Fiscal Year 2023 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Final Rule

On August 1, 2022, the Centers for Medicare & Medicaid Services (CMS) released its final rule describing federal fiscal year (FY) 2023 policies and rates for Medicare's inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS). The final rule will be published in the *Federal Register* on August 10, 2022.

The payment rates and policies described in the IPPS/LTCH final rule (CMS-1771-F) affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in LTCHs. The FY 2023 IPPS final rule also updates CMS' quality reporting, value-based purchasing and promoting electronic health record interoperability programs. The final rule also sets forth rate-of-increase limits for inpatient services provided by certain IPPS-Exempt providers, such as cancer, children's hospitals, and religious nonmedical health care institutions which are paid based on reasonable costs. Unless otherwise specified, policies will be effective October 1, 2022.

CMS included requests for information (RFIs) in the proposed rule on social drivers of health, how CMS can support health care providers prepare for the harmful effects of climate change, approaches for measuring health care disparities, advancing digital quality measurement, and the U.S. maternal health crisis. The final rule presents the comments CMS received on all of these issues, which CMS said will inform future policy development.

The rule also finalizes CMS proposals requiring hospitals and critical access hospitals to continue reporting COVID-19 and seasonal influenza infections after the end of the COVID-19 public health emergency as a condition of participation in Medicare and revisions to Medicare's direct graduate medical education (DGME) regulations in response to adverse litigation against the agency. CMS did not finalize a proposal for the 2nd consecutive year for how section 1115 waiver days are counted for determining the Medicare disproportionate share percentage (DSH) percentage.

CMS makes many data files available to support analysis of the proposed rule. These data files are generally available at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page.

Table of Contents

Table of Contents

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

CMS estimates that the final rule will increase FY 2023 combined operating and capital payments to approximately 3,142 acute care hospitals paid under the IPPS by an estimated $1.4 billion. This estimate is accounted for by the following:

Combined Expenditure Change Estimate ($ in Billions)	
IPPS Operating	2.84
Uncompensated Care	-0.032
Indian Health Service/Tribal/Puerto Rico Supplemental Payments	0.096
Capital Payments	0.039
New Technology Add-On	-0.75
Expiration of the Low-Volume Payment Adjustment	-0.437
Expiration of the Medicare Dependent Hospital Program	-0.180
Change to the Direct Medical Education Weighting methodology	0.17
Total	**1.42**

A. Inpatient Hospital Operating Update

The above are changes to IPPS payments. The estimated percentage increase in IPPS *payment per service* is estimated at 4.3 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 4.3 percent rate increase is the net result of a market basket update of 4.1 percent less 0.3 percentage points for total factor productivity, and +0.5 percentage points for documentation and coding required by section 414 of the Medicare Access and CHIP Reauthorization Act (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) are paid. However,

the documentation and coding adjustment does not apply to the hospital-specific rates resulting in a 3.8 percent increase rather than a 4.3 percent increase for SCHs.

Factor	Percent Change
FY 2023 Market Basket	4.1%
Total Factor Productivity	-0.3
MACRA Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	4.3%

Hospitals that fail to participate successfully in IQR or are not meaningful users of EHR do not receive the full payment rate increase. The below table shows the update (before application of the 0.5 percentage point increase for documentation and coding). The reduction is ¼ of the market basket for hospital failing IQR, ¾ of the market basket for hospitals that are not meaningful users of EHR, and 100 percent of the market basket for hospitals failing both programs.

Updates for Hospitals Failing IQR and/or EHR

	Penalty	Market Basket (MB)	Market Basket Net of MFP	Reduction (Percentage Points)	Update	Hospitals
No IQR	25% of the MB	4.1%	3.8%	-1.025	2.775%	24
No EHR	75% of the MB	4.1%	3.8%	-3.075	0.725%	158
No IQR/EHR	100% of the MB	4.1%	3.8%	-4.1%	-0.3%	20

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2023 payments increasing 2.6 percent. Not all policy changes are reflected in this total. For example, the total does not include estimated reductions in UCP and NTAPs. The factors that are included in this total are shown in the following table.

