does not require a blood culture and DNA testing is not routinely performed with blood cultures. After consideration of the comments and the information submitted in its application, CMS believes T2Bacteria® Panel has a unique mechanism of action and therefore meets the newness criterion.

Cost. Based on the information presented in the application and discussed in the proposed rule, CMS concludes 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 was 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 was concerned that the use of the T2Bacteria® Panel may not be a substantial clinical improvement over blood cultures.

CMS discusses the additional information the applicant and commenters submitted to address CMS' concerns. After consideration of the additional data provided, CMS believes the T2Bacteria® Panel meets the substantial clinical improvement criterion because it reduces the proportion of patients on inappropriate therapy which reduces the rate of subsequent diagnostic or therapeutic intervention as well as the mortality rate associated with sepsis.

CMS finalizes that T2Bacteria® Panel meets all three criteria for new technology add-on payments and approves add-on payments for FY 2020. Cases involving the use of T2Bacteria® Panel will be identified by ICD-10-PCS code XXE5XM5. The applicant estimates the average total cost of the T2Bacteria® Panel is $150. For 2020, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving the

T2Bacteria® Panel is $97.50. CMS estimates the FY 2020 add-on payments at approximately $3,669,803 based on 37,639 patients.

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

In the proposed rule, CMS discussed it was 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. CMS requested 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. CMS appreciates the many comments it received and will use this information as it continues to work on this issue in future rulemaking.

7. Revisions and Clarification to the New Technology Add-On Payment Substantial Clinical Improvement Criterion for under the IPPS

In the proposed rule, CMS requested 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:

- Adopt 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.
- 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.
- 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.
- Adopt a policy that the relevant information for purposes of a finding of substantial clinical improvement may not require a peer-reviewed journal article.
- 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.
- Adopt a policy that specifically addresses that the substantial clinical improvement criterion can be met without regard to the FDA pathway for the technology.

Comments/Responses: CMS discusses comments it received on the specific following issues related to substantial clinical improvement:

Broad adoption. Some commenters urged CMS to proceed cautiously with this proposal and that it should not be a prerequisite for new technology add-on payment technologies. MedPAC stressed that broad adoption did not equate with substantial clinical improvement and did not think it was appropriate for Medicare to provide higher payment for services that are not proven to provide a clinical advantage. MedPAC also noted it has written extensively about items with broad adoption but lacked evidence of clinical effectiveness.

Clinical outcomes that are different from existing technologies. Some commenters were concerned that this standard might restrict alternative study designs and that many novel technologies may not have existing comparative technologies. Other commenters indicated this should not be a requirement and if CMS were to consider this criterion, the comparator should be the standard of care rather than existing technology.

Real world data and evidence. Many commenters supported the development of real-world evidence to demonstrate clinical improvement and provided examples of such data including: a decreased mortality rate, a reduction in length of stay, a reduction in at least one clinically significant adverse event, improvement in one or more activities of daily living. Some commenters stated this would allow applicants greater flexibility to gather evidence as part of data registries. Other commenters suggested CMS should consider real world evidence from markets outside the U.S. Some commenters thought CMS should consider how the FDA and the National Evaluation System for Health Technology (NEST) consider real world data. Some commenters indicated that real world evidence should not be required as a criterion.

Peer-reviewed journal articles. Many commenters supported not requiring a peer-reviewed journal article for demonstrating substantial clinical improvement and cited the long timelines that may be required for publication. Some commenters indicated that CMS should accept the information submitted to FDA as part of the FDA approval process. Commenters indicated that CMS should explicitly state that peer-reviewed publications are not required and that other forms of evidence are acceptable.

Subset of beneficiaries. Many commenters supported demonstrating substantial clinical improvement for any subset of beneficiaries, regardless of the size of that subset patient population. Commenters indicated this would incentivize development of treatment for populations without adequate treatment options, including new anti-infective drugs.
CMS agrees with commenters that it may be premature to incorporate broad adoption of a technology into its evaluation of substantial clinical improvement. It notes that many of the comments are consistent with current approaches for evaluating substantial clinical improvement.

Final Decision: CMS believes it would be helpful to codify in regulations at §412.87 the following aspects related to the evaluation of substantial clinical improvement for purposes of the new technology add-on payments under the IPPS:

(1). The totality of circumstances is considered when making a determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries.

(2). A determination of substantial clinical improvement for the diagnosis or treatment of Medicare beneficiaries means the new service or technology offers:

- A treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; or
- The ability to diagnose a medical condition in a patient population where that condition is currently undetectable; the ability to diagnose a medical condition earlier than methods currently available and the evidence supports that making a diagnosis affects the management of the patient; or
- Significant improvement in clinical outcomes relative to services or technologies previously available as demonstrated by one of the following:
    - Reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication;
    - Decreased rate of at least one subsequent diagnostic or therapeutic intervention;
    - Decreased number of future hospitalizations or physician visits;
    - More rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time;
    - Improvement in one or more activities of daily living;
    - Improved quality of life; or
    - Demonstrated greater medication adherence or compliance; or
- The totality of the circumstances otherwise demonstrates substantially improvements, relative to available technologies, for the diagnosis or treatment of Medicare beneficiaries.

(3). Evidence from published or unpublished sources from the US or elsewhere may be sufficient to establish an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries includes the following sources: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

(4). The medical condition diagnosed or treated may have a low prevalence among Medicare beneficiaries.

(5). The service or technology may represent an advance that substantially improves, relative to available options, the diagnosis or treatment of a subpopulation of patients with the medical condition.

CMS appreciates the many comments it received and will use this information as it continues to work on this issue in future rulemaking.

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

CMS discussed 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.[16] 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 proposed 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.[17] CMS also proposed 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 did not propose an alternative inpatient new technology add-on payment for drugs. CMS considered the application of 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.

Comments/Responses: The majority of commenters supported the proposed alternative new technology add-on payment pathway for new devices. Commenters provided a range of reasons for supporting this policy including an increase in beneficiary access to new technologies, reduce burden and redundancy, and provide predictability and certainty in the regulatory and reimbursement process. Some commenters did not think it was appropriate to include a device with 510(k) clearance in the proposal. A few commenters did not support this proposal because they believed it would offer a financial incentive for the use of devices without evidence of improved clinical outcomes.

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[16] 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.

[17] In the 2020 OPPS proposed rule, CMS proposes a similar alternate pathway to obtain OPPS pass-through status for medical devices that receive FDA marketing authorization and are part of the FDA's Breakthrough Devices Program

Many commenters requested that CMS include all expedited FDA pathways (for example Fast Tract, and Priority Review, including Qualified Infectious Disease Products (QIDP)) and other categories of technologies, such as those with a Regenerative Medicine Advanced Therapy (RMAT) designation and devices that do not currently fit into existing benefit categories, such as Software as a Medical Device (SaMD). Many of these commenters also thought the proposal should be expanded to include drugs. Several commenters specifically urged CMS to extend the proposal to a product that the FDA designates as a QIDP because resistant infections result in higher costs to the healthcare systems and appropriate antimicrobial therapy is critical for treatment.

CMS appreciates the commenters' support of the proposed pathway and reiterates it believes that the benefits of providing early access to new technology that improve beneficiary health outcomes supports establishing this alternative pathway. CMS does not agree that a medical device that receives a 510(k) clearance cannot be "new" and not substantially similar to an existing technology for the purposes of the new technology add-on payment. CMS notes that under its current policy, a new technology, including a 510(k) device can be considered "new" for purposes of the new technology add-on payment. CMS reiterates its concerns about drug affordability; it will continue to evaluate this issue and commenters suggestions to develop additional criteria for technologies that receive approval under an FDA expedited program for future rulemaking.

CMS agrees with commenters' concerns about antimicrobial resistance and it believes it would be appropriate to extend the proposed alternative payment pathway to a product that is designated by the FDA as a QDIP.

Final Decision: For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, if the device is part of the FDA's Breakthrough Devices Program or a product designated by the FDA as a QIDP, and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology for the purposes of the new technology add-on payment under the IPS, and not need to meet the requirement that it represents a substantial clinical improvement. Medical devices and QIDPs will still need to meet the cost criterion.

Time period for the newness period. In the proposed rule, CMS requested comments about the time period for the newness period under the proposed alternative new technology add-on payment pathway. Specifically, would a one to two-year time period be sufficient for the evidence base to be used for determination of substantial clinical improvement determination? Some commenters supported limiting the duration of the alternative pathway to 2 years but other commenters recommended that the timeframe align with the full eligibility period available under the existing new technology add-on payment policy. Commenters discussed that one to two years might not be sufficient time to collect and evaluate data needed to demonstrate substantial clinical improvement. CMS appreciates this feedback and may consider adopting such a policy in future rulemaking.

9. 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 proposed 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.

Comments/Responses: The vast majority of comments supported an increase in the new technology add-on payment. Many commenters indicated that a percentage between 80 and 100 percent would be more appropriate to sufficiently incentivize the use of new technologies and indicated that an add-on payment of 80 percent would be consistent with the IPPS outlier payment and other CMS shared risk mechanisms. Some commenters indicated that the percentage for certain technologies (e.g. CAR T-cell therapy) needed to be higher due to the high cost of the therapy. Several commenters recommended CMS adopt an add-on payment percentage of 100 percent for products designated by the FDA as QIDPs. A few commenters, including MedPAC, indicated that an increase to 65 percent should be sufficient to achieve access to new technology.

CMS reiterates 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 disagrees with comments that the proposed 65 percent payment does not adequately reflect the estimated average cost of a new technology. It also does not agree that the new technology add-on payment amount needs to align with the IPPS outlier payment methodology. CMS believes that CAR T-cell therapy should not receive a percent payment higher than 65 percent. CMS agrees with commenters' concerns about antimicrobial resistance and it believes it would be appropriate to apply a higher new technology add-on payment of 75 percent for a product that is designated by the FDA as a QIDP and receives FDA marketing authorization.

Final Decision: CMS finalizes an increase in the new technology add-on payment percentage. For a new technology other than a medical product designated by the FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs) 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 less of (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment.
For a new technology that is a medical product designated by the FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs) 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 less of (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.
Under this finalized policy, unless the discharge qualifies for an outlier payment, the additional Medical payment will be limited to the full MS-DRG plus 65 percent (or 75 percent for a product designated by the FDA as a QIDP) of the estimated costs of the new technology or medical services.

For new technology add-on payments for FY 2020, CMS estimates the IPPS spending will increase by approximately $94 million, approximately $4 million is due to the differential new technology add-on payment percentage increase from 50 to 65 percent. CMS states it does not have sufficient information to estimate the costs associated with the alternative new technology add-on payment pathway. CMS has not received any new technology add-on payment application for a medical device that was part of the Breakthrough Devices Program and received FDA market authorization. The FDA has granted 147 QIDP designations of which 74 were novel and only 12 QIDPs were antibiotics. Since this policy will be effective beginning with FY 2021, there is no impact on this policy in FY 2020.

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

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). Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index.

Core-Based Statistical Areas (CBSAs) for the FY 2020 Hospital Wage Index. Hospitals are assigned to labor market areas and the wage index reflects the weighted (by hours) average hourly wage reported on Medicare cost reports. CMS uses Office of Management and Budget (OMB) CBSA delineations as labor market areas. OMB implemented the current delineations in 2015 (based on the 2010 census) 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.

A. Worksheet S-3 Wage Data

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

CMS calculates the FY 2020 wage index based on wage data of 3,239 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 final wage index includes FY 2016 data submitted to CMS as of June 19, 2019.

General wage index policies are unchanged from prior years. However, CMS notes that it proposed to exclude 81 providers due to aberrant data. In the final rule, CMS restores data to the wage index calculation for 16 of these hospitals. An additional 3 hospitals were deleted for having aberrant data and an additional 3 hospitals were dropped from the wage index calculation because they converted to CAH status.

Of the 81 hospitals excluded in the proposed rule, 8 are part of a 38-hospital health system in California where salaries reflect union negotiated agreements. In the proposed rule, CMS indicated that the average hourly wage for these hospitals does not represent prevailing wages in the local labor market. CMS proposed to exclude these hospitals from the wage index because 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. CMS provided a legal justification for its proposal as well as precedent for where it acted similarly.

Comments/Responses: Commenters strongly opposed the exclusion of these hospitals' wage data as being inconsistent with the statute and arbitrary and capricious. The statute does not provide the authority for CMS to delete accurately-reported wage data according to these commenters. CMS responded that it will allow more time to consider the appropriateness of including or excluding the wage data of this unique health care chain.

Final Decision: The wage data of all eight hospitals in this health care chain that were deleted from the proposed rule calculation are included in the FY 2020 final rule wage index.

B. 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 proposed and final rules, CMS is restating the steps 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 (to 2 places for dollar amounts), hours and other numerical values in wage index calculations.

Comments/Responses: One commenter suggested that average hourly wages be treated as a ratio rather than a dollar amount and opposed rounding average hourly wages to two decimal places arguing that it decreases precision and accuracy. CMS disagreed with these comments indicating that the average hourly wage is accurately expressed as a dollar amount and rounding to 2 decimal places does not bias the average hourly wage either up or down.

Final Decision: Finalize as proposed. The final unadjusted national average hourly wage is $44.19.

C. 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 reports having occupational mix data for 97 percent of hospitals (3,136 of 3,239) used to determine the FY 2020 wage index.

Comments/Responses: One commenter suggested CMS abandon the occupational mix survey because of its burden, or apply a penalty to ensure that all hospitals report. CMS responded that it is required to collect the occupational mix survey by statute and will consider the commenter's suggestion about imposing a penalty for not submitting it in the future.

Final Decision: The FY 2020 national average hourly wage, unadjusted for occupational mix, is $44.19. The occupational mix adjusted national average hourly wage is $44.15.

D. Occupational Mix Adjusted Wage Index

The final 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	$41.64
National LPN and Surgical Technician	$24.69
National Nurse Aide, Orderly, and Attendant	$16.97
National Medical Assistant	$18.13
National Nurse Category	$34.99

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	232 (56.6%)
Number of Rural Areas Increasing	23 (48.9%)
Number of Urban Areas Increasing by 1%<= and <5%	114 (27.8%)

Effect of the Occupational Mix Adjustment on the Unadjusted Average Hourly Wage	
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	177 (43.2%)
Number of Rural Areas Decreasing	24 (51.1%)
Number of Urban Areas Decreasing by 1%<= and <5%	79 (19.3%)
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%)

E. Rural, Imputed 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 164 hospitals—99 fewer hospitals than are receiving the rural floor in FY 2019. This impact results, in part, from CMS' policy to no longer include urban to rural reclassifications in the calculation of the rural wage index (described below) and has the most effect in Arizona and Massachusetts. In Arizona, 33 hospitals are receiving the rural floor in FY 2019 and only 2 will receive it in FY 2020. In Massachusetts, 55 of 56 hospitals are being paid at the rural floor wage index in FY 2019.[18] In FY 2020, it will be only 11 hospitals.

CMS calculates a national rural floor budget neutrality adjustment factor of 0.997081 (-0.29 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 0.4 percent increase in payments, primarily due to the application of the rural floor in Massachusetts.

Imputed Floor. The imputed floor was a policy that allowed for an adjustment to the wage index for hospitals in all urban states (Rhode Island, New Jersey and Delaware). As there are no rural hospitals in all urban states, there are not hospitals upon which a rural floor could be calculated. CMS adopted two different methodologies for increasing the wage index for hospitals in all urban states. Both of these methodologies expired at the end of FY 2018. Unlike the rural floor, there is no statutory provision that explicitly authorizes the imputed floor. CMS asked for comments on the imputed floor in the FY 2020 IPPS proposed rule.

Comments/Responses: Multiple commenters wrote in support of reinstating the imputed floor arguing that hospitals in these states are disadvantaged by close proximity to some of the most

[18] Of these 55, 29 hospitals receive the rural floor and the remaining 26 receive a rural floor wage index as a result of CMS' application of section 1886(d)(8)(C)(iii) that, prior to CMS' policy change, did not allow an urban county's wage index to be below the rural area of the state.

competitive and densely populated labor markets in the country. Commenters further articulated the revenue loss from CMS discontinuing the imputed floor. CMS responded by reiterating its concern that application of the rural and imputed floors requires transfer of payments from hospitals in states with rural hospitals but where the rural floor is not applied to hospitals in states where the rural or imputed floor was applied. In the past, CMS has expressed a preference for such a policy only when explicitly authorized by statute.

Final Decision: CMS indicates that it was only requesting comments on the imputed floor and summarizing the comments received. It made no commitment to further action.

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.

F. Wage Index Tables

Final 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-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Tables.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

Select #2.

G. 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 did not propose any changes to the geographic reclassification criteria. However, it proposed 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. CMS finalized the technical changes as proposed.

Geographic Reclassifications

There are 294 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2020. There are 290 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2018 that will continue for FY 2020, and 275 hospitals approved for wage index reclassification in FY 2019 that will continue for 2020. Eight hundred and fifty-nine hospitals are in an MGCRB reclassification status for FY 2020 (with 30 of these hospitals reclassified back to their geographic location).

The deadline for withdrawing or terminating a wage index reclassification for FY 2020 approved by the MGCRB was 45 days from publication of the FY 2020 proposed rule in the *Federal Register* (June 17, 2019). Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process have been incorporated into the final FY 2020 wage index values.

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/index.html. CMS proposed to dispense with the requirement that applications and other information furnished to the MGCRB also be provided to CMS electronically by email.

Comments/Responses: Commenters supported CMS' proposal and appreciated its concern about relieving provider burden.

Final Decision: Finalize without change.

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.

In the proposed rule, CMS explained a complex set of interactive effects between calculation of the outmigration adjustment and waiver of Lugar status that could result in a hospital waiving Lugar status to receive a non-existent outmigration adjustment. In this situation, the proposed rule clarified that CMS would not allow a hospital to disadvantage itself by waiving Lugar status to receive an outmigration adjustment that is not in its interest. Once finalized, the decision is not changed even though exclusion of the Lugar hospital from the rural area may result in an outmigration adjustment for the remaining hospitals with rural status. A Lugar hospital could revisit this decision in either of the next two rulemaking cycles for which the outmigration adjustment remains effective. CMS presents this issue as a clarification, not a proposal, and it does not indicate whether or not it received any public comments.

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 proposed to revise that standard to include commuting patterns to outlying counties as well based on an alternative interpretation of the statute from a Henderson, Texas hospital. The revised policy would affect 10 counties in Alabama, Georgia, Mississippi, Ohio, Pennsylvania, Texas and Virginia that include a total of 4 IPPS hospitals.

Comments/Responses: CMS received one comment in support of the policy.

Final Decision: Finalize without change.

H. Out-Migration Adjustment

CMS proposed to use the same policies, procedures and computation that were used for the FY 2012 out-migration adjustment, and estimates increased payments of approximately $44 million in FY 2020 for 176 hospitals receiving the out-migration adjustment. This provision is not budget neutral.

Final Decision: Finalize without change.

I. Reclassification from Urban to Rural

A qualifying IPPS hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Not later than 60 days after the receipt of an application from an IPPS hospital that satisfies the statutory criteria, CMS must treat the hospital as being located in the rural area of the state in which the hospital is located.

Lock-in Date

In the proposed and final rules, CMS described the "lock-in date," or the date by which CMS would need information that a hospital has reclassified from an urban to a rural area in order to include its wage data in the rural wage index calculations for the following year's IPPS rates. That date is the same as the closing date for the comment period on the annual IPPS proposed rule. The lock-in date only affects the calculation of the following year's wage index. It does not affect eligibility or timing for when a hospital can be eligible or approved for an urban to rural reclassification.

Allowing Electronic Applications

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 proposed to revise § 412.103(b)(3) to allow applications by mail, facsimile or other electronic means.

Comments/Responses: Commenters supported CMS' proposal and appreciated its concern about relieving provider burden.

Final Decision: Finalize without change.

Cancelling a Rural Reclassification

CMS proposed several changes to the regulations:

- 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;
- 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) if the request is made not less than 120 days prior to beginning of the next federal fiscal year; and
- Codify into regulations a longstanding policy 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 outmigration 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.

Comments/Responses: Commenters supported all of these proposals.

Final Decision: CMS is finalizing all of these proposals without change. However, CMS expresses concern about a hospital reclassifying from urban to rural after the lock-in date in order to get a higher wage index without affecting the rural wage index calculation. CMS says that it will monitor this situation over the course of FY 2020 to determine if it is necessary to prevent this type of gaming in future rulemaking. This may occur in the situations where the rural wage index is higher than the rural floor and the urban hospital's wage index is between these two amounts. Prior to FY 2020, the rural wage index and the rural floor were the same. However, CMS' policy to exclude urban to rural reclassifications from the rural floor could make the rural wage index different and higher than the rural floor as is occurring in Massachusetts in FY 2020.

J. 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 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.

K. 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 has 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.

L. Policies to Address Wage Index Disparities

Narrowing Variation in the Wage Index

Proposal 1 – Allow Time for Low-Wage Hospitals to Raise Wages. CMS proposed to increase the wage index values in the lowest quartile by one-half the difference between the hospital's wage index and the 25th percentile.[19] The policy would be effective for at least 4 years in order to allow employee compensation increases sufficient time to be reflected in the wage index calculation.

Comments/Responses: Comments in support of the proposal said it would allow employee compensation at low wage hospitals to rise to more competitive levels to help attract and retain skilled health care workers. Employee compensation changes would then be reflected in the wage index data beginning in four years. Other commenters requested the policy be expanded to additional hospitals that have experienced a decline in their wage index over the past twenty years.

Opponents of the policy argued there is no guarantee hospitals will use the higher payments to increase employee compensation. These commenters said the 4-year lag between when wages are paid and reflected in the hospital wage index does not impact low wage hospitals' ability to pay higher wages as CMS asserted in the proposed rule. Other market factors will affect the wage rate paid by these hospitals. Some commenters argue raising low wage indexes removes the wage index's ability to provide a relative measure for wages across different geographic

[19] 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.

regions. One commenter stated the policy was intended to address the overall financial health of hospitals in low wage areas, or the broader issue of wage index reform. These commenters indicated that CMS should not be using the wage index to address these issues.

Other commenters were concerned that once a transitional policy like the one CMS proposes is established, it becomes difficult to terminate because of its effect on those that benefit from it. Some commenters requested the policy be in place for longer than 4 years because low wage index hospitals may not be immediately able to increase wages.

CMS responded that once there has been sufficient time for increased employee compensation to be reflected in the wage data, there should not be a continuing need for this policy. At the expiration of the policy, hospitals that have not increased their employee compensation may experience a reduction in their wage index. Conversely, at the expiration of the policy, hospitals that have increased their employee compensation may experience relatively little change in their wage index.

In response to commenters who asserted that increasing the wage index for low wage index hospitals removes the wage index's ability to provide a relative measure for wages across different geographic regions, CMS responded that its proposal continues to preserve the rank order of wage index values and reflect meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. CMS rejected comments for expanding the policy to other hospitals that have experienced a decline in their wage index due to concern that it would inhibit the agency's ability to maintain the rank order of the wage index.

CMS disagreed that its change to the wage index is being used as a policy tool to address non-wage issues related to rural hospitals, the overall financial health of hospitals in low wage areas or broader wage index reform. While one effect of CMS' proposal may be to improve the overall well-being of low wage hospitals, that is not its primary rationale. Its primary purpose is to maintain meaningful rank order differences in the wage index but narrow the disparity that results from the lag time between when wages are reported and reflected in the final index.

In response to comments about the duration of the policy and allowing it to sunset, CMS intends to revisit the issue in future rulemaking as it gains experience under the policy. CMS says that it routinely allows transition policies to expire and referenced the transition to new labor market areas following the 2010 Census changes and expiration of the imputed floor policy in FY 2019.

Final Decision: Finalize as proposed for a minimum of 4 years. The 25th percentile wage index is 0.8457. Any wage index below this level will be increased by ½ the value of the difference between hospital's own wage index and 0.8457.

<u>Proposal 2: Make Proposal Budget Neutral by Lowering Wage Index for High Wage Hospitals</u>
CMS proposed to make the increase in the wage index for low wage hospitals budget neutral by applying a uniform 4.3 percent reduction to the portion of a hospital's wage index above the 75th percentile wage index (1.0351).

Comments/Responses: The vast majority of commenters argue that CMS does not have the statutory authority for its budget neutrality proposal and that it arbitrarily results in an inaccurate wage index for high wage hospitals. Commenters claimed selective budget neutrality whereby a small subset of hospitals bears the entire burden of budget neutrality for a given CMS policy change is unprecedented, and it violates both the statutory purpose of the wage index and CMS' own long-standing policy of spreading the cost of payment adjustments across all hospitals equally. CMS furnished no evidence to suggest that the high wage indexes being reduced are inaccurate.

The final rule further details legal arguments articulating why there is no statutory authority for CMS' proposal. A key feature of these legal arguments is that where Congress directed the Secretary to deviate from his section 1886(d)(3)(E) wage index authority, it did so explicitly (e.g. the frontier wage index, setting the labor share at 62 percent for hospitals with below average wages).

Some commenters said that CMS is not under a requirement to make the wage index increases budget neutral. These commenters support the increase in the wage index for low wage index hospitals without making the policy budget neutral.

CMS disagrees with the legal argument that the wage index authority is limiting because Congress specified the only adjustments permitted to the standard wage index methodology (the frontier floor and 62 percent labor share). Section 1886(d)(3)(E) gives the Secretary broad authority to establish the wage index according to CMS. The fact that section 1886(d) of the Act sets forth certain adjustments to the wage index calculation does not limit CMS' exercise of discretion in other respects CMS argues.

Section 1886(d)(3)(E) of the Act requires the wage index adjustment to be implemented budget neutral according to CMS. However, even if the wage index were not required to be budget neutral, CMS believes it would be inappropriate to use the wage index to increase or decrease overall IPPS spending as the wage index is not a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage–related costs of IPPS hospitals. As a result, CMS cites 1886(d)(5)(I) of the Act in support of its budget neutrality adjustment were section 1886(d)(3)(E) found not to require budget neutrality.

CMS does, however, acknowledge that some commenters have presented reasonable policy arguments regarding the relationship between its proposed budget neutrality adjustment targeting high wage hospitals and the design of the wage index to be a relative measure of the wages and wage–related costs of IPPS hospitals. For this reason, CMS is not finalizing the proposed budget neutrality adjustment and is instead applying a uniform budget neutrality adjustment to the standardized amounts.

Final Decision: Finalize a budget neutrality adjustment of 0.997987 (-0.2 percent) to the national standardized amount for all hospitals.

Preventing Urban to Rural Reclassifications from Raising the Rural Floor

In the proposed rule, CMS expressed concerns about urban hospitals reclassifying as rural to raise the rural floor wage index to benefit itself and other hospitals in its state. To address what CMS described as a manipulation of the wage index, CMS proposed to no longer include hospitals that have reclassified from urban to rural areas in the rural floor wage index that applies to urban hospitals not reclassified as rural. In addition, CMS proposed not to allow increases to the wage index of an urban hospital not reclassified as rural that would occur under section 1886(d)(8)(C)(iii) when a different hospital does an urban to rural reclassification.[20]

Comments/Responses: Many commenters, including MedPAC, supported the proposal commending CMS for curbing a manipulative and abusive practice that raises the rural floor wage index value exacerbating the wage index disparity between urban and rural hospitals.

CMS also received many comments opposed to the proposal. These commenters argued that the current calculation of the rural floor should be left in place until there is a broader wage index reform from Congress. There were comments saying that CMS' proposal is inconsistent with *Geisinger Community Medical Center v Burwell*, and *Lawrence + Memorial Hospital v Burwell* that found the law requires a reclassified hospital to be treated as a rural hospital for all IPPS purposes including geographic reclassification.

Some commenters opposed the proposal indicating that CMS' policy would create a competitive advantage for large, high cost urban hospitals that are able to reclassify as rural. These hospitals would receive the benefit of an increased rural area wage index while their lower cost competitors that are not reclassified as rural are left with a reduced area wage index. Other commenters suggested alternatives to CMS' policy including one that would only allow an urban hospital to reclassify as rural if its average hourly wage is less than 108 percent of the rural average hourly wage.

CMS responded that it is appropriate to revise the rural floor calculation as part of an effort to reduce wage index disparities even in the absence of comprehensive wage index reform.

With regard to the court precedents cited by the commenters, CMS indicated that its 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. CMS stated that the courts found that *hospitals* reclassified as rural must be considered rural for all purposes. The treatment of the *hospital's data* for calculating the rural floor is separate from treatment of the hospital itself. CMS' policy is that a hospital with an urban to rural reclassification would receive the rural wage index and

[20] Section 1886(d)(8)(C)(iii) is a little known provision that states a decision of the MGCRB or an urban to rural reclassification "may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the State in which the county is located." Under this provision 26 of 55 hospitals in Massachusetts had their wage index raised to the rural area of the state after an urban to rural reclassification in FY 2019. The remaining 26 received the rural floor wage index. CMS is making two changes: 1) Not including an urban to rural reclassification in the state rural floor wage index and 2) not including an urban to rural reclassification in "the wage index for rural areas in the State in which the county is located" so as not to raise an urban wage index when there is an urban to rural reclassification.

use the rural mileage and wage criteria when applying for an MGCRB reclassification and be treated as rural for all other IPPS purposes consistent with the statute and court precedent. The response states that section 1886(d)(8)(E) of the Act does not specify where the wage data of reclassified hospitals must be included. Therefore, CMS believes it has discretion to exclude the wage data of such hospitals from the calculation of the rural floor.

In response to concerns the policy will create a competitive advantage for large, high cost urban hospitals that are able to reclassify as rural, CMS notes that the wage data of an urban to rural reclassified hospital is included in both the hospital's geographic CBSA and the CBSA to which the hospital is reclassified for the wage index calculation. Accordingly, the wage index for urban area competitors to the urban to rural reclassified hospital will not decline as a result of the high wage hospital reclassifying as rural.

While CMS was appreciative of the alternatives suggested by a number of commenters, it does not believe it has the statutory authority to adopt some of them while others it considered to be out-of-scope of the proposed rule.

Final Decision: Finalize without modification.

Transitioning Wage Index Reductions and Transition Budget Neutrality

Following past practice when large changes to wage indexes have been transitioned, CMS proposed 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 proposed 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. CMS invoked section 1886(d)(5)(I) of the Act as its authority to make the 5 percent cap on wage index reductions budget neutral.

Comments/Responses:

1. Transition Policy

Commenters, including MedPAC, commended CMS for proposing the 5 percent cap to help transition providers through the wage index changes. One commenter agreed with applying the cap for one year while others supported a longer transition; some for the entire 4 years that CMS proposed to retain the increase in the wage index for low wage hospitals. One commenter recommended a permanent stop-loss of 10 percent; another recommended an exemption from any wage index reductions if the hospital is rural. MedPAC recommended caps on increases in the wage index as well as decreases. Other commenters opposed any transitional cap arguing that hospitals with a declining wage index as a result of these proposals benefitted in earlier years from an inappropriately high wage index.

There were also comments asking for clarification of whether the 5 percent cap on reductions applies for any reason or is limited to reductions that result from CMS' proposed changes to the wage index. Some commenters suggested the 5 percent cap apply earlier in the process and not just to the final wage index. There were also comments requesting clarification whether the 5

percent cap applies to urban to rural reclassifications that occur mid-year after the wage index for the fiscal year has been finalized.