Contributing Factor	National Percentage Change
FY 2023 increase in payment rates	+4.2[1]
Imputed and Frontier Wage Index Floors and Outmigration Adjustment	+0.3[2]
Expiration of the MDH Program	-0.2[3]
Outliers	-1.7[4]
Total	+2.6

[1]Weighted average of hospital-specific rate update of 3.8 percent and 4.3 percent for all other hospitals.
[2]Wage index provisions that do not require budget neutrality.
[3]MDH program is a temporary program that has been set to expire many times previously before being extended again by Congress—sometimes retroactively.
[4]CMS targets 5.1 percent of IPPS payments as outliers but estimates that it will pay 1.7 percent more than the amount targeted in FY 2022. As a result, CMS estimates total payments will decline by 1.7 percent due to targeting 5.1 percent of total IPPS payments as outliers for FY 2023.

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 Proposed Rule Changes
All Hospitals	2.6%
Urban	2.6%
Rural	2.4%
Major Teaching	2.5%

To the extent the impact on a given hospital category deviates from the national average of 2.6 percent, it suggests that there is a factor resulting in more of an impact on that category of hospital compared with all other hospitals. The impact would be redistributive from a policy that is budget neutral. The redistributive payment changes from the DRG relative weight and wage index changes are reasonably modest. Most of the changes are within a few tenths of a percentage point from the national average. Geographic reclassification generally benefits rural hospitals while imputed floor and the rural floor can only benefit urban hospitals. Imputed floor is not budget neutral while rural floor is made budget neutral through an adjustment to hospital wage indexes.

The largest deviation from the average increase of 2.6 percent is occurring from expiration of the MDH program. While that program has been set to expire numerous times in its 30+ years of existence, Congress has always temporarily extended the program. Nevertheless, at this point in time, the MDH program is set to expire at the end of FY 2022 and CMS is showing the impact of its expiration on payments in FY 2023. CMS estimates that expiration of the MDH program will affect 91 hospitals and decrease spending $180 million.

Other provisions having an impact include:

Rural Floor. The rural floor raises the wage index of 275 urban hospitals so that it is not below the wage index for the rural area of its state. CMS calculates a national rural floor budget neutrality adjustment factor of 0.991909 (-0.81 percent) applied to hospital wage indexes. CMS projects that rural hospitals in the aggregate will experience a 0.2 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in urban areas would experience no average change in payments; and urban hospitals in the New England region can expect a 3.8 percent increase in payments relative to the rural floor not being applied, primarily due to the application of the rural floor in Massachusetts.

Imputed Floor. The imputed floor was established by section 9831 of the American Rescue Plan Act enacted on March 11, 2021. Under section 9831, CMS is required to use a formula to establish a statewide wage index floor in all urban states, Washington, DC, and Puerto Rico. The imputed floor provision is not subject IPPS budget neutrality. CMS estimates the imputed floor will increase payment to 66 hospitals by $124 million.

Frontier Wage Index and Outmigration. In the IPPS impact table, CMS includes a column for the frontier hospital wage index floor that increases payments by about $71 million to 44 hospitals and the outmigration adjustment that increases payments by about $53 million to 210 hospitals.

NTAP. NTAP payments are not subject to budget neutrality. CMS is continuing NTAP payments for 15 technologies that remain eligible. These technologies are estimated to receive $620 million in FY 2023 NTAP payments. CMS approved an additional 10 applications (six under the alternative pathway and four under the traditional pathway). These technologies are estimated to receive $163.6 million in FY 2023 NTAP payments. In total, CMS estimates it will pay $783.6 million in NTAP payments in FY 2023. CMS estimates FY 2022 NTAP payments of $1.4 billion meaning there would be a reduction in FY 2023 NTAP payments of $651 million.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by 4.4 percent or about $318 million. However, about $96 million of this reduction is offset by supplemental payments to Puerto Rico, Indian Health Service and Tribal Hospitals that CMS will make to replace low-income insured days proxy to calculate uncompensated care payments for these hospitals. The net reduction in uncompensated care/supplemental payments is estimated at $221 million. More detail on these calculations is in section IV.

Low-Volume Hospitals. Like the MDH program, the low-volume hospital program is set to expire at the end of FY 2022. While the low-volume hospital program has also been set to expire many times before and been extended, CMS' final rule assumes current law and the program will not be extended into FY 2023. Absent another extension of the low-volume hospital program, CMS estimates that 632 providers will no longer qualify for a special adjustment and aggregate payments will decrease by $437 million.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2023 payments to an estimated 2,849 hospitals or 79.8 percent of all hospitals eligible to receive a readmissions penalty. The readmissions penalty is estimated to affect 0.42 percent of payments to the hospitals that are being penalized for excess readmissions. The impact section of the rule 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 2023.