CMS responded that it believes a one-year 5 percent cap is sufficient to mitigate any significant decreases in the wage index for FY 2020. A longer transition period would neither be needed nor appropriate. A one-year cap provides hospitals with declining payments sufficient time to plan appropriately for FY 2021 and future years, especially because some hospitals may be able to make reclassification choices to mitigate the decline. CMS disagrees with commenters that say there should be no transition. The wage index changes being finalized have significant payment implications, and consistent with past policy, CMS believes it would be appropriate to provide a wage index transition as proposed for FY 2020.

In response to the commenter requesting that CMS exempt IPPS rural hospitals from any wage index reduction for FY 2020 and subsequent years, CMS does not believe that such an exemption would promote an accurate wage index. As the transition is intended to mitigate the impact of payment reductions, CMS does not agree with MedPAC that payment increases should also be transitioned.

CMS confirmed that the 5 percent cap on reductions is applicable for all changes in the wage index, not just those resulting from CMS' proposals. Further, a decrease in a hospital's wage index caused by a midyear FY 2020 wage index change would also be capped at 5 percent.

Final Decision: Finalize without modification a policy to apply a 5 percent cap on any decrease in a hospital's FY 2020 wage index from the hospital's final wage index in FY 2019.

2. Budget Neutrality for the 5 Percent Cap

MedPAC agreed that the 5 percent cap should be applied budget neutral. One commenter requested that CMS apply a budget neutrality adjustment for the impact of the 5 percent cap transition by reducing the wage indexes of the upper quartile rather than the standardized amount.

CMS responded that it is appropriate and consistent with past practice to budget neutralize this transition wage index policy by applying an adjustment to the standardized amount for all hospitals.

Final Decision: Finalize as proposed. Based on the final rule data, the budget neutrality adjustment factor for the transition policy is 0.998838 (-0.12 percent).

IV. Other Decisions and Changes to the IPPS

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

1. Background

A post-acute care 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. Changes for FY 2020

CMS proposed 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 proposed 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. There was one comment commending CMS for consistent application of the post-acute transfer policy. CMS is finalizing its decision to remove MS-DRGs 273 and 274 from the list of MS-DRGs subject to the post-acute care transfer policy.

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:

- The 10-year moving average of economy-wide multifactor productivity.
- 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.

The IHS Global Insight, Inc. (IGI) second quarter 2019 forecast (with historical data through the first quarter of 2019) for the hospital market basket is 3.0 percent. Using IGI's second quarter 2019 forecast (with historical data through the first quarter of 2019), CMS is adopting an MFP adjustment of -0.4 percentage points.

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.

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	3.0	3.0	3.0	3.0
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.75	-0.75
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.25	0.0	-2.25
MFP Adjustment	-0.4	-0.4	-0.4	-0.-4
Applicable Percentage Increase	**2.6**	**0.35**	**1.85**	**-0.4**

For updates to the hospital-specific rate for SCHs and MDHs, CMS will adopt 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 revises 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, 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—

- 1.68645 (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 938 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 median regional CMIs and median regional numbers of discharges listed in the final rule 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 that receive the full 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.

Comment/Response: One commenter requested CMS adopt the same process it has for sole community hospitals and allow a low-volume hospital to retain its status and only notify CMS within 30 days of a change in circumstances that results in the hospital no longer qualifying for the low-volume adjustment. CMS will consider this suggestion in future rulemaking.

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 is making conforming changes to its regulations consistent with this statutory enactment.

E. Indirect Medical Education Payment Adjustment

For discharges occurring in FY 2020, CMS will continue to apply the IME adjustment factor of 5.5 percent for every approximately 10-percent increase in a hospital's resident-to-bed ratio.

F. Disproportionate Share and Uncompensated Care

1. Background

Medicare makes disproportionate share (DSH) payment and uncompensated care payments (UCP) 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 FY 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 using the pre-ACA formula;
- 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. FY 2020 Factor 1

CMS estimates this figure based on the most recent data available. It is not later adjusted based on actual data. For the proposed rule, 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 applied 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 were $16.857 billion. The proposed Factor 1 amount was seventy-five percent of this amount or $12.643 billion, about $389 million more than the final Factor 1 for FY 2019.

Comment/Responses: Commenters continue to express concern about transparency in the methodology used by OACT to estimate Factor 1. Some commenters requested that CMS use the traditional payment reconciliation process to calculate final Medicare uncompensated care payments. Some commenters expressed concern about whether underreporting of Medicaid coverage was factored into the calculation of Factor 1, as it was for Factor 2. Another commenter indicated that CMS should make an adjustment to the Medicare fraction as a result of the *Allina* decision by the U.S Supreme Court.

CMS reiterates its response to similar comments from prior years stating that Factor 1 is not estimated in isolation from other OACT projections. The Factor 1 estimates are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget and Midsession Review of the President's Budget and notes that its actuarial projections are subject to periodic review by independent experts to ensure their validity and reasonableness.

With respect to Medicaid, CMS indicates that the discussion in the proposed rule made clear that OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the

expansion to be 50 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary due to the better health of beneficiaries in the expansion population. Regarding an adjustment for Factor 1 similar to one made for Factor 2 to account for Medicaid underreporting on survey data, CMS indicates that such an adjustment is unnecessary because the Factor 1 calculation uses Medicaid enrollment data not survey data.

CMS further states no adjustment is necessary for the Supreme Court's *Allina* decision because that decision related to procedural issues regarding CMS' policy to include MA days in the Medicare fraction prior to FY 2014. The same policy was adopted through notice and comment rulemaking beginning in FY 2014. CMS states MA days are appropriately included in the Medicare fraction for the years under consideration to estimate Factor 1.

With respect to reconciling estimates, CMS continues to believe that applying its best estimates prospectively is most conducive to administrative efficiency, finality, and predictability in payments. The law provides authority to the Secretary to estimate Factors 1, 2 and 3 and prohibits administrative or judicial review of those estimates. CMS argues that Congress recognized the importance of finality and predictability under a prospective payment system by allowing CMS to determine UCP using estimates and precluding administrative or judicial review.

Final Decision: Finalize as proposed. For the final rule, OACT used the most recently submitted Medicare cost report data from the March 2019 update of HCRIS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File published in conjunction with the publication of the FY 2019 IPPS/LTCH PPS final rule. OACT applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The June 2019 OACT estimate for Medicare DSH payments for FY 2020 was approximately $16.583 billion. Empirically justified Medicare DSH payments are estimated to be 25 percent of this amount or $4.146 billion. Factor 1 is the difference between these two amounts or $12,437,591,742.69.

OACT's estimates for FY 2020 began with a baseline of $13.981 billion in Medicare DSH expenditures for FY 2016. The table below shows the factors applied to update this baseline to the current 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	1.0021	1.004	1.071400	1.0796	15.093
2018	1.018088	0.9845	1.018	1.031850	1.0528	15.891
2019	1.0185	0.9687	1.005	1.012075	1.0121	16.084
2020	1.031	0.9939	1.005	1.001200	1.0311	16.583

The "Other" column shows the increase in factors not accounted for in the prior columns such as 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 like the 2-midnight stay policy. In addition, the "Other" column includes a factor using public information

and statements for each state regarding its intent to implement the Medicaid expansion. CMS assumed 50 percent of all individuals who were potentially newly eligible Medicaid enrollees in 2016 resided in states that had elected to expand Medicaid eligibility and, for 2017 and thereafter, that 55 percent of such individuals would reside in expansion states.

The table below shows the factors that are included in the "update" column of the "Increases from 2017" table.

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	1.85
2020	3.0	0	-0.4	0.5	3.1

3. FY 2020 Factor 2

Factor 2 adjusts Factor 1 based on the percent change in the uninsured since implementation of the ACA. 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.[21] The proposed Factor 2 was 0.6714 (67.14 percent). The product of proposed Factor 1 ($12.643 billion) and Factor 2 (0.6714) produced a total proposed pool of uncompensated care payments of $8.489 billion.

Comments/Responses: A few commenters asserted that CMS underestimated Factor 2 and expressed concerns generally about the amount of money available to make uncompensated payments. These commenters stated that as the number of uninsured people in the country increases, it is imperative that hospitals receive adequate Medicare DSH and UCP payments to cover the costs of increasing numbers of underinsured and uninsured patients. One commenter requested that CMS either revise Factor 2 to account for the estimated reduction in Medicaid enrollment as suggested by the 0.9932 "Other" adjustment in determining Factor 1 or explain why such a revision is unnecessary.

CMS responded that the proposed rule included a detailed discussion of the proposed Factor 2 methodology and the data sources used in making the estimate. In response to the commenter that requested that CMS revise its estimate of Factor 2 consistent with the 0.9932 in the "Other" column, the final rule explains that other variables besides the change in Medicaid enrollment affect the figure in that column. Further, CMS notes that the "Other" figure is now 1.0012.

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

Final Decision: CMS is finalizing Factor 2 for FY 2020 as proposed. The estimates of the percent of uninsured individuals have been certified by the Chief Actuary of CMS. The calculation of the final Factor 2 for FY 2020 using a weighted average of OACT's projections for CY 2019 and CY 2020 is 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: 9.4 percent

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

The product of Factor 1 ($12.438 billion) and Factor 2 (0.6714) produces a total pool of uncompensated care payments of $8.350 billion. **The FY 2020 uncompensated care amount to be distributed is $8,350,599,096.**

FY 2020 Change in UCP
($ in Billions)

	FY 2019	FY 2020	$Change	% Change
Factor 1	$12.254	$12.438	$0.184	1.5%
Factor 2	0.6751	0.6714	-	-0.55%
UCP	$8.273	$8.350	$0.216	0.94%

4. Factor 3 for FY 2020

Factor 3 equals the proportion of hospitals' aggregate uncompensated care attributable to each IPPS hospital (including Puerto Rico hospitals). 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 while it made improvements to Worksheet S-10 of the Medicare hospital cost report. Worksheet S-10 was specifically designed for reporting hospital uncompensated care costs.

For FY 2017, CMS moved from using 1 year of data to using 3 years of data to allocate UCP. This policy was intended to smooth year-to-year fluctuations in Factor 3 and the resulting uncompensated care payments. It also allowed CMS to transition from using low-income patient days to Worksheet S-10 to distribute uncompensated care payments.

In FY 2018, CMS began transitioning to use of Worksheet S-10 by using two years of low-income patient days[22] and one year of Worksheet S-10 data (FY 2014). In FY 2019, CMS continued that transition by using one year of low-income patient days[23] and two years of Worksheet S-10 data (FY 2014 and FY 2015).

[22] Medicaid inpatient days were from the two fiscal years beginning prior to the Medicaid expansion (FY 2012 and FY 2013) while SSI days were from FY 2014 and FY 2015).
[23] Medicaid inpatient days from FY 2013 and SSI days from FY 2016.

In 2016 and 2017, CMS issued two transmittals to improve instructions for reporting Worksheet S-10 data. In November 2016, CMS issued Transmittal 10 which made a number of changes to Worksheet S-10 including that hospitals may report discounts given to uninsured patients who meet the hospital's charity care criteria in effect for that cost reporting period as charity care. This clarification was effective for cost reporting periods beginning prior to and on or after October 1, 2016. Effective for cost reporting periods beginning on or after October 1, 2016, Transmittal 10 provides that charity care charges must be determined in accordance with the hospital's charity care criteria/policy and written off in the cost reporting period, regardless of the date of service.

Transmittal 11 issued in September, 2017[24] clarified effective October 1, 2013:

- 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; and
- The CCR would not be applied to deductible and coinsurance amounts and non-reimbursed Medicare bad debt.

Further, effective October 1, 2016, Transmittal 11 clarified that only discounted charity care or financial assistance policy charges rather than full charges should be reported on line Worksheet S-10 line 20. For cost reporting periods beginning on or after October 1, 2016, these instructions significantly improved clarity for hospitals about reporting charity care and financial assistance discounts, actual amounts received for charges written off to charity care and reporting of non-reimbursed bad debt.

a. Using Audited FY 2015 or Unaudited FY 2017 Data

CMS proposed to use a single year of Worksheet S-10 data from FY 2015 cost reports to calculate Factor 3 in the FY 2020 methodology. Audited hospitals accounted for about half of the proposed total uncompensated care payments for FY 2020. CMS used the most recent available HCRIS extract available – updated through February 15, 2019 for the proposed rule. CMS indicated that it expected to use the March 2019 HCRIS extract for the final rule.

As an alternative to using a single year of FY 2015 data, CMS asked for comments on using FY 2017 for the FY 2020 uncompensated care distribution because of the improvements to the cost reporting instructions that were effective for FY 2017.

Comments/Responses: The comments and responses fall into several categories:

Use of 2015 Data versus 2017 Data

Comments in support of CMS' proposal argued that the corrective actions resulting from the FY 2015 Worksheet S-10 data audits outweigh the improved cost reporting instructions for the FY 2017 Worksheet S-10. FY 2017 Worksheet S-10 data may benefit from improvements in cost

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

reporting instructions but with unknown precision as the data have not yet been audited according to these commenters. Further, commenters added that instructional changes typically result in varying interpretations of how to report data suggesting there would be inconsistencies with reporting information in the FY 2017 Worksheet S-10.

Supporters of using FY 2017 data stated increased clarity in the cost reporting instructions in place for the FY 2017 Worksheet S-10 outweighs the benefit derived from the audit work performed on a subset of FY 2015 data. Commenters provided analyses showing fewer reporting errors using the FY 2017 Worksheet S-10 instructions than the FY 2015 Worksheet S-10 instructions, in particular for reporting high amounts of charity care coinsurance and deductibles. Other commenters believe that using data from the FY 2017 Worksheet S-10 would better address the issue of data lag, which could be a concern with the FY 2015 data.

Additionally, commenters were opposed to using FY 2015 Worksheet S-10 data on the basis that FY 2015 instructions were unclear and confusing resulting in incomplete and inaccurate uncompensated care data. They believe that since the audited hospitals represent only half of the proposed total uncompensated care payments for FY 2020, the remaining half is highly susceptible to errors. Opponents of using FY 2015 data also argued that audited hospitals are harmed to the benefit of those hospitals that were not audited.

CMS responds that it finds FY 2015 to be the better data source because it has been audited for hospitals accounting for ½ of uncompensated care payments and used previously in the distribution. It disagrees with comments suggesting that all hospital Worksheet S-10s need to be audited for a given data year to be used. It was not feasible to audit all hospitals' FY 2015 report data for the FY 2020 rulemaking. The selection of hospitals for the FY 2015 Worksheet S-10 audits was based on a risk-based assessment process (e.g. ¼ of hospitals accounting for approximately ½ of uncompensated care payments were audited) which CMS believes is effective and appropriate.

Use of 3 Years of Data versus 1 Year of Data

Comments both in support of and opposed to use of FY 2015 data raised concerns about using 1 year of data versus a 3-year average indicating that the potential for anomalies and undue fluctuations in uncompensated care payments increases with use of 1 year of data. Several commenters asked whether CMS' move to one year of data is permanent or temporary. If the move is permanent, a number of commenters requested a stop-loss policy to protect hospitals that have more than a threshold percent decrease in uncompensated care payments for any given year.

There were also concerns about mixing audited and unaudited data with commenters recommending an average three years of audited data. Conversely, other commenters supported the use of 1 year of data rather than a 3-year average on the basis that a "3-year average makes for a slow response." Many commenters suggested alternatives for blending data including permutations of audited and unaudited Worksheet S-10 data with low-income patient days over various 3-year combinations.

With respect to a stop-loss, CMS responded that the statute does not provide authority to implement a stop-loss policy. However, when more years of audited data are available, CMS may consider returning to use of an average of more than 1 year (for example, a 3-year average). Regarding the comments recommending that CMS place a cap on the amount of per-discharge uncompensated care payments, CMS may consider whether modifying the amount of interim uncompensated care payments would be administratively feasible in specific situations.

Auditing Process

Concerns about the auditing process on FY 2015 Worksheet S-10 data included:

- It was subjective and biased against providers with either high uncompensated care costs or with uncompensated care costs that may have changed significantly.
- Lack of standardization resulted in inconsistencies in the review adjustments made by the MACs and/or subcontractors as well as variation in documentation requirements.
- Further clarifications are required to the cost report instructions.
- Concerns about the shortness of the schedule to do audits and respond to adjustments.
- Concerns about auditor misunderstanding or interpretation of charity care and financial assistance policies.
- Auditor lack of training.
- Extrapolation from small samples.

Despite these concerns, many commenters were supportive of CMS' efforts to continue auditing Worksheet S-10 data and offered suggested improvements such as:

- Use a single auditor for all hospitals, or establish and enforce a formal and uniform audit process, similar to the desk reviews conducted for the wage index.
- Target specific data elements to reduce the scope of the audits and burden placed on providers.
- Make audit instructions publicly available to improve accuracy in reporting and interpretation of audit guidelines by the MACs and providers more consistent.
- Make public the results of the audits of the FY 2015 Worksheet S-10 data to develop outreach and educational materials for providers.
- Provide examples of acceptable language for financial assistance policies to increase the reliability of provider reporting and MAC review.
- Establish an appeals process and use an experienced third party to mediate audit adjustment disputes.

CMS acknowledges concerns that hospitals had about the FY 2015 Worksheet S-10 audits. It explains in detail why it selected that year and the providers it chose to audit as well as its own limitations that led to the concerns raised by the commenters. With respect to audit timeframes, CMS explains that it is not generally possible for providers to have extensions as that would lead to administrative inefficiencies and delays in completing audits across all providers. Nevertheless, in recognition of the importance of additional audits and to allow for additional lead time, CMS states that the audits of the FY 2017 Worksheet S-10 data are currently in progress with the goal having the FY 2017 audited data available for future rulemaking.

Regarding commenters' requests that CMS release the audit instructions, CMS states that it does not make the MACs' review protocol public. All CMS desk review and audit protocols are confidential and are for CMS and MAC use only. However, CMS will continue to work with stakeholders to address their concerns regarding the accuracy and consistency of data reported on the Worksheet S-10 through provider education and further refinement of the instructions for the Worksheet S-10 as appropriate. CMS strives for increased standardization as MACs continue to gain experience with Worksheet S-10 audits.

Regarding an appeals process, CMS generally rejected the idea of an appeals process but may consider this topic further in the future. CMS does not explicitly address the commenters suggestion for creating a wage index like audit for Worksheet S-10 data. However, the annual process for review of wage data does have an abbreviated and informal appeals process while including a strict timeline for raising issues. If a deadline is missed without an issue being raised, a provider is foreclosed from raising the issue later in the process.

Final Decision: CMS is finalizing its proposal to use the FY 2015 Worksheet S-10 cost report data in the methodology to determine Factor 3. Due to feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data, CMS believes that the FY 2017 Worksheet S-10 data should be audited before being used in the uncompensated care distribution.

In the proposed rule, CMS indicated that it would use the March, 2019 extract of the HCRIS for the final rule. However, public commenters were concerned that audit adjustments made to the FY 2015 were not included in the proposed rule Worksheet S-10s that went into determining the FY 2020 Factor 3 and expressed concern those audit adjustments would not be included in the March HCRIS extract used for the final rule.

CMS recognizes that some hospitals' data in the March HCRIS update may not have reflected all corrections and/or adjustments made to Worksheet S-10 data in response to CMS' hospital outreach and auditing efforts. Given those circumstances and consistent with historical practice of using the best data available, CMS is using a June 30, 2019 HCRIS extract, the most recent available for the final rule, to calculate Factor 3 for FY 2020. CMS expects to use the March HCRIS in future rulemaking, which is generally a more appropriate source because the data is available to the public to review for a longer period of time prior to the publication of the final rule, and the use of the June 30th extract presents challenges for CMS to incorporate the data in time for statutory publication of the final rule. CMS is not using any data provided with public comments to determine Factor 3.

Hospitals have August 31, 2019, to review and submit comments on the accuracy of their uncompensated care data and Factor 3. That information may be found at:
https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Data-Files.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending. Select #9.

Comments may be provided to: Section3133DSH@cms.hhs.gov.

b. Definition of "Uncompensated Care"

CMS is not proposing any changes to its definition of "uncompensated care." It will continue to define "uncompensated care" (line 30 of Worksheet S-10), as the sum of charity care (line 23), non-Medicare bad debt and non-reimbursable Medicare bad debt (line 29).

As in the past, some commenters suggested that uncompensated care should include shortfalls from Medicaid, CHIP, and State and local indigent care programs. However, CMS restates its reasons for excluding Medicaid shortfalls from the definition of uncompensated care and further adds that even if it were to adjust the definition of uncompensated care to include Medicaid shortfalls, it would be operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid "shortfalls." Further, in some states, providers return a portion of their Medicaid revenues to the State via provider taxes, making the computation of "shortfalls" even more complex.

c. Methodological Considerations for Calculating Factor 3

Hospital Mergers, Cost Report Shorter than 12 Months, Puerto Rico and Indian Health Service Hospitals and Providers with Multiple Cost Reports

CMS is continuing its prior merger policies. The final rule file of mergers and Factor 3 can be found at the same link provided immediately above. **Hospitals affected by a merger have until August 31, 2019 to comment on the accuracy of data in the merger table.**

Comments may be provided to: Section3133DSH@cms.hhs.gov.

Other policies continuing unchanged:

- FY 2015 Worksheet S-10 data from cost reports shorter than 12-months will be annualized.
- Low income patient days in place of Worksheet S-10 for Puerto Rico and Indian Health Service hospitals will continue to be used.
- If a provider has multiple FY 2015 cost reports, the longest one will be used and annualized if shorter than 12 months.
- If a provider has multiple cost reports beginning in the same year, but one report also spans the entirety of the following fiscal year, CMS will use data from the cost report that spanned both fiscal years if the hospital had no cost report beginning in FY 2015.

New Hospitals

CMS proposed a methodology where a new hospital with a CCN established after October 1, 2015 eligible for DSH based on its FY 2020 cost report would receive uncompensated care payments based on its FY 2020 uncompensated care costs as a percent of FY 2015 national uncompensated care costs. An analogous policy would be adopted for new Puerto Rico hospitals with uncompensated care payments made based on low-income patient days. The final rule does not indicate whether CMS received any comments or if it is finalizing the policy as proposed.

All-Inclusive Rate Providers

CMS believes it is no longer necessary to have specific Factor 3 policies for all-inclusive providers, as it did for FY 2019. It believes the risk that the data is aberrant is mitigated by its policy to apply trim methodologies for potentially aberrant uncompensated care costs for all hospitals.

Comment/Response: A commenter noted that CMS indicated that it was no longer necessary to propose specific Factor 3 policies for all-inclusive providers, yet later indicated that CMS would remove all-inclusive providers from the CCR trimming methodology because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals. The commenter requested that CMS correct this inconsistency in the final rule.

There are two trims. One trim applies when a hospital's uncompensated care costs are more than 50 percent of its total costs. All-inclusive rate providers are subject to this trimming methodology. However, no hospitals (all-inclusive rate providers or other hospitals) were excluded based on this trim point. The second trimming methodology applies to aberrant CCRs. CMS excludes all-inclusive rate provider from the determination and application of the trim point for aberrant CCRs.

Application of Statistical Trim Methodologies

CMS is continuing its policies on applying statistical trim methodologies to potentially aberrant CCRs and uncompensated care costs reported on the Worksheet S-10. The final rule provides the 4-step process for determining statistical trim methodologies that is the same as was provided in prior years.

Methodology for Trimming CCRs	
Step 1	Remove Maryland hospitals and all-inclusive rate providers.
Step 2	For FY 2015 cost reports, 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. In the proposed rule, this step removed 8 hospitals that have a CCR above the calculated ceiling of 0.925 for FY 2015. In the final rule, CMS removed 6 hospitals.
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 statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR greater than 3 standard deviations above the corresponding national geometric mean (that is, the CCR "ceiling"). For the proposed rule, the statewide average CCR would therefore by applied to 8 hospitals, of which 4 had Worksheet S-10 data. There is no indication of this figure for the final rule.

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

In the proposed rule, CMS explained that a large portion of the backlog of appeals before the PRRB relates to the calculation of the Medicaid portion of the hospital's disproportionate patient percentage. Hospitals obtain Medicaid data later than the cost report settlement date that would either qualify the hospital for DSH or increase its DSH payments. CMS explored options to use later Medicaid data that would make it unnecessary for the hospital to appeal its cost report in order to benefit from having later Medicaid eligibility information that is different than when the hospital submitted its cost report. Options explored included:

1. The provider would submit a cost report with Medicaid days based on the best available Medicaid eligibility data at the time of the filing. At a later point the hospital could request a reopening that the MAC would be directed to grant to provide the hospital with a realistic time period to submit updated data.
2. Allowing hospitals for a one-time per cost reporting period option to resubmit a cost report with updated Medicaid eligibility information.

Public comments were supportive of both options.

6. Impact Analysis

The regulatory impact analysis presented in Appendix A of the final rule includes the estimated effects of the changes to UCP for FY 2020 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,432 hospitals that are projected to be eligible for DSH in FY 2020. CMS presents estimates based on its policy to use one year of FY 2015 data to determine Factor 3.

As explained earlier, changes in FY 2020 UCP compared to FY 2019 are accounted for by an increase in Factor 1 partially offset by a slight decrease in Factor 2 as well as by a decrease in the number of hospitals eligible to receive DSH in FY 2020. Factor 1 will increase from $12.254 billion to $12.437 billion while Factor 2 will decrease from 67.51 percent to 67.14 percent. As a result, the total amount of UCP is estimated at $8.351 billion, a 0.9 percent increase from FY 2019 UCP (about $78 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 0.9 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 0.9 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	Number of Hospitals	FY 2019 Estimated UCP	FY 2020 Estimated UCP	$ Change	% Change
All Hospitals	2,432	$8,273	$8,351	$78	0.9%
Urban	1,931	$7,806	$7,811	$6	0.1%

Hospital Type	Number of Hospitals	FY 2019 Estimated UCP	FY 2020 Estimated UCP	$ Change	% Change
Large Urban	977	$4,326	$4,543	$217	5.0%
Other Urban	954	$3,480	$3,269	-$211	-6.1%
Rural	501	$467	$539	$72	15.4%
Beds: 0-99 (Urban)	336	$254	$291	$37	14.4%
Beds: 250+ (Urban)	766	$5,704	$5,633	-$71	-1.2%
New England (Urban)	91	$279	$249	-$30	-10.8%
Middle Atlantic (Urban)	242	$1,058	$1,061	$3	0.3%
West South Central (Urban)	243	$1,423	$1,696	$273	19.2%
Pacific (Urban)	321	$899	$656	-$243	-27.0%
Major Teaching	246	$2,947	$2,985	$38	1.3%
Non-Teaching	1,457	$2,479	$2,574	$95	3.8%
Voluntary	1,451	$4,898	$4,552	-$346	-7.1%
Proprietary	600	$1,270	$1,245	-$25	2.0%
Government	381	$2,104	$2,553	$449	21.3%

Under its policy, rural hospitals are projected to receive a larger percentage increase in uncompensated care payments (15.4%) than urban hospitals (0.1%) 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 27.0 percent decrease. In contrast, urban hospitals in the West South-Central region (Arkansas, Louisiana, Oklahoma, and Texas) are projected to receive a 19.2 percent increase. Government hospitals are projected to receive a larger than average payment increase of 21.3 percent. Proprietary hospitals are projected to receive a slightly larger average payment increase of 2.0 percent, whereas voluntary hospitals are projected to receive a payment decrease of -7.1 percent.

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 2020 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)[25].

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[26] and the HRRP formula compares a hospital's performance to the median for its peer group.

[25] 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.

[26] 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

Several modifications to HRRP policies are finalized for FY 2020 in this rule. The changes 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 adopts a set of factors it will use to determine whether a measure should be removed from the HRRP; no measures are removed at this time. The factors are the same as those previously 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 will not be used for automatic removal of measures but instead are to be applied on a case-by-case basis. The 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);
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.

In responding to comments seeking clear criteria and guidelines for the use of removal factor 8, CMS states that each measure fills a different need and will be considered for removal on a case-by-case basis, so it would not be meaningful to identify assessment criteria that would apply to all measures.

3. Definition of Dual Eligible Beneficiary

The definition of dual eligible is modified 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 will be used. Although the change only affects a small number of beneficiaries, CMS believes it is important to use the most accurate information available in counting dual

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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.

eligibles for purposes of the HRRP adjustment. The change will be effective beginning in FY 2021. Responding to comments for more detail on the impact, CMS states that the new definition increases the number of dual eligible stays by 16,756 or 0.2 percent for the period July 1, 2014 through June 30, 2017.

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.

In this rule a similar process is adopted for nonsubstantive modifications to other components of the HRRP adjustment in order to provide for rapid adoption of minor changes. Substantive changes will continue to go through notice and comment rulemaking. Examples of nonsubstantive changes offered include updated naming or locations of data files and/or other minor discrepancies that do not change the intent of the policy, such as the change described immediately above regarding how dual eligible status is determined for beneficiaries who die in the same month as a hospital discharge.

CMS responds to concerns of commenters seeking more clarity about when this policy would be used. It says that the policy is intended to make minor and technical changes that would not substantively impact previously finalized policies. Nonsubstantive changes would not be expected to impact internal hospital monitoring policies or result in hospital burden. CMS understands the concerns of commenters who indicated that the example of the change in the dual eligible definition is substantive and would not be appropriate for a subregulatory process. However, it believes that when minor and previously unknown data discrepancies are discovered that frustrate but do not change the stated intent of existing policies, a subregulatory process may be the best approach for a timely solution. CMS will consider the feedback from commenters in any future potential application of the subregulatory process.

Elaborating further CMS notes that in FY 2020 it will begin providing additional details regarding the payment adjustment factors in the technical appendix of the Hospital Specific Reports User Guide[27] to provide greater insight and detail about the HRRP payment methodology. This information includes details about how CMS processes data, such as the removal of duplicate stays, and the files it uses to produce the final payment adjustment factors. CMS sought flexibility to amend and update the nonsubstantive standard processing rules and data processing to ensure that quality data are used for the payment adjustment calculations, rather than have to delay data improvements.

5. Applicable Period for FY 2022

Consistent with current policies, CMS finalizes that for FY 2022 the applicable period from which data will be collected for calculating the readmission payment adjustment factor is the

[27] See the QualityNet website at: https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772412669.

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. Applicable period for payment years beginning with 2020 are shown below.

Finalized HRRP "Applicable Periods"	
Payment Year	**Discharge Dates**
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 made 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)[28] 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)[29] that is the same across all hospitals and all conditions.

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

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 will occur in the fall of 2019.

7. Confidential Reporting of Stratified Readmissions Data

As early as the spring of 2020 CMS 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

[28] 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.

[29] 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.

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

Additionally, CMS adds 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)). As previously adopted, review is also prohibited 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 final rule CMS estimates that 2,583 hospitals, or 85 percent of those eligible, will be penalized under the HRRP in FY 2020, with aggregate penalties representing 0.69 percent of payments to hospitals. A table shows the variation in these impacts by hospital characteristics. In general, larger hospitals and teaching hospitals are more likely than average to be penalized under the HRRP but the penalties for these groups represent a smaller than average share of payments.

H. Hospital Value-Based Purchasing Program

One administrative change is made to policies under the 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 change 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 are continued. In this final 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 summary 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 March 2019 update of the FY 2018 MedPAR file, CMS estimates that the total amount available for VBP Program payments for FY 2020 is approximately $1.9 billion (i.e., 2.0 percent of base operating DRG payments).

CMS has posted on the FY 2020 IPPS final rule web page a Table 16A 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. 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 finalizes in this rule use of 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. This policy will 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) will also apply.