Hospital Value-Based Purchasing (HVBP) Program. The HVBP program is budget neutral but redistributes 2 percent of base operating MS-DRG payments based on hospitals' performance scores. For FY 2023, CMS is finalizing a proposal that results in all hospitals receiving an incentive payment of 2 percent equal to the 2 percent reduction in base operating rates. Effectively, CMS is not applying any HVBP adjustments for FY 2023.

Hospital Acquired Conditions (HAC) Reduction Program. CMS is not applying any HAC penalties in FY 2023. Table 1 in the HAC impact section of the final rule shows the number of hospitals participating the program but does not show the number and percent of hospitals that would be in the worst performing quartile by hospital category.

DGME. In response to adverse litigation, CMS is changing its DGME calculation such that there will be no adjustment to a hospital's FTE count unless both the unweighted and weighted counts of residents are above the hospital's DGME FTE cap. CMS estimates this change will increase payments by $170 million in FY 2023.

Rural Community Hospital Demonstration Program. CMS estimates costs for the Rural Community Hospital Demonstration Program at $72.5 million for FY 2023 and $36.0 million using reconciled cost reports for FY 2017 when no budget neutrality adjustment was applied. CMS is applying a budget neutrality adjustment to the IPPS standardized amounts based on total costs of $108.5 million in FY 2023.

C. IPPS Standardized Amounts

The following four rate categories continue in FY 2023 (before adjustments):

	Update
Full Update	3.8%
No IQR	2.775%
No EHR	0.725%
No EHR/IQR	-0.3%

The applicable percentage changes above are prior to budget neutrality factors applied to the standardized amount and the documentation and coding adjustment. The adjustments to the standardized amounts are as follows:

- MS-DRG recalibration, 1.000509 (an increase of 0.05 percent);
- MS-DRG recalibration cap, 0.999764 (a decrease of 0.02 percent)
- Wage index, 1.000968 (an increase of 0.10 percent);
- Geographic reclassification, 0.984399 (a reduction of 1.56 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.998146 or -0.19 percent;
- 5 percent cap on wage index reductions, 0.999689 or -0.03 percent;
- The outlier offset factor is 0.949 or -5.1 percent; and
- The rural community hospital demonstration program adjustment is 0.998935 or -0.11 percent.

Of the adjustments above, MS-DRG recalibration and wage index are maintained on the standardized amount from year-to-year. The prior year adjustments for geographic reclassification, wage indexes below the 25th percentile, transitioning reductions to the wage index, the outlier adjustment, and rural community hospital demonstration project are removed from the FY 2022 standardized amount before the FY 2023 adjustments are applied. The net increase in the standardized amount results as follows:

Factor	Net Change
Update	3.8%
DRG Recalibration	0.05%
DRG Recalibration Cap	-0.02%
Wage Index	0.10%
Geographic Reclassification	-0.24%
25th Percentile	0.01%
5% Cap on Wage Index Reductions	-0.02%
Outlier	0.00%
Rural Community Hospital	-0.04%
Doc and Coding	0.50%
Net Change*	4.1%

*Net change is the product of the prior factors, not the addition

The increase in the capital rate is 2.36 percent from $472.59 to $483.76. The combined increase in the operating standardized amount and the capital rate will be 4.02 percent for FY 2023.

The standardized amounts do not include the 2 percent Medicare sequester reduction that began in 2013 and will continue until at least 2030 under current law. The sequester reduction is applied as the last step in determining the payment amount for submitted claims and does not affect the underlying methodology used to calculate MS-DRG weights or standardized amounts. (The sequester reduction was suspended during the pandemic beginning May 1, 2020 through March 31, 2022 and is 1 percent from April 1, 2022 through June 30, 2022).

STANDARDIZED AMOUNTS FY 2023

	Full Update=3.8%	**Reduced Update Failed IQR = 2.775%**	**Reduced Update Failed EHR =0.725%**	**Reduced Update Failed IQR and EHR = -0.3%**
Wage Index >1.0				
Labor (67.6%)	$4,310.00	$4,267.44	$4,182.32	$4,139.76
Non-Labor (32.4%)	$2,065.74	$2,045.34	$2,004.54	$1,984.15
WI<=1.0				
Labor (62%)	$3,952.96	$3,913.92	$3,835.85	$3,796.82
Non-Labor (38%)	$2,422.78	$2,398.86	$2,351.01	$2,327.09
National Capital Rate (All Hospitals)	$483.76			

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, UCP and NTAP plus the "outlier threshold" or "fixed-loss" amount, which is $30,988 for FY 2022. 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 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 2023 outlier threshold. CMS proposed to adopt an outlier threshold for FY 2023 of $43,214, an increase of 39.5 percent and $12,266 from the FY 2022 amount. In the final rule, CMS is adopting an outlier threshold of $38,859, an increase of 25.4 percent and $7,871 from the FY 2022 amount. CMS projects the outlier threshold for FY 2023 will result in outlier payments equal to 5.1 percent of operating DRG payments and 5.52 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.944837 to the capital federal rate to fund operating and capital outlier payments respectively.

FY 2023 outlier threshold methodology. CMS is following past practice targeting total outlier payments at 5.10 percent of total operating DRG payments including the adjustment for outlier reconciliation explained below (including outlier, all wage adjustments and UCP but continuing to exclude adjustments for value-based purchasing and the readmissions reduction program).

CMS' historical practice has been to calculate the outlier threshold based on the latest claims and cost report data. For FY 2023, the latest year of claims data is the March 2022 update to the FY 2021 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data is the March 2022 update of the Provider-Specific File (PSF).

Charge Inflation. Normally, CMS would compute the charge inflation factor using data from the MedPAR files for FYs 2020 and 2021. However, CMS' analysis indicates that the one-year increase in charges between FY 2020 and FY 2021 is 10 percent compared to 6 percent between FY 2018 and FY 2019. CMS believes this abnormally high charge inflation compared to historical levels was partially due to the number of COVID-19 cases with higher charges that were treated in IPPS hospitals in FY 2021. CMS believes there will be fewer COVID-19 cases in FY 2023 than in FY 2021 and the increase in charges will return to historical levels.

For this reason, CMS proposed to use the one-year charge inflation factor between FY 2018 and FY 2019 to inflate FY 2021 charges to determine the FY 2023 outlier threshold. These are the same charge inflation factors used to determine the FY 2021 and FY 2022 outlier thresholds and are based on the March 2019 MedPAR for FY 2018 and the March 2020 MedPAR for FY 2019.

These data are shown in the table below.

	Charges	Cases	Average Charge Per Case
FY 2018	$584,618,863,834	9,493,830	$61,578.82
FY 2019	$604,209,834,327	9,221,466	$65,522.10
Annual Rate of Increase			1.064 (6.4%)
Squared for 2 Years of Inflation			1.132 (13.2%)

CCRs. Normally, CMS would propose to adjust CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR between the December 2020 and December 2021 updates of the PSF. However, the operating and capital CCR adjustment factors using this methodology are above 1.0 (1.03 for both operating and capital) when they would normally be below 1.0 (approximately 0.97 and 0.96 for operating and capital respectively based on the March 2019 and March 2020 updates to

the PSF). As with charge inflation, CMS believes the CCR adjustment factor is abnormally high due to the high number of COVID-19 cases treated in IPPS hospitals in FY 2021. CMS believes there will be fewer COVID-19 cases in FY 2023 than in FY 2021 and the change to CCRs will return to historical levels.

Therefore, CMS proposed to adjust the CCRs from the December 2021 update of the PSF by comparing the percentage change in the national average case-weighted operating and capital CCRs between the March 2019 and March 2020 updates to the PSF—the last update of the PSF prior to the PHE. These are the same data used to adjust the CCRs for FY 2022 and are shown in the table below.

	Operating	Capital
March 2019 PSF	0.254027	0.0207300
March 2020 PSF	0.247548	0.0019935
% Change	-2.55%	-3.84%
Factor	0.974495	0.96165

CMS indicates that if did not take these special actions with regard to the charge inflation factor and the CCR adjustment, the proposed FY 2023 outlier threshold would have been $58,798.