Responding to comments regarding the proposed use of the "same data," CMS states that it did not propose and is not changing the performance period for the NHSN HAI measures for

purposes of the VBP Program. Commenters had noted that for the HAC Reduction Program a two-year performance period is used for these measures compared with one year for the VBP Program.

3. Impact Analysis

A table in the regulatory impact analysis section of the final rule shows the estimated effects of VBP payments for FY 2020 by type of hospital based on TPS data for FY 2019. Across all hospitals the net estimated VBP adjustment averages 0.164 percent; averages 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		
Patient and Caregiver Centered Experience of Care/Care Coordination ***(Person and Community Engagement)***					
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)					

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

I. Hospital-Acquired Condition Reduction Program

Several changes to HAC Reduction Program policies are finalized for FY 2020, although the program measures, data collection processes, scoring methodology, and the policies for review and correction of program data remain unchanged. Under the changes described below, CMS establishes factors for removal of program measures, finalizes the data collection period for the FY 2022 program year, and clarifies certain data validation and data collection policies finalized in the FY 2019 IPPS/LTCH final rule. CMS also updates the regulatory text to reflect previously adopted policies 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 change parallel to one made for the HRRP described in IV.G.2 above, CMS adopts a set of eight factors it will use to determine whether a measure should be removed from the HAC Reduction Program; no measures are removed at this time. The factors are the same as those already in place for the IQR Program, the Hospital VBP Program, and other hospital quality reporting programs. As is the case in these other programs, the factors will not be used for automatic removal of measures but will be applied on a case-by-case basis. The 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 for 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 finalizes its proposal 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, with the intention of reducing the likelihood that a hospital 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 made to the previously finalized policy of selecting 40 cases annually from each hospital selected for validation.

In addition, CMS adopts its proposal to use a filtering method to better target "true events," or those that meet NHSN HAI criteria. The filtering method will 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. 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 finalizes 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 final 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. While by definition, 25 percent of hospitals overall will be in the worst quartile and subject to the penalty (792 hospitals total), this proportion varies from about 17 percent for rural hospitals with 100-149 beds to 48 percent of teaching hospitals with 100 or more medical residents. High-DSH and safety net 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.						

Summary Table: HAC Reduction Program Measures and Performance Periods						
	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019	FY 2020
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. 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, the Affordable Care Act (ACA) amended the IME and DGME statutory provisions to address time spent by residents training outside of the hospital in "non-provider" settings. 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 proposed to reverse this position effective for portions of cost reporting periods beginning October 1, 2019. The proposed policy would allow a hospital to include FTE residents training at a CAH provided it incurs the costs of the resident's salary and fringe benefits and the resident is providing patient care.

Comments/Responses: Most commenters supported the policies articulating a great variety of ways it will help facilitate training in CAHs to the benefit of rural communities and the residents themselves. Other commenters supported the policy and specifically requested it be made effective retroactive to FY 2014. These commenters were concerned that new teaching hospitals in their cap building period engaged in training arrangements with CAHs under the new rules during the last six years that would have qualified to be included in the new teaching hospital's cap were the rules not changed in FY 2014. Some commenters did not ask for a retroactive effective date but to adjust new teaching hospital caps to reflect past arrangements back to FY 2014 but only for purposes of future payments under the new policy. Other commenters

suggested reexamining past arrangements between CAHs and teaching hospitals allowing the teaching hospital to count the resident training time in a CAH only with the CAH's assent and if the CAH did not claim the costs for that time as a reasonable cost.

One commenter disagreed with the proposal as being inconsistent with the statute as a CAH is explicitly defined as a "provider" setting and teaching hospitals are only allowed to count resident training time outside their own hospital in "non-provider" settings. Other concerns of this commenter included:

- There will be duplication of payment (particularly for IME) as the CAH will be paid 101 percent of reasonable costs that will be difficult to distinguish from other costs while the teaching hospital counts the resident for both its IME and DGME payments.
- The provision will be unable to be used by teaching hospitals above their caps but instead by new teaching hospitals in their cap building period who will then be able to use those resident slots for purposes other than training in a CAH once the cap applies.

CMS acknowledges the legal arguments from the commenter disagreeing with the proposed policy change but references section 1886(h)(5)(K) of the Act arguing that the proposed policy is consistent with a CAH being a "non-provider setting that is primarily engaged in furnishing patient care." This language provides sufficient flexibility for CMS to consider CAHs to be non-providers for purposes of direct GME and IME payments. Regarding duplicative payments, the hospital must clearly show it had the residents training at a CAH on its payroll or that it made payments to the CAH to cover the residents' salaries and fringe benefits in order for the hospital to count the residents. CMS conceded that a teaching hospital could establish a cap for a new training program using resident training in CAHs that it later uses for other purposes. However, the policy being finalized is intended to address stakeholders' concerns that the previous policy was negatively affecting residency training in rural areas. CMS would expect the revised policy to promote residency training at CAHs rather than the CAH acting as a temporary training site for cap-building purposes.

In response to comments about making the policy retroactive or allowing for prospective cap adjustments, CMS indicates the revised interpretation of CAHs as non-providers does not invalidate the previous policy. CMS does not believe in engaging in retroactive rulemaking.

Final Decision: Finalize without change. Effective with portions of cost reporting periods beginning October 1, 2019, a hospital may include FTE residents training at a CAH in its FTE count as long as it incurs the costs of the residents' salaries and fringe benefits and the resident is involved in patient care. If a hospital remains in its 5-year cap-building period as of October 1, 2019, residents training in a CAH on or after that date may be counted by the teaching hospital for purposes of determining its cap provided regulations governing non-provider training are met. Alternatively, a CAH that incurs the costs of training residents in an approved residency training program(s) may receive payment based on 101 percent of the reasonable costs. If the CAH receives reasonable cost payment for resident training, no hospital can include the residents training at the CAH in its direct GME and IME FTE counts.

3. Teaching Hospital Closure: Application Process for Resident Slots

Section 5506 of the ACA 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 Providence Hospital, located in Washington, DC (CCN 090006):

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
090006	Providence Hospital	Washington, DC	47894	April 30, 2019	50.50	52.12

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 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 October 31, 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 15 due to the closure of Providence Hospital in Washington, DC. 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. 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

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.

FY 2020 Budget Neutrality Adjustment

CMS identifies 28 hospitals participating in the program in FY 2020; one participating hospital closed earlier this year. For three of these hospitals, the 5-year participation or extension period will end in FY 2020. CMS prorates 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 $60,972,359 in FY 2020. From this amount, CMS subtracts $14,932,060 for reconciled FY 2014 cost reports and $20,297,477 for reconciled FY 2015 cost reports.

The total budget neutrality adjustment will be based on $25,742,822 or a proposed adjustment to the IPPS standardized amounts of 0.999771 (-0.02 percent).

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 proposed a national capital Federal rate of $463.81 for FY 2020. The final capital Federal rate for FY 2020 will be $462.61.

Update Factor:

For FY 2020, CMS will 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. For FY 2020, CMS projects a 0.5 percent total increase in the case-mix index. CMS estimates that real case-mix increase will equal 0.5 percent for FY 2020. The net adjustment for change in case-mix

is the difference between the projected total increase in case-mix and real increase in case-mix. Therefore, CMS is applying an adjustment for case-mix change in FY 2020 of 0.0 percentage points. There is no adjustment for FY 2018 reclassification and recalibration or forecast error correction.

Table 1

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:	
Projected Case-Mix Change	0.5
Real Across DRG 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 such, CMS is reflecting changes to the wage data as well as its policy changes to the wage index (increasing the wage indexes below the 25th percentile and capping reductions in wage indexes at 5 percent) in the budget neutrality adjustment. CMS determines a net GAF budget neutrality adjustment of -0.44 percent (0.9956) in two steps as follows:

1. Isolate the impact of just the change to the wage data (e.g. without the increase to the lowest quartile wage indexes and 5 percent cap on wage index decreases) on FY 2019 payments. Adjustment = 1.0005.
2. Isolate the impact of just the wage index due to the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases on the FY 2020 payments. Adjustment = 0.9964

The budget neutrality adjustment for the changes in the GAFs will be 0.9968 (1.0005 x 0.9964). CMS incorporates an adjustment for MS-DRG changes and recalibration of the relative weights of 0.9987. This combined adjustment for GAFs and MS-DRG changes and recalibration is 0.9956 (0.9968 x 0.9987 or -0.44 percent).

For FY 2020, CMS is taking outlier reconciliation into account in determining the outlier adjustment. CMS estimates that capital outlier payments will be 5.47 percent of total capital payments. Taking into account outlier reconciliation, CMS is subtracting 0.08 percentage points for amounts refunded to hospitals. This makes capital outlier payments 5.39 percent of total capital payments. Therefore, the FY 2020 outlier adjustment factor is 0.9461 (-5.39 percent), compared to 0.9494 in FY 2019. The net change is -0.35 percent (0.9461/0.9494). Thus, the outlier adjustment decreases the FY 2020 capital federal rate by 0.35 percent.

Final Calculation:

The final rule includes the following chart to show how each of the factors and adjustments affect the computation of the 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 FY 2020 Capital Federal Rate

	FY 2019	FY 2020	Change	Percentage Change
Update Factor*	1.0140	1.0150	1.015	1.50
GAF/DRG Adjustment Factor*	0.9969	0.9956	0.9956	-0.44
Outlier Adjustment Factor**	0.9494	0.9461	0.9965	-0.35
Capital Federal Rate	$459.41	$462.61	1.0070	0.70

* The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2019 to FY 2020 resulting from the application of the 0.9956 GAF/DRG budget neutrality adjustment factor for FY 2020 is a net change of 0.9956 (or -0.44 percent).
** The outlier adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2020 outlier adjustment factor is 0.9461/0.9494, or 0.9965 (or -0.35 percent).

Considering the update factor and the budget neutrality adjustments, CMS is adopting a national capital Federal rate for FY 2020 of $462.61, representing a 0.7 percent increase over the FY 2019 rate of $459.41.

Exception Payments. The final rule continues exception payments 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. Religious non-medical health care institutions are also paid reasonable costs subject to a limit.

The annual update to the TEFRA limit is based on IGI's 2019 2nd quarter forecast of the hospital market basket. CMS is setting a 3.0 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. A hospital paid under TEFRA may also request a new base year (a permanent revised TEFRA target amount per discharge for determining the ceiling).

In the proposed rule, CMS requested public comments for improvements to the exceptions process and criteria for determining a new base year for a TEFRA provider. Several commenters stated their appreciation for CMS' consideration of improvements to the TEFRA adjustment and rebasing process. CMS will take these comments into consideration for future rulemaking.

C. Report on Adjustment (Exception) Payments

CMS is required to do an annual publication in the *Federal Register* of the total amount of adjustment payments made to excluded hospitals and hospital units in the previous fiscal year. CMS provides the following table on adjustment payments that were processed by the MAC or CMS during FY 2018. The adjustments made during FY 2018 only pertain to cost reporting periods ending in years prior to FY 2018.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Children's Hospitals	6	$6,047,405	$3,911,362
Cancer Hospitals	3	$20,652,458	$16,175,760
Religious Nonmedical Health Care Institutions	1	$103,147	$7,934
Total	**10**	**$26,803,010**	**$20,095,056**

D. Critical Access Hospitals

Change to CAH Payment for Ambulance Services

Section 1834(l)(8) of the Act specifies that payment to a CAH or CAH-owned and operated entity is 101 percent of the reasonable costs incurred in furnishing ambulance services "only if the critical access hospital or entity is the only provider or supplier of ambulance services that is located within a 35–mile drive of such critical access hospital." Otherwise, payment is made under the Ambulance Fee Schedule (AFS).

CMS proposed to exclude ambulance providers or suppliers not *legally* authorized to furnish ambulance services to or from the CAH in applying the 35-mile distance criterion. This policy would allow payment at 101 percent of reasonable costs if an ambulance was within 35 miles of

the CAH but located in a different state and not legally authorized to provide services to the CAH's patients.

Comments/Responses: Commenters supported CMS' proposal saying it supports rural health care, removes artificial reimbursement barriers to regional health care delivery, and will improve access to care for 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.

Several commenters urged CMS to expand the availability of cost-based reimbursement to:

- Ambulance services where patient transfer is required based on the CAH conditions of participation as CAHs often struggle to find medical transport for facility-to-facility transfers.
- All CAHs providing paramedic-level ambulance services.
- Provide sustainable payments for CAH-operated ambulance services that are functionally the only ambulance services available to a CAH and its community.

CMS acknowledges that because CAHs have a legal obligation to transfer patients, the reimbursement they receive for ambulance services should reflect that requirement. However, the commenters described situations where there are other providers or suppliers of ambulance services within a 35-mile drive of the CAH that is not legally precluded from providing ambulance services to individuals living within the CAH's service area. As section 1834(l)(8) of the Act limits 101 percent of reasonable cost payment to a CAH or CAH-owned and operated entity that is "the *only* provider or supplier of ambulance services…located within a 35–mile drive of the critical access hospital," CMS does not have the authority to expand its policy beyond what it proposed.

Final Decision: Finalize as proposed. The term "provider" of ambulance services means all Medicare-participating providers that submit claims under Medicare for ambulance services (for example, hospitals, CAHs, skilled nursing facilities, and home health agencies), and the term "supplier" of ambulance services means an entity that provides ambulance services and that is independent of any Medicare-participating or non-Medicare-participating provider.

Effective for cost reporting periods beginning on or after October 1, 2019, payment for ambulance services furnished by a CAH or by an entity that is owned and operated by a CAH is 101 percent of the reasonable costs of the CAH or the entity in furnishing those services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals either to or from the CAH.

If there is no provider or supplier of ambulance services located within a 35-mile drive of the CAH and there is an entity that is owned and operated by a CAH that is more than a 35-mile drive from the CAH, payment for ambulance services furnished by that entity is 101 percent of the reasonable costs of the entity in furnishing those services, but only if the entity is the closest provider or supplier of ambulance services to the CAH.

The Frontier Community Health Integration Project (FCHIP) Demonstration[30]

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 participated in the 3-year demonstration beginning August 1, 2016.

The demonstration is intended to be budget neutral through reduced transfers and admissions to other health care providers that offset any increase in payments under the waivers. However, if that is not the case, CMS would recoup any additional expenditures attributable to the FCHIP through a reduction in payments to all CAHs nationwide beginning with CY 2020. CMS indicates that "this policy will likely have no impact for any national payment system for FY 2020."

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 finalizes payment 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. CMS made conforming changes to the regulations to implement the extended transitional blended payment.

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

Summary of Changes to LTCH PPS Rates for FY 2020*	
Standard Federal Rate, FY 2019	$41,558.68
Final Rule Update Factors	
Update as required by Section 1886(m)(3)(C) of the Act	+2.5%
Penalty for hospitals not reporting quality data	-2.0%
Net update, LTCHs reporting quality data	+2.5% (1.025)
Net update LTCHs not reporting quality data	0.5% (1.005)
Final Rule Adjustments	
Final average wage index budget neutrality adjustment	1.0020203
Final budget neutrality adjustment to eliminate the 25-percent threshold policy	0.999858
Final Standard Federal Rate, FY 2020	
LTCHs reporting quality data	$42,677.63
LTCHs not reporting quality data	$41,844.89
Final Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$26,778
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$26,473
Impact of Policy Changes on LTCH Payments in 2020	
Total estimated impact	1.0% ($43 million)
LTCH standard federal payment rate cases (71% of LTCH cases)	+2.7% (+$91 million)
Site neutral payment rate cases (29% of LTCH cases)**	-5.9% (-$49 million)
*More detail is available in Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2020" on pages 2232-2233 of the 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 continues 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 are also incorporated into the MS-LTC-DRG system for FY 2020 since the two systems share an identical base. Finalized MS-DRG changes are described elsewhere in this summary and details can be found in section II.F. of the preamble.