Comments/Responses: Many commenters were concerned about the large increase in the outlier threshold and supported CMS' proposed interventions to mitigate its increase. Other commenters did not support CMS' use of pre-COVID trends to determine a charge inflation factor and CCR adjustment appearing to misunderstand that CMS' proposal was intended to lower the outlier threshold not understate inflation hospitals are experiencing.

There were a variety of comments about other actions CMS could take to mitigate the increase in the outlier threshold including: removing high-cost or all COVID cases from the model; using various blends of different years of data with and without COVID cases; and using an average of prior year and current year thresholds. One commenter indicated that CMS should include the 20 percent increase in Medicare payments for patients with COVID-19 as required by the Coronavirus Aid, Relief and Economic Security (CARES) Act and the New COVID-19 Technology Add-on Payment (NCTAP) when determining the FY 2023 outlier threshold. As these payments would increase non-outlier payments, it would contribute towards determining a lower outlier threshold. Similarly, there were comments suggesting a higher update could make the outlier threshold lower. MedPAC suggested calculating the FY 2023 fixed-loss amount as an average of the outlier fixed-loss amounts calculated with and without COVID-19 cases in the FY 2021 data.

CMS is adopting the approach suggested by MedPAC when determining the FY 2023 outlier fixed loss amount. It also agrees with the commenter to include the increase in payments for COVID-19 cases provided by the CARES Act when modeling the FY 2023 outlier threshold. However, NCTAP are not used in the determination of outlier payments, do not impact the calculation of the outlier threshold, and are not being included in CMS' outlier modeling. CMS notes that, consistent with the comments, it is incorporating a higher payment update in the final rule than in the proposed rule which also contributes to lowering the outlier threshold.

After consideration of the public comments, CMS is finalizing its proposed methodology with the modification of calculating two fixed-loss thresholds—one using FY 2021 claims data including COVID-19 cases that reflect the payment increase provided by the CARES Act and one using FY 2021 claims data excluding COVID-19 cases. The average of these two fixed-loss thresholds will be the final fixed-loss threshold for FY 2023. As CMS is not changing its proposal with respect to applying a pre-COVID charge inflation and CCR adjustment factor, the data for those adjustments is unchanged from what is shown in the tables above.

Reconciliation. 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. Continuing a practice begun in FY 2020, CMS is reflecting reconciliation in the determination of the FY 2023 outlier threshold.

For the FY 2023 outlier threshold, CMS will use the historical outlier reconciliation amounts from the FY 2017 cost reports (cost reports with a beginning date on or after October 1, 2016, and on or before September 30, 2017). CMS indicates these are the most recent and complete set of cost reports which are finalized and/or approved by the Medicare Administrative Contractor (MAC). For the FY 2023 final rule, CMS is using the March 2022 extract of the Hospital Cost Report Information System (HCRIS) to determine the reconciliation amounts.

CMS determined reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2017 for FY 2023). It then subtracts 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. There were no public comments on CMS' proposed methodology for determining outlier reconciliation payments.

In the final rule, CMS estimates that reconciliation in FY 2017 resulted in 17 hospitals being owed $17.153 million or -0.019401 percent of total operating IPPS payments. This figure rounds to -0.02 percent. Subtracting -0.02 percentage points from 5.10 percent is 5.12 percent. CMS targeted 5.12 percent of operating payments as outliers assuming that -0.02 percentage points of that amount will be repaid to hospitals under the reconciliation process. Reconciliation will have the effect of slightly decreasing the FY 2023 outlier threshold to target a slightly higher percentage of operating payments as outliers.

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. For capital, CMS estimates that 14 hospitals were owed $1,101,225 in reconciled capital outlier payments or -0.01 percent of total capital outlier payments.

FY 2021 Outlier Payments. CMS' current estimate, using available FY 2021 claims data, is that actual outlier payments for FY 2021 were approximately 5.66 percent of actual total MS-DRG payments or 0.56 percentage points more than the target of 5.1 percent—the amount the standardized amount was reduced by to fund outliers. Following long-standing policy, the

agency will not make retroactive adjustments to ensure that total outlier payments for FY 2021 are equal to the projected 5.1 percent of total MS-DRG payments and the amount of the reduction in the standardized amounts.

FY 2022 Outlier Payments. CMS says that FY 2022 claims data are unavailable to estimate the percentage of total payments made as outliers in FY 2022. However, in the impact section of the final rule, CMS estimates that, using FY 2021 data, outlier payments will be 1.7 percentage points higher (or 6.8 percent) than the 5.1 percent targeted and removed from the standardized amounts to fund outlier payments.

II. Medicare Severity (MS) Diagnosis-Related Groups (DRGs)

A. Adoption of the MS-DRGs and the Documentation and Coding Adjustment

CMS provides an abbreviated history of the MS-DRGs and documentation and coding adjustment going back to adoption of the MS-DRGs in FY 2008. In summary, CMS adopted 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 changes require CMS to make a series of annual positive adjustments from FY 2018 to FY 2023 to offset prior negative ones that occurred from FY 2014 through FY 2017. For FY 2023, consistent with MACRA, CMS proposed to implement a positive 0.5 percentage point adjustment to the standardized amount.

This 0.5 percentage point positive adjustment is the final adjustment prescribed by MACRA. Along with the 0.4588 percentage point positive adjustment for FY 2018, and the 0.5 percentage point positive adjustments for FY 2019, FY 2020, FY 2021, and FY 2022, this final adjustment will result in a combined positive adjustment of 2.9588 percentage points (the sum of the adjustments for FYs 2018 through 2023) to the standardized amount. In total, CMS reduced rates by 3.9 percent to recoup excess spending for documentation and coding while MACRA prescribed returning 2.9588 percent—for a net reduction of 0.9412 percentage points overall.[1] CMS received no comments on the proposed adjustment for FY 2023 and is finalizing application of the adjustment without change.

B. Changes to Specific MS-DRG Classifications

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

In the FY 2021 IPPS proposed rule, CMS proposed to change the deadline to request updates to the MS-DRGs from November 1 to October 20 of each year.[2] CMS stated this would provide more time to evaluate requests. CMS finalized this proposal but due to the PHE maintained the deadline of November 1, 2020 for FY 2022 and FY 2023 MS-DRG classification change

[1] Of this 0.9412 net reduction, 684 hospitals disputed 0.7 percentage points of the adjustment made by CMS for FY 2017 in *Fresno Community Hospital, et al., v Cochran*. The Court declined to require that CMS restore 0.7 percentage points adjustment beginning in FY 2018.
[2] 85 FR 32472

requests**. Beginning with FY 2024 MS-DRG classification change requests, CMS is changing the deadline to request changes to the MS-DRGs to October 20 of each year**.

Beginning with FY 2024, CMS is also changing the process for submitting MS-DRG classification change requests and will only accepted requests submitted through the Medicare Application Request Information System™ (MEARIS). The MEARIS system will also be used to submit new technology add-on payment applications, requests for ICD-10-PCS procedure codes, and other requests. Effective January 5, 2022, MEARIS was available for users to submit ICD-10-PCS procedure code requests. Information about MEARIS, including the mechanism for submitting MS-DRG classification changes, is available at https://mearis.cms.gov. This website includes a resource section and a link for technical support. Questions about the MEARIS system can be submitted to CMS using the form available under "Contact" at https://mearis.cms.gov/public/resources?app=msdrg.

CMS notes that it may not be able to fully consider all the requests it receives for the upcoming fiscal year. CMS has found that ICD-10 requires more extensive research to identify and analyze all of the data relevant to potential changes and notes in the discussion for MS-DRG classification changes which topics it will continue to consider in future rulemaking. Interested parties should submit any comments and suggestions for FY 2024 by October 20, 2022 via MEARIS at https://mearis,cms,gov/public/home.

This section of the preamble discusses changes that CMS finalizes to the MS-DRGs for FY 2023. CMS used claims data from the September 2021 update of the FY 2021 MedPAR file, which contains hospital bills received through October 1, 2020 through September 30, 2021, for discharges occurring through September 30, 2021. For this final rule, CMS generally did not perform any addition MS-DRG analysis of claims data and used the September 2021 update of the FY 2021 MedPAR file, except as otherwise noted.

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.

In the FY 2021 final rule, CMS expanded these criteria to include the NonCC subgroup for a three-way severity level split.[3] CMS believes that this will better reflect resource stratification and promote stability in the relative weights by avoiding low volume counts for the NonCC level MS-DRG. The table below, reproduced from the rule, illustrates all five criteria and how they are applied to each CC.