Development of the MS-LTC-DRG Relative Weights

In developing the FY 2020 relative weights, CMS uses 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 relative weights are derived from the March 2019 update of the FY 2018 MedPAR file. These data are filtered to identify LTCH cases meeting the established site neutral payment exclusion criteria (or would have met the exclusion criteria had the dual rate LTCH PPS payment structure been in effect at the time of discharge). 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 final FY 2020 MS-LTC-DRG relative weights.

Hospital-Specific Relative-Value Methodology (HSRV)

CMS continues 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 continues 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.
- If an MS-LTC-DRG has 1-24 cases, it is assigned to one of five quintiles based on average charges CMS then determines a 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.
- If an MS-LTC-DRG has zero cases (i.e., no volume) after data trims are applied, it is cross-walked to another MS-LTC-DRG based on clinical similarities in resource use intensity and relative costliness in order to assign an appropriate relative weight. If the MS-LTC-DRG that is clinically similar is a low-volume DRG that has been assigned to one of the five quintiles noted above, then the no volume MS-LTC-DRG is assigned to that same quintile.

The low-volume quintiles and no-volume crosswalk data previously published in Tables 13A and 13B are now made available on the CMS website at http://www.cms.hhs.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

CMS assigns 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 does not calculate a weight for the 15 psychiatric and rehabilitation MS-LTC-DRGs because these MS-LTC-DRGs would never include any LTCH cases meeting the site neutral payment rate exclusion criteria. However, to determine a transitional blended payment amount for FY 2020, CMS uses 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. For relative weights that decrease as severity increases in a DRG ("nonmonotonic"), CMS continues 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.

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

CMS continues 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 applies its two-step methodology to achieve budget neutrality for the FY 2020 MS-LTC-DRG and relative weights update (Step 7). First, CMS calculates a normalization factor of 1.27367 that is applied to the recalculated relative weights to ensure that the recalibration does not change the average case mix index. Second, CMS calculates and applies a budget neutrality factor of 0.9959342 to each normalized relative weight.

Extensive discussion of the entire 7-step process to determine MS-LTC-DRG relative weights is provided in the final rule (pages 1,276 to 1,294 of the display copy). Table 11 (listed in section VI. of the Addendum to the final rule and also available on the CMS website) lists the MS-LTC-DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2020.

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

Background

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 to 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.

Notice and Payment Adjustment

CMS implemented the notice 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 this final 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 clarifies that the discharge payment percentage is calculated based on the LTCH as a whole—not individual locations of the hospital. Responding to commenters' concern about the IPPS-exempt status of an LTCH that is subject to a payment adjustment for a discharge payment percentage of less than 50 percent, CMS says the hospital will remain an LTCH as long as it maintains an average length of stay of 25 or more days.

CMS finalizes its policies and timelines for determination of the discharge payment percentage (six months after the end of the LTCH's cost reporting period) and the application of the payment adjustment for LTCHs with a discharge payment percentage is less than 50 percent. Where the discharge payment percentage is less than 50 percent, CMS will notify the LTCH that it will be paid for all of its discharges at IPPS comparable amounts for discharges occurring during 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 and each succeeding cost reporting period (subject to reinstatement). CMS codifies these policies in new §§412.522(d)(3) and 412.522(d)(4).

In the proposed rule, CMS clarified that LTCHs subject to the payment adjustment would receive payment at the IPPS-comparable *per diem* amount (which also used to calculate payments under the SSO policy and site neutral payment rate payments) with an additional payment for high-cost outlier cases that would be based on the IPPS fixed-loss amount in effect at the time of the LTCH discharge. In response to questions, CMS clarifies that the payment adjustment will be the full amount calculated under §412.529(d)(4)(i)(A)—not the per diem amount. CMS revises the final regulation text to refer to the amount paid under the payment adjustment to be an amount equivalent to the IPPS amount (as opposed to what the agency had proposed which was a reference to an amount comparable to the IPPS amount) determined under §§412.529(d)(4)(i)(A), (ii) and (iii), with an additional payment for high cost outlier cases based on the IPPS fixed-loss amount in effect at the time of the LTCH discharge.

CMS also clarifies that the outlier payment under this payment adjustment policy differs from its policy for making LTCH PPS outlier payments for site neutral discharges. The agency notes this is attributable to the language of the statute which states that the payment adjustment shall be the amount that "would apply under subsection (d) for the discharge if the hospital were a subsection (d) hospital."

Finally, CMS confirms that payment adjustments are appealable to the PRRB.

Reinstatement Process

The statute also requires that CMS establish a reinstatement process for the payment adjustment to be discontinued. Under the final policy, an LTCH can be reinstated to receiving payment at the LTCH standard federal payment 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 codifies the reinstatement process for LTCHs in new §412.522(d)(5).

In response to commenters who requested that the payment adjustment be discontinued at any point when an LTCH demonstrates it meets the discharge payment percentage threshold, CMS notes that the statute calls for application of the policy on the basis of cost reporting periods.

Although CMS believes the reinstatement process 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 provides for 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, there is a probationary cure period of six months. During the cure period, payment based on the IPPS comparable amount will 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 is not ultimately 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 will 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 will be lifted, and the 2022 cost report settlement will be made using an IPPS-comparable amount for all discharges.

While CMS acknowledges that the special probationary cure process is not required by statute, it believes that use of the probationary cure period is the best way to balance administrative simplicity while allowing for unusual circumstances. CMS also recognizes that the special probationary cure process requires additional time between when discharges may be subject to the payment adjustment and when a final determination is made to apply the adjustment. CMS notes that the timing of the final settlement of the cost report is unaffected. However, the agency may reexamine the need for this process taking into account the burden it imposes on LTCHs.

CMS codifies the special probationary reinstatement process at §412.522(d)(6).

D. LTCH PPS Payment Rates and Other Changes

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 will be paid in FY 2020 at a rate that is based on the lower of the IPPS comparable *per diem* amount or 100 percent of the estimated cost of the cases.

Update for LTCHs

Using IGI's second quarter 2019 forecast, CMS calculates an annual update to the LTCH PPS standard federal payment rate of 2.5 percent. The update is equal to the 2013-based LTCH market basket of 2.9 percent less 0.4 percentage points for multifactor productivity. For LTCHs failing to submit data to the LTCH Quality Reporting Program (QRP), the annual update is further reduced by 2.0 percentage points. The LTCH update for FY 2020 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	2.9%	2.9%
Multifactor Productivity	-0.4	-0.4
Quality Data Adjustment	0.0	-2.0
Total	2.5%	0.50%

Area Wage Levels and Wage-Index

CMS finalizes a labor-related share of 66.3 percent for FY 2020 based on IGI's second quarter 2019 forecast of the 2013-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (62.2%) 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 computes the wage index as it has done with prior years. After publication of the proposed rule, CMS identified an error in the proposed rule wage index values. CMS explains that a programming error caused the data for all providers in a single county to be included twice, which affected the national average hourly rate, and therefore affected all wage index values. In the final rule, CMS changed the programming logic so this error cannot occur again. In addition, it corrected the classification of one county in North Carolina to rural status, as this county was erroneously identified as being in an urban CBSA.

Using the same methodology as in prior years, CMS calculates an area wage level budget neutrality factor of 1.0020203.

LTCH Standard Federal Payment Rate Calculation

CMS determines the following LTCH PPS standard federal payment rates for FY 2020; CMS notes that the calculations are performed on rounded numbers:

FY 2020 payment rate = $41,558.68 (FY 2019 payment rate) * 1.025 (statutory update factor) * 1.0020203 (area wage budget neutrality factor) * 0.999858 (25% threshold budget neutrality factor) = $42,677.63

For LTCHs not reporting data to the LTCH QRP: FY 2020 payment rate = $41,558.68 (FY 2019 payment rate) * 1.005 (statutory update factor less quality adjustment) * 1.0020203 (area wage budget neutrality factor) * 0.999858 (25% threshold budget neutrality factor) = $41,844.89

Elimination of the 25 Percent Rule

In the FY 2019 IPPS rule, CMS adopted a policy to eliminate the 25 percent rule. The 25 percent 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: 0.990878 for FY 2019 and 0.990737 for FY 2020 and 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 0.990878 adjustment and adding the 0.990371 adjustment is 0.999858.

Cost-of-Living (COLA) Adjustment

CMS updates 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.

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

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 agency 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 and using the most recent available data, CMS determines an HCO fixed-loss amount of $26,778 which CMS estimates will result in 7.975 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 final fixed-loss amount of $26,778 for FY 2020 for LTCH PPS standard Federal payment rate cases is significantly lower than the proposed fixed-loss amount of $29,997. CMS notes it used the most recent data for the final rule (LTCH claims data from the March 2019 update of the FY 2018 MedPAR file and CCRs from the March 2019 update of the PSF).

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 establishes $26,473 as the fixed-loss amount for site neutral payment rate cases.

CMS finalizes 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 does not apply the HCO budget neutrality adjustment 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.

IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS continues its policy that the calculations of the "IPPS comparable amount" (42 CFR §412.529) and the "IPPS equivalent amount" (§412.534 and §412.536) include an applicable operating Medicare DSH and uncompensated care payment amount. For FY 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 1.0 percent or $43 million in aggregate payments (from $4.271 billion to $4.314 billion). This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard federal payment rate cases of approximately 2.7 percent ($91 million) and the projected decrease in payments to site neutral payment rate cases of approximately 5.9 percent (-$49 million estimated). CMS modeling assumes that approximately 71 percent of LTCH cases will meet the criteria for exclusion from the site neutral payment rate (that is, those cases will be paid the LTCH PPS standard federal payment rate) and approximately 29 percent of LTCH cases will be paid the site neutral payment rate (calculated using FY 2018 LTCH claims data).

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 Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2020" in the final rule shows the detailed impact by location, participation date, ownership type, region, and bed size for only LTCH PPS standard federal payment rate cases and does not include the detailed impact in payments for site neutral payment rate cases. 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 not meet the 50 percent threshold 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 $50 million in FY 2022.

Summary of Impact of Changes to LTCH PPS Standard Federal Payment Rate Cases for FY 2020		
	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%

	Number of LTCHs	Estimated Percent Change in payments per discharge
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 Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2020" on pages 2232-2233 of the display copy.		

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

VIII. Quality Data Reporting Requirements for Specific Providers and Suppliers

In this section of the rule, changes are adopted for the quality reporting programs that apply to acute inpatient hospital stays, PPS-exempt cancer hospitals, and long-term care hospitals. In addition, changes to the Medicare and Medicaid Promoting Interoperability Programs are finalized.

A. Hospital Inpatient Quality Reporting (IQR) Program

CMS adopts two new IQR Program measures both of which involve electronically reported data submission; a third measure that was proposed is not finalized. Safe Use of Opioids—Concurrent Prescribing electronic clinical quality measure (eCQM) (NQF #3316e) is added to the program beginning with the 2021 reporting period/FY 2023 payment determination, with clarifications in the measure specifications from the proposed rule. In addition, the Hybrid Hospital-Wide Readmission measure which had a 6-month voluntary reporting period in 2018 is 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 will be removed at that time. The proposed measure Hospital Harm—Opioid Related Adverse Events eCQM is not finalized.

All other current IQR Program measures are retained. A table at the end of this section shows previously and newly finalized IQR Program measures for FYs 2019 through 2023.

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). CMS emphasizes that although the measure was broadly specified, it is being adopted for the IQR Program and limited to

inpatient discharges. Reporting on the measure will begin with 2021 for the FY 2023 payment determination.

Specifically, CMS addresses commenter concerns about how this measure treats patients discharged from the ED by acknowledging that the measure specifications referenced in the proposed rule were overly broad, and that the measure was always intended to exclude discharges from the ED and observation stays. It is providing a "minor refinement" and updating the measure specifications to clarify that the IQR Program measure clearly reflects only discharges from inpatient hospitalizations. Data for ED or observation stay encounters will only be captured for patients who are admitted and subsequently discharged from the inpatient setting. The final specifications are available at https://ecqi.healthit.gov/ecqm/eh/2020/cms506v2.

In discussing other comments, CMS emphasizes that it does not expect the measure rate to be zero, and does not intend the measure to discontinue concurrent prescriptions of these drugs that are clinically appropriate. It understands there may be adverse outcomes if appropriate pain management is discouraged but is confident that hospitals will continue to focus on appropriate pain management as part of their commitment to quality of care. It reiterates that the goal of the measure is to help systems identify and monitor patients at risk and to provide valuable data about a high-risk prescribing at discharge from inpatient hospitalizations, including care that originates in the ED. It believes that it is important to monitor concurrent prescribing of opioids and benzodiazepines whether the prescriptions are new or existing. Various clinical guidelines for avoiding concurrent prescribing of opioids and benzodiazepines are cited. Finally, CMS notes that the IQR Program is pay-for-reporting and there are no financial penalties based on performance.

Beginning with the 2022 reporting period/FY 2024 payment determination, CMS finalizes that all hospitals participating in the IQR Program must report this eCQM. That is, for that year, hospitals must report this eCQM and 3 others of their choosing. (See VIII.A.6 below for more on eCQM data submission requirements.)

2. (Not finalized) Hospital Harm—Opioid Related Adverse Events eCQM

This measure was proposed but is not adopted for the IQR Program in the final rule. It 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 measure was submitted for NQF review in spring 2019 and the Patient Safety Standing Committee voted not to move forward with endorsement. As a result, CMS has decided to reevaluate the measure and is not finalizing it at this time. It will consider the NQF's concerns and consider whether the measure should be changed for future use. CMS also discusses and responds to many concerns raised by stakeholders, which it will also consider.

3. 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 received a confidential hospital-specific report in July 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 finalizes 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 are established: July 1, 2021 through June 30, 2022 and July 1, 2022 through June 30, 2023. The hybrid measure will then become mandatory beginning with the FY 2026 payment determination, with the first year of mandatory reporting running from July 1, 2023 through June 30, 2024. CMS strongly encourages hospitals to participate in the voluntary reporting periods. Once the Hybrid HWR measure becomes mandatory, failing to meet the data submission requirements will result in the hospital receiving the IQR Program update penalty.

To report this measure, hospitals must 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 must submit six linking variables that 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 must 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 will 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.

Initial electronic specifications for the voluntary data collection period will 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 will be provided for the two new

voluntary reporting periods, with the first delivered to hospitals in the spring of 2023. No public reporting of the Hybrid HWR measure will occur during the voluntary reporting periods.

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

CMS responds to several logistical concerns raised by commenters. First, it recognizes concerns about the CMS infrastructure for receiving eCQM data. It cites success with the 2018 voluntary reporting period for this measure, in which 150 hospitals participated. It says it continues to pursue efficiencies in its data receiving systems, and encourages all hospitals to participate in the upcoming voluntary reporting. Second, CMS acknowledges the reliance on EHR vendors in reporting of eCQM data, and it anticipates that by finalizing future mandatory reporting of the Hybrid HWR measure vendors will have incentive for greater participation. Third, CMS believes that while the different measurement periods and reporting timelines for this measure compared with eCQMs (discussed VIII.A.6 below) may be confusing, this difference will allow hospitals and health information technology (IT) vendors to stagger data submission during the year.

Numerous other comments are addressed. CMS anticipates that hospitals will experience a "slight" information collection burden increase for reporting this measure, which it believes is outweighed by the value of improving risk adjustment of the readmissions measure.

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

In conjunction with adoption of the Hybrid HWR measure for the IQR Program effective with the FY 2026 payment determination, the current claims-based HWR measure will be removed from the program at that time. CMS 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.

5. Potential Future Hospital IQR Program Measures

In the proposed rule CMS discussed in detail and sought comment on the following three potential future IQR Program measures, all of which are eCQMs also under consideration for future addition to the Promoting Interoperability Program. In this rule, the comments CMS received are described, which will be considered for future rulemaking.

- 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 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 the spring 2019 cycle, and CMS

reports in the final rule that it was recommended for endorsement by the Patient Safety Standing Committee after favorable review by the Scientific Methods Panel[31].