Criteria Number	**Three-Way Split** 123 (MCC vs CC vs NonCC)	**Two-Way Split** 1_23 MCC vs (CC+NonCC)	**Two-Way Split** 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three-way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

For analysis of requests to create a new MS-DRG, CMS evaluates the most recent year available of MedPAR claims data. For evaluation of requests to split an existing base MS-DRG into severity levels, CMS analyzes the most recent 2 years of data. Using 2 years of data reduces changes related to an isolated year's data fluctuation. CMS first evaluates if the creation of a new CC subgroup is warranted to determine if all criteria are satisfied in a three-way split. If the criteria fail, CMS will determine if criteria are satisfied for a two-way split and apply the two-way split with the highest R2 value. If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for the base MS-DRG. CMS will evaluate the criteria for both of the two-way splits but it will not also evaluate the criteria for a three-way split.

[3] 85 FR 58448

CMS analyzed how applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would affect the MS-DRG structure for FY 2023. This analysis used the September 2021 update of the FY 2021 MedPAR file. CMS found that applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would delete 123 MS-DRGs (41MS-DRGs x 3 severity levels = 123) create 75 new MS-DRGs. These updates would also involve a redistribution of cases, which would impact the relative rates and thus the payment rates. Table 6P.1b associated with the proposed rule contains the list of the 123 MS-DRGs that would be subject to deletion and the list of the 75 new MS-DRGs that would be proposed if the NonCC subgroup criteria were applied.

Because of the PHE, CMS continues to have concerns about the impact of implementing these MS-DRGs changes and believes it may be appropriate to continue to delay the application of the NonCC subgroup criteria to maintain more stability in the current structure. For FY 2023, CMS proposed not to apply the NonCC subgroup criteria to existing MS-DRGs with and three severity level split and to maintain the current structure of the 41 MS-DRGs that currently have a three-way severity level split (123 MS-DRGs).

Commenters overwhelmingly supported the proposal to delay application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split. Commenters also requested that CMS provide for public comment the impacts to the relative weights before a proposal is finalized. Some commenters requested CMS delay implementation beyond the PHE and use hospital claims data that is not impacted by the pandemic. A commenter recommended CMS conduct a full analysis similar to the analysis performed for the transition from CMS DRGs to MS-DRGs in FY 2008. In response to comments asking for clarification about the differences between MS-DRGs proposed to be removed in FY 2022 from the list proposed to be removed in FY 2023, CMS explains the difference is a result of the claims data used for the MS-DRG analysis and rulemaking for each fiscal year.

After consideration of public comments, CMS finalizes its proposal to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2024 or later. For FY 2023 finalizes maintaining the current structure of the 41 MS-DRGs that currently have a three-way severity level split. CMS intends to conduct a comprehensive analysis of the NonCC subgroup criteria that will be made publicly available for review and comment in connection with any proposed MS-DRG changes for future rulemaking.

2. Pre-MDC: MS-DRG 018 Chimeric Antigen Reception (CAR) T-Cell and Other Immunotherapies

In the FY 2022 IPPS PPS final rule, CMS finalized assigning procedure codes describing CAR T-cell, non-CAR T-cell, and other immunotherapies to Pre-MDC MS-DRG 018. In response to commenter's recommendation that it continue to assess the appropriateness of the therapies assigned to this MS-DRG, in the proposed rule CMS provided the results of its data analysis using the September 2021 update of the FY 2021 MedPAR file for cases reporting the administration of a CAR T-cell or other immunotherapy and the number of cases reporting a secondary diagnosis of Z00.6 (Encounter for examination for normal comparison and control in clinical research program). The data showed there is a wide range of case (4 vs. 435), average

length of stay (11.3 days vs. 20.3 days), and average costs ($157,950 vs. $310,561). A table in the final rules summarizes this information. CMS continues to believe these results are to be expected since these therapies continue to evolve and the ICD-10-PCS codes continue to be refined. CMS will continue to evaluate claims data to determine if future modifications to Pre-MDC MS-DRG are warranted.

Several commenters expressed support for CMS' proposal to maintain the current structure of this MS-DRG. Some commenters acknowledged it is difficult to predict what the associated costs will be for CAR T-cell and other immunotherapies being developed and urged CMS to consider factors such as new or different side effects as CMS continues to monitor resource utilization and data analysis for this DRG.