- 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. CMS reports in the final rule that the measure was recently recommended for endorsement by the Patient Safety Standing Committee after favorable review by the Scientific Methods Panel. The committee's report, cited above, indicates some concerns about the measure's feasibility, particularly integrating this measure across multiple EHRs that may not have structured fields to capture pressure ulcer data in a standardized way.
- 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 conditioned on NQF review and endorsement. (The chart-abstracted version has received NQF endorsement.) `

6. 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 and updated in April 2019. 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.

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. 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. Public reporting will be considered through future notice and comment rulemaking.

7. Form, Manner and Timing of Quality Data Submission

No changes are made to data submission requirements for the Hospital IQR Program which involve procedural requirements, data submission for chart-abstracted measures, data submission deadlines, sampling and case thresholds, Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) administration and submission requirements, data validation,

[31] The report of the NQF Patient Safety Standing Committee is available at http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=90662.

data accuracy and completeness acknowledgement, public display of measures on *Hospital Compare*, reconsideration and appeals, and the extraordinary circumstances exception policy.

The final rule establishes 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, hospitals will continue to 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 changes. All hospitals will be required to report one self-selected calendar quarter of data for the Safe Use of Opioids Concurrent Prescribing eCQM plus three additional self-selected eCQMs.

Responding to comments, CMS strongly encourages hospitals to choose the Safe Use of Opioids Concurrent Prescribing measure as one of its four self-selected eCQMs during the 2021 reporting period in order to gain experience with this eCQM. CMS believes that hospitals and vendors will have had sufficient time to work through implementation, testing, and reporting challenges in time for mandatory reporting in 2022.

Finalized for the FY 2022 payment determination (2020 reporting period) and subsequent years is a continuation of 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 IT vendor testing of 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. Readers are referred to the resources available to hospitals and vendors including the eCQI Resource Center Collaborative Measure Development Workspace and the Office of the National Coordinator's JIRA eCQM issue tracker.

For reporting of the Hybrid HWR measure finalized in this rule, updated implementation guidance, schematrons, and sample files will be made available on the eCQI Resource Center website. Current zero-denominator declaration and case threshold exemption policies for eCQMs will also apply to hybrid measure 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 will 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, are exempted from reporting on that hybrid measure.

The deadline for submission of the Hybrid HWR core clinical data elements and linking variables will 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 is September 30, 2022.

8. Impact Analysis

In the Regulatory Impact Analysis section of the final rule, CMS estimates that for FY 2020, 41 hospitals will not receive the full market basket rate of increase for failure to meet the IQR

Program requirements or choosing not to participate in the program, but are meaningful users under the Medicare Promoting Interoperability Program. These hospitals will be subject to a payment reduction of 0.75 percentage points from the update factor they would otherwise receive. Another 30 hospitals are estimated to receive a combined payment reduction of 3.0 percentage points because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program.

<table>
<tr><th colspan="6">Summary Table: IQR Program Measures by Payment Determination Year
X= Mandatory Measure</th></tr>
<tr><th></th><th>2019</th><th>2020</th><th>2021</th><th>2022</th><th>2023</th></tr>
<tr><td colspan="5">Chart-Abstracted Process of Care Measures</td><td></td></tr>
<tr><td>STK-4 Thrombolytic therapy for acute ischemic stroke</td><td>Removed</td><td></td><td></td><td></td><td></td></tr>
<tr><td>VTE-5 VTE discharge instructions</td><td>Removed</td><td></td><td></td><td></td><td></td></tr>
<tr><td>VTE-6 Incidence of potentially preventable VTE</td><td>X</td><td>X</td><td>Removed</td><td></td><td></td></tr>
<tr><td>Severe sepsis and septic shock: management bundle (NQF #500)</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td>ED-1 Median time from ED arrival to departure from the emergency room for patients admitted to the hospital (NQF #0495)</td><td>X</td><td>X</td><td>Removed</td><td></td><td></td></tr>
<tr><td>ED-2 Median time from admit decision to time of departure from the ED for patients admitted to the inpatient status (NQF #0497)</td><td>X</td><td>X</td><td>X</td><td>Removed</td><td></td></tr>
<tr><td>IMM-2 Immunization for influenza (NQF #1659)</td><td>X</td><td>X</td><td>Removed</td><td></td><td></td></tr>
<tr><td>PC-01 Elective delivery < 39 weeks gestation (NQF#0469)</td><td>X</td><td>X</td><td>X</td><td>X</td><td>X</td></tr>
<tr><td colspan="6">Electronic Clinical Quality Measures</td></tr>
<tr><td>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</td><td colspan="2">Report 4 of the following 15 eCQMs:
AMI-8a
CAC-3
ED-1
ED-2
EHDI-1a
PC-01
PC-05
STK-02
STK-03
STK-05
STK-06
STK-08
STK-10
VTE-1
VTE-2</td><td></td><td>Report 4 of the following 8 eCQMs:
ED-2
PC-05
STK-02
STK-03
STK-05
STK-06
VTE-1
VTE-2</td><td>Report 4 of the following 9 eCQMs
ED-2
PC-05
STK-02
STK-03
STK-05
STK-06
VTE-1
VTE-2
Safe use of Opioids*</td></tr>
</table>

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure					
	2019	**2020**	**2021**	**2022**	**2023**
Safe Use of Opioids – Concurrent Prescribing					
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			
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			

Summary Table: IQR Program Measures by Payment Determination Year X= Mandatory Measure					
	2019	**2020**	**2021**	**2022**	**2023**
Gastrointestinal hemorrhage clinical episode-based payment	X	Removed			
Aortic Aneurysm Procedure clinical episode-based payment	X	Removed			
Cholecystectomy/Common Duct Exploration episode-based payment	X	Removed			
Spinal Fusion clinical episode-based payment	X	Removed			
Patient Experience of Care					
HCAHPS survey + 3-item Care Transition Measure	X	X	X	X	X
Structural Measures					
Participation in a Systematic Clinical Database Registry for Nursing Sensitive Care	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			
*Beginning with the FY 2024 payment determination, hospitals must report this eCQM and 3 other self-selected eCQMs. **Beginning with the FY 2026 payment determination, this measure will be replaced by the Hybrid HWR measure. *** This measure will be mandatory beginning in FY 2026. Two more voluntary reporting periods will be held before that (July 1, 2021 through June 30, 2022 and July 1, 2022 through June 30, 2023).					

B. PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

The PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program began in FY 2014 and follows many of the policies established for the Hospital IQR Program, including the principles for selecting and removing measures and the procedures for hospital participation in the program. Currently, there are 11 PPS-exempt cancer hospitals.[32] 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 (1) removes the pain management questions from the HCAHPS patient experience of care measure effective October 1, 2019; (2) removes the measure External Beam Radiotherapy for Bone Metastases from the measure set beginning with FY 2022 payment determination; and (3) adds the measure Surgical Treatment Complications for Localized Prostate Cancer beginning with FY 2022.

Removal of Pain Management Questions. Three HCAHPS pain management questions[33] that were previously removed from the HCAHPS survey for purposes of the IQR Program and the

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

[33] 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); and (14) During this

Inpatient VBP Program are now also removed from the PCHQR Program beginning with FY 2022 payment. In all cases 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 removes the questions out of an abundance of caution, in light of the national opioid epidemic. CMS had proposed that data collected on these questions be removed from Hospital Compare beginning with October 2018 discharges, but now it has targeted January 1, 2020 for removal due to planned website improvements. Performance results for four quarters of 2018 data will be provided to PCHs in confidential preview reports. CMS does not intend for these data to be made public.

Responding to commenters, some of whom opposed removal of these questions and others who supported a different approach to assessing pain management, CMS notes its plans to continue to work with stakeholders on alternative approaches and potential future measures. The treatment of pain management is discussed further under "Future Topics" below.

Removal of External Beam Radiotherapy for Bone Metastases Measure. This measure is removed from the PCHQR Program beginning with FY 2022 payment based on 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 will 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/. Responding to comments, CMS commits to providing confidential reporting for this measure prior to publicly reporting performance data. Public reporting for the measure will be addressed in future rulemaking.

Future Topics. In the proposed rule CMS sought comment on possible future topics for PCHQR Program measures. In particular, commenters were asked about alternatives to quality measures that assess cancer patient pain in light of the removal of the HCAHPS pain management questions, including patient reported outcome measures. CMS reports that commenters encouraged CMS to continue to facilitate research and development of patient reported outcome performance measures for health-related quality of life and pain in breast, colon, and non-small lung cancer patients receiving chemotherapy with curative intent as well as for cancer patients receiving palliative care. In addition, some comments supported CMS efforts to identify measures that assess pain management for cancer patients and do not involve opioid use, such as structuring measures that evaluate the use of device-based alternatives to opioids. Exclusion

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hospital stay, how often did the hospital staff do everything they could to help you with your pain? (Never, Sometimes, Usually, Always).

from measurement for patients discharged to hospice, receiving palliative care, or with cancer and other serious illnesses was also recommended, along with measures that consider causes of pain, pain effects on sleep, and pain interference with therapy or day-to-day activities.

Public Display. Public display of performance on the Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy measure is finalized to begin as soon as feasible. CMS had proposed that public display would begin in 2020, but other changes to the *Hospital Compare* website may delay its ability to publicly report the measure. CMS has recently provided a first round of confidential reports to PCHs on this measure, and another round is planned before public display is effective. In addition, CMS finalizes that public display of the Methicillin-resistant Staphylococcus aureus (MRSA), Clostridium Difficile Infection (CDI), colon/abdominal hysterectomy surgical site infection (SSI) measures and the influenza vaccine for healthcare personnel measure will begin as soon as feasible, with a target data of January 2020. After earlier deferrals, these measures had been proposed for public display beginning with the October 2019 *Hospital Compare* release. Because 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, public display continues to be deferred, and CMS expects that the earliest public display possible for these measures is 2022.

Confidential Reporting. To prepare PCHs for public reporting, CMS will 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	
Measure	**Public Display**
Safety and Healthcare Associated Infection	
Colon/Abdominal Hysterectomy SSI (NQF #0753)	As soon as feasible*
NHSN CDI (NQF #1717)	As soon as feasible*
NHSN MRSA bacteremia (NQF #1716)	As soon as feasible*
NHSN Influenza vaccination coverage among health care personnel (NQF #0431)	As soon as feasible*
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	

PCHQR Program Measures for 2022	
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
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	As soon as feasible
30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188)	
Surgical Treatment Complications for Localized Prostate Cancer	
*CMS is targeting January 2020 for the initial public reporting release of these measures. **Beginning with October 1, 2018 discharges, responses to the Pain Management questions will not be public. Note: Public reporting for the measure External Beam Radiotherapy for Bone Metastases (EBRT) (NQF #1822) began in 2017. This measure is removed from the PCHQR Program effective with 2022 payment.	

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 measures previously adopted for the LTCH QRP for FYs 2019 through 2021 and the newly finalized measures for FY 2022.

1. New Measures and Measure Update for FY 2022

CMS finalizes 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 updates 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 these measures are available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Final-Specifications-for-LTCH-QRP-Quality-Measures-and-SPADEs.pdf. 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 measure assesses 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, it is 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 is 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 is 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.

- Transfer of Health Information to the Patient -- PAC Measure. This related new measure assesses 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 measure denominator is the total number of LTCH patient stays ending in discharge to the locations listed above, and the numerator is 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. The specifications for this measure are updated to remove baseline nursing facility residents beginning with the FY 2020 LTCH QRP. 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. Baseline NF residents are 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.

CMS responds to a number of comments regarding the transfer of information measures. It states that it plans to submit them for NQF endorsement as soon as feasible. CMS believes these measures will not substantially increase burden on LTCHs because many hospitals already generate medication lists as a best practice for discharge planning. Further, CMS rejects a suggestion that the "not applicable" answer choice available in the home health version of this measure be applied to all PAC settings, including LTCHs. It says that this option is available because, unlike facility settings, a home health agency may not be immediately aware of a patient's status, for example, when a patient is taken to the emergency room.

Regarding exclusion of baseline nursing facility residents from the discharge to community measure, CMS reports that all commenters except MedPAC supported this change. CMS disagrees with MedPAC and says that community is generally understood by policy makers, providers and other stakeholders to mean non-institutional settings, and that baseline nursing facility residents are an inherently different patient population.

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

In the proposed rule CMS sought 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 describes but does not respond to the comments it received, which 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 this rule, CMS finalizes requirements that LTCHs report a new series of SPADEs. The list of newly adopted SPADEs, along with information on their current use in PAC patient assessment instruments and whether changes apply to the LCDS are summarized in a table below. Detailed specifications for the SPADEs are available https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting/Downloads/Final-Specifications-for-LTCH-QRP-Quality-Measures-and-SPADEs.pdf. A final change table and mockup of 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 data elements associated with the new transfer of health information measures discussed above. (Note that unlike for all the other SPADEs, the preamble omits the specific declaration of adoption of the health literacy SPADEs, but its adoption is implied elsewhere in the discussion.)

The required reporting will begin with the FY 2022 LTCH QRP. For FY 2022 the data will 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 will 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 SPADE, the final rule discusses the rationale, whether the element is currently used in any PAC patient assessment instruments, describes past comments from stakeholders and pilot testing and responds to comments on the proposed rule. Most of the newly adopted SPADEs were proposed but not finalized as part of FY 2018 rulemaking. Those that were newly discussed in this year's rulemaking involve functional status (six mobility-related data elements already adopted for the other three PAC settings); high risk drug classes; pain interference; and social determinants of health, which is a newly added category of SPADEs. These address race, ethnicity, preferred language and interpreter services, health literacy, transportation, and social isolation.

With a change from the proposed rule, CMS finalizes that if certain SPADEs are submitted with respect to admission only, they will be deemed to have been submitted for both admission and discharge as generally required. This policy is finalized because assessment of certain elements is unlikely to change between admission and discharge. As proposed, this policy is finalized for the Hearing, Vision, and Race and Ethnicity SPADEs. In addition, based on comments received from stakeholders, CMS will also apply this policy to the new SPADEs regarding preferred language and interpreter services. CMS disagrees with comments suggesting the policy also apply to other SPADEs, including social isolation and health literacy.

Responding to commenters concerned with low frequency of a number of the SPADEs, CMS states that tracking important clinical information has value in care planning and transfer of information, even when events are rare. CMS also responds to numerous specific comments on individual SPADEs. Regarding its plans for using SPADEs, CMS reiterates its intention to use SPADE data to inform care planning, the common standards and definitions to facilitate interoperability, and for developing standardized measures. It intends to continue to collaborate with stakeholders during the policy development process and through future rulemaking.

In the collection of information requirements section of the final rule CMS estimates that the changes to the LTCH QRP (i.e., data collection for the new transfer of information measures and the SPADEs) will require additional data collection efforts and annual costs will total about $5,675 per LTCH or $2.35 million across all LTCHs.

New 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

New Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to LCDS**
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 PAC PRD	New item
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 OASIS	Modify LCDS items**
Ethnicity		
Preferred Language and Interpreter Services	MDS	Modify LCDS item**

New Standardized Patient Assessment Data Elements, by Category		
Data Elements	**Current Use/Test of Elements***	**Change to LCDS**
	LCDS	
Health Literacy		New item
Transportation	PREPARE/AHC screening tool	New item
Social Isolation	PROMISE/AHC screening tool	New item
*This column reflects whether the specific elements, 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 will 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 makes 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

The implementation date of any new version of the LCDS is moved from April to October, beginning October 1, 2020. This aligns 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 will 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 will 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 will be May 15, 2021. The final rule includes tables displaying the reporting deadlines for the FY 2022 and FY 2023 payment determinations.

Schedule for Reporting Transfer of Health Information Quality Measures and SPADES

As summarized in section VIII.C.1 above, two new measures are adopted beginning with FY 2022 payment. LTCHs must collect data for these measures beginning with patients discharged on or after October 1, 2020. The initial reporting schedule described above applies.

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

5. Removal of the List of Compliant LTCHs

CMS will 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

The LTCH QRP measure "Drug Regimen Review Conducted with Follow-Up for Identified Issues" will be added for public display to the *Long Term Care Hospital Compare* website at https://www.medicare.gov/longtermcarehospitalcompare/.

Display will begin with 2020 or as soon as technically feasible. The data display will 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 will not be publicly displayed. For those LTCHs, the website will 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**	**FY 2022**
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (NQF #0138)	X	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (NQF #0139)	X	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	X	X
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)	X	X	Removed	
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	X	X	X	X
NHSN Facility-Wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure (NQF #1716)	X	X	Removed	

LTCH QRP Measures, by Year				
Measure Title	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717)	X	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	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	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	X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632)	X	X	X	X
NHSN Ventilator Associated Event Outcome Measure	X	X	Removed	
Medicare spending per beneficiary MSPB-PAC LTCH	X	X	X	X
Discharge to Community PAC LTCH*	X	X	X	X
Potentially Preventable Readmissions 30 Days Post LTCH Discharge	X	X	X	X
Drug Regimen Review Conducted with Follow-up		X	X	X
Mechanical Ventilation Process Measure: Compliance with Spontaneous Breathing Test by Day 2 of the LTCH Stay		X	X	X
Mechanical Ventilation Outcome Measure: Ventilator Liberation Rate		X	X	X
Transfer of Health Information to the Provider – PAC Measure				X
Transfer of Health Information to the Patient – PAC Measure				X
* Measure updated to remove baseline nursing facility patients beginning in FY 2020.				

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 2.25 percentage points in the update factor for FY 2020. In the impact analysis section of this final rule, 167 hospitals are estimated to not meet the meaningful use requirements for FY 2019 payment; an additional 30 hospitals fail to meet both the meaningful use and IQR Program requirements and therefore are subject to a combined update factor reduction of 3.0 percentage points.

1. Reporting Periods in 2019 and 2021

A continuous 90-day reporting period was previously adopted for the Medicare Promoting Interoperability Program reporting during 2019 and 2020. 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 eliminates the October 1, 2019 reporting period deadline for hospitals that had not previously demonstrated meaningful use. These hospitals will then have all of 2019 to

complete the reporting requirement for the FY 2020 payment adjustment. (In the proposed rule, CMS had conditioned this deadline change on modifying the conversion of the Query of Prescription Drug Monitoring Program (PDMP) measure to yes/no attestation, which is finalized as described below.)

A continuous 90-day reporting period will also apply for returning participants during 2021 (for the FY 2023 payment adjustment). Eligible hospitals that have not previously demonstrated meaningful will use a continuous 90-day reporting period within 2021 for the FY 2022 and 2023 payment adjustment years, and for FY 2022 payment the self-selected reporting period must end before the October 1, 2021 deadline for registering and attesting to meaningful use.

2. 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 may be counted in the numerator if they occurred after the start of the reporting year and before the date of attestation.

CMS now finalizes 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, 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 will only increment based on actions that have occurred during the hospital's chosen EHR reporting period. This policy is codified in regulatory text. An exception is applied for 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.

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

4. Changes to Measures

In response to many concerns raised by stakeholders, the two opioid-related measures that were adopted in the FY 2019 IPPS/LTCH final rule are changed in this rule.

- Changes to Query of PDMP Measure. CMS modifies this measure in three ways: (1) the measure remains optional for 2020 reporting and eligible for 5 points, (2) beginning with 2019 reporting it is changed to a yes/no measure instead of a numerator/denominator measure, and (3) the exclusion for this optional measure is removed. Hospitals electing to report this measure will report "yes" if for 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.

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

- Removal of Verify Opioid Treatment Measure. CMS removes this 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. 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; and 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 modifies the regulatory text to clarify that for this measure 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

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.

Scoring for the 2020 reporting period is modified to reflect the changes described above, and is shown in the following table.

Performance-Based Scoring Methodology for EHR Reporting Periods in 2020

Objective	Measures	Maximum Points
e-Prescribing	e-Prescribing	10 points

Objective	Measures	Maximum Points
	Query of Prescription Drug Monitoring Program (PDMP)	5 points (bonus)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Incorporating Health Information	20 points
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	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

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 eligible hospitals and CAHs must report on four of the available 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 eCQMs available for 2020 reporting 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

This rule adds one new eCQM to the list of those available for reporting beginning with the 2021 reporting period; a second proposed new eCQM is not finalized for addition. The same change was adopted for the IQR Program, as discussed above in section VIII.A.1. Specifically, Safe Use of Opioids—Concurrent Prescribing eCQM (NQF #3316e) is added to the list of available eCQMs for reporting in 2021, and reporting on this eCQM is made mandatory beginning with the 2022 reporting period. As discussed in the IQR Program section of this summary, the measure specifications are modified from the proposed rule to clarify that this eCQM pertains to patients discharged from a hospital inpatient stay only.

As discussed earlier, the proposal to also add the measure Hospital Harm—Opioid Related Adverse Events eCQM is not finalized. The NQF Patient Safety Standing Committee recently voted not to endorse the measure, and CMS is re-evaluating this measure in light of that decision and the many other stakeholder comments.

For 2020 and 2021 reporting, the reporting rules in place for 2019 will continue. That is, eligible hospitals and CAHs will be required 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 and which report by attestation will report for a full calendar year on all available eCQMs. The data submission period ends 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, the new Concurrent Prescribing eCQM will be mandatory, with hospitals and CAHs selecting 3 other eCQMs to report.

Previously adopted requirements that EHRs be certified to all CQMs adopted for the Promoting Interoperability Program are extended for the 2020 reporting period and subsequent years. No changes are made to previously adopted policies regarding use of 2015 Edition 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 all eligible hospitals and CAHs must submit eCQM data electronically – attestation will 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 2023 allows for an adequate transition period for hospitals and CAHs to move to electronic reporting. Responding to a comment, CMS notes that the Medicare Promoting Interoperability Program offers hardship exceptions for extreme and uncontrollable circumstances.

IX. MedPAC Recommendations

In its March 2019 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by 2 percent with the difference between this and the update amount specified in current law to be used to increase payments in a new suggested Medicare quality program, the "Hospital Value Incentive Program (HVIP)." CMS responded that consistent with the statute, it is establishing an applicable percentage increase for FY 2020 of 2.6 percent, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements.

X. Other Required Information

This section includes a listing and a description of the data files that are available with the final 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 the final 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 provided 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 requested 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. The final rule refers readers to the earlier section on DSH for a discussion of public comments and the agency's response.

Appendix

TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2020

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2020 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2020 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2020 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Frontier State Wage Index and Outmigration Adjustment (6)[7]	Lowest Quartile Wage Index Adjustment and Transition with Application of Budget Neutrality (7)[8]	All FY 2020 Changes (8)[9]
All Hospitals	3,239	3	0	0	0	0	0.1	0	2.9
By Geographic Location:									
Urban hospitals	2,476	3.1	0	0	-0.1	0	0.1	0	2.9
Large urban areas	1,259	3.1	0.1	0	-0.7	-0.1	0.1	-0.1	2.8
Other urban areas	1,217	3	0	0	0.5	0.1	0.2	0	3
Rural hospitals	763	2.7	-0.2	0	1.1	-0.1	0.1	0.3	2.8
Bed Size (Urban):									
0-99 beds	635	3	-0.3	0	-0.8	0	0.3	0	2.6
100-199 beds	766	3.1	-0.1	-0.1	-0.2	0.1	0.2	0.1	2.8
200-299 beds	438	3.1	-0.1	0	0.1	0.1	0.1	0	2.8
300-499 beds	416	3.1	0	0.1	-0.1	0	0.1	-0.1	3
500 or more beds	221	3	0.2	0	-0.1	-0.1	0	-0.1	2.9
Bed Size (Rural):									
0-49 beds	317	2.7	-0.1	-0.1	0.4	-0.1	0.2	0.7	3.4
50-99 beds	262	2.6	-0.3	0	0.7	0	0.2	0.4	2.8
100-149 beds	101	2.8	-0.2	0	1	-0.1	-0.1	0.2	3
150-199 beds	45	2.8	-0.3	0	1.6	-0.1	0.2	0.3	2.7
200 or more beds	38	2.8	-0.1	0.1	1.9	-0.1	0	0.2	2.4
Urban by Region:									
New England	112	3.1	0.1	-0.4	1.8	0.4	0.1	0.9	0.8
Middle Atlantic	307	3.1	0.1	-0.1	0.6	-0.2	0.1	-0.2	3.3
South Atlantic	399	3.1	0	-0.1	-0.7	-0.1	0	-0.2	2.6
East North Central	386	3.1	0	-0.2	-0.3	-0.2	0.1	-0.3	2.8
East South Central	147	3.1	0	-0.2	-0.3	-0.1	0	0.7	3.8
West North Central	157	3	0	0.3	-0.9	-0.1	0.6	-0.2	3.2
West South Central	375	3.1	0	0	-0.8	-0.1	0	0	2.9
Mountain	169	3	-0.1	0.2	0	0.1	0.3	0.1	2
Pacific	374	3	0	0.5	0.2	0.5	0.1	-0.2	3.6
Puerto Rico	50	3.1	-0.1	-0.2	-1.1	0.3	0.1	12.5	14.8
Rural by Region:									
New England	20	2.9	-0.1	-0.8	0.7	-0.1	0	-0.1	1.2
Middle Atlantic	53	2.6	-0.2	-0.1	0.9	0	0	-0.1	2.6
South Atlantic	120	2.7	-0.1	-0.2	1.7	0	0	0.5	3.2
East North Central	114	2.7	-0.3	0	0.9	-0.1	0	0	2.5
East South Central	149	2.9	-0.2	0.5	1.7	-0.1	0.1	0.9	3.6
West North Central	93	2.5	-0.3	0.1	0.3	0	0.3	0.1	2.5

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West South Central	140	2.9	-0.3	-0.1	1.5	-0.1	0.1	0.7	3.4
Mountain	50	2.5	-0.4	0.2	0.2	0	0.6	-0.1	2.2
Pacific	24	2.7	-0.3	0.1	1	0	0	0	2.4
By Payment Classification:									
Urban hospitals	2,183	3.1	0	0	-0.6	0	0.1	0	2.9
Large urban areas	1,281	3.1	0.1	0	-0.7	-0.1	0.1	-0.1	2.8
Other urban areas	902	3.1	-0.1	0	-0.4	0.3	0.2	0.1	3
Rural areas	1,056	2.9	-0.1	0.1	1.6	-0.1	0.1	0.1	2.9
Teaching Status:									
Nonteaching	2,116	3	-0.1	0.1	0.1	0.1	0.1	0.1	2.9
Fewer than 100 residents	873	3.1	-0.1	-0.1	-0.1	0	0.2	0	2.9
100 or more residents	250	3	0.2	0	0.1	-0.1	0	-0.1	2.9
Urban DSH:									
Non-DSH	522	3.1	-0.1	-0.1	-0.2	-0.1	0.2	-0.1	2.7
100 or more beds	1,400	3.1	0	0	-0.6	0.1	0.1	0	2.9
Less than 100 beds	358	3.1	-0.2	0	-0.7	0.1	0.2	0	2.6
Rural DSH:									
SCH	258	2.5	-0.3	0	0	0	0	0.1	2.4
RRC	446	3	0	0.2	1.9	-0.1	0.1	0.1	3
100 or more beds	28	3.1	0	-1	0.3	-0.2	0	0.2	2.2
Less than 100 beds	227	2.8	0	-0.2	0.3	-0.1	0.2	1.3	3.9
Urban teaching and DSH:									
Both teaching and DSH	781	3.1	0.1	-0.1	-0.7	0	0.1	-0.1	2.9
Teaching and no DSH	76	3.1	0	-0.1	-0.2	-0.2	0	-0.2	2.8
No teaching and DSH	977	3.1	-0.1	0	-0.4	0.2	0.1	0.1	2.8
No teaching and no DSH	349	3.1	-0.2	0	-0.8	-0.1	0.2	-0.1	2.8
Special Hospital Types:									
RRC	383	3.1	0	0.1	2.2	-0.1	0.2	0.1	3.1
SCH	306	2.5	-0.3	0	0	0	0	0.1	2.4
MDH	150	2.7	-0.3	-0.1	0.5	-0.1	0.3	0.6	3.2
SCH and RRC	144	2.6	-0.3	0	0.3	0	0	0.1	2.5
MDH and RRC	19	2.8	-0.5	-0.1	0.5	0.2	0	0.1	2.1
Type of Ownership:									
Voluntary	1,892	3	0	0	0.1	0	0.1	0	2.9
Proprietary	853	3.1	-0.1	0	-0.2	0	0.1	0.1	2.8
Government	494	3	0.1	-0.1	-0.1	0.1	0	0	3
Medicare Utilization as a									
0-25	613	3	0.1	0.2	-0.4	0	0	0	3
25-50	2,140	3	0	0	0	0	0.1	0	2.9
50-65	396	3	-0.2	-0.2	0.5	0.1	0.2	0.1	2.6
Over 65	68	2.6	1.1	0.3	-0.9	0.2	0.6	0.9	5.8
FY 2020 Reclassifications									
All Reclassified Hospitals	821	3	0	0.1	2.2	-0.1	0	0	3.1
Non-Reclassified Hospitals	2,418	3	0	0	-0.9	0	0.1	0	2.8

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Urban Hospitals	548								
Urban Non-Reclassified	1,835	3.1	0	0	-1.1	0.1	0.1	-0.1	2.9
Rural Hospitals Reclassified Full Year	273	2.8	-0.3	0.1	1.8	0	0	0.2	2.7
Rural Non-Reclassified Hospitals Full Year	436	2.6	-0.2	-0.2	-0.3	-0.1	0.2	0.6	3
All Section 401 Reclassified Hospitals	347	3	0	0.1	1.9	-0.1	0.1	0	3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	2.9	-0.2	-0.2	2.1	-0.1	0	0.2	2.7

[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 hospital rate update and other adjustments, including the 2.6 percent adjustment to the national standardized amount and the hospital-specific rate (the estimated 3.0 percent market basket update reduced by 0.4 percentage point for the multifactor productivity adjustment), and the 0.5 percentagepoint adjustment to the national standardizedamount requiredunder section 414 of the MACRA.

[3] This column displays the payment impact of the changes to the Version 37 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights basedon FY 2018 MedPAR data in accordance with section 1886(d)(4)(C)(iii) of the Act. This column displays the application of the recalibration budget neutrality factor of 0.997649in accordance with section 1886(d)(4)(C)(iii) of the Act.

[4] This column displays the payment impact of the update to wageindex 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 wage budget neutrality factor, which is calculated separately fromthe recalibration budget neutrality factor, and is calculated in accordance with section 1886(d)(3)(E)(i) of the Act. The wagebudget neutrality factor is 1.001573.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The 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 bearingon the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.985425.

[6] This column displays the effects of the rural floor. For FY 2020 and subsequent years, we are calculating the rural floor without including the wage data of hospitals that have reclassified as rural under § 412.103. The statute requiresthe rural floor budget neutrality adjustment to be 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is0.997081.

[7] This column showsthe combinedimpact of the policy required under section 10324 of the Affordable Care Act that hospitals located in frontier States have a wageindex 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 wageindex if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wageindexes. These are not budget neutral policies.

[8] This column displays the effects of increasing the wageindex for hospitals with a wageindex value below the 25th percentile wage index (that is, the lowest quartile wage index adjustment), the 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 5-percent cap), andthe associated budget neutrality factors,. This column reflects the budget neutrality factor of 0.997987 for the lowest quartile wageindex adjustment and the budget neutrality factor of 0.998838 for the 5-percent cap.

[9] This column shows the estimated change in payments from FY 2019 to FY 2020.