Some commenters again expressed concerns with the non-CAR T-cell therapies and other immunotherapies assigned to the same MS-DRG because these potential assignments could lead to fluctuations in the relative weight. CMS notes these comments are similar to the public comments received in response to the FY 2002 IPPS PPS proposed rule and references the FY 2022 IPPS final rule (86 FR 44798-44806) for its detailed response. CMS notes that additional claims data is needed to fully analyze and consider all the recommendations it has received, and to potentially develop alternative proposals for these therapies.

A commenter suggested CMS consider establishing a timeframe that would allow public comment on procedure codes assigned to Pre-MDC MS-DRG upon being approved and finalized after the spring ICD-10 Coordination & Maintenance (C&M) Committee meeting. In response, CMS acknowledges the uniqueness of CAR T-cell, gene, and cellular therapies and believes it is necessary to examine how and when it could alter its current methodology and timelines to provide the opportunity to allow comments in the assignment of new procedure codes finalized after the spring meeting. CMS notes that following the March meeting, new procedure codes were established for the Administration of afamitresgene autoleucel (a specific peptide enhanced affinity receptor T-cell therapy) and Administration of Tabelecleucel (an allogeneic Epstein-Barr virus-specific T cell immunotherapy) and these procedure codes have been finalized for assignment to Pre-MDC MS-DRG 018 effective with discharges on and after October 1, 2022.[4]

3. MDC 01 (Diseases and Disorders of the Nervous System

a. Laser Interstitial Thermal Therapy (LITT)

In the FY 2022 IPPS PPS final rule, CMS finalized the reassignment of 31 ICD-10 PCS procedure codes describing laser interstitial therapy (LITT) of various body parts to more clinically appropriate MS-DRGs.[5] This included the reassignment of procedure codes D0Y0KZZ (LITT of brain) and D0Y1KZZ (LITT of brain stem) from MS-DRGs for craniotomy and endovascular procedures (MS-DRGs 023 – 027) to MS-DRG assignments for peripheral, cranial nerve and other nervous system procedures (MS-DRGs 041 – 042). CMS also finalized the

[4] Table 6B available on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS
[5] 86 FR 44812 through 44814

redesignation of these two LITT procedures from extensive O.R. procedures to non-extensive O.R. procedures.

As discussed in the proposed rule, CMS received two separate requests from the manufacturers of the LITT technology (Medtronic and Monteris Medical) to reverse the MS-DRG reassignment for the two ICD-10 procedure codes that identify LITT of the brain and brain stem (codes D0Y0KZZ and D0Y1KZZ) from the MS-DRGs for peripheral, cranial nerve and other nervous system procedures back to the MS-DRGs for craniotomy and endovascular procedures. CMS summarized the information and data analysis submitted by both requestors.

Medtronic and Monteris Medical also submitted a joint code proposal requesting an overall change in how LITT is classified within the ICD-10-PCS classification. This proposal was presented and discussed at the March 2022 ICD-10 Coordination and Maintenance Committee meeting.[6] Public comments in response to the code proposal were due by April 8, 2022. CMS acknowledged the unique circumstances relating to these procedures having both a request to reclassify LITT within ICD-10-PCS and for new procedure codes, as well as an MS-DRG reclassification request to reassign the existing codes describing these procedures. Because of these requests, in the proposed rule, CMS discussed both the code proposal and the possible MS-DRG assignments for any new codes that may be approved and the requested reassignment of the existing codes, in the event the new codes were not approved.

i. LITT code proposal and possible MS-DRG assignment for potential new codes

The code proposal was to reclassify LITT procedures from the Radiation Therapy section of ICD-10-PCS (Section D) to the Medical and Surgical section of ICD-10-PCS. The specific request was to reclassify LITT procedures to the root operation Destruction[7]. The requestors stated that LITT is misclassified to section D-Radiation Therapy because of the terminology that was used for predicate devices included "interstitial irradiation or thermal therapy" in describing LITT's method of action. The requestors stated LITT would be more appropriately classified as an ablation procedure with the root operation Destruction. According to the requestors, LITT was initially used to treat of variety of anatomic sties but is currently used to treat brain tumors and epileptic foci. To reflect this current use, the Indications for Use for the Monteris Medical LITT system has been updated to the current use in the brain and to align with the intended neurosurgical patient population.

CMS believed it was appropriate to utilize the assignments and designations of the procedure codes describing Destruction of the respective anatomic body site as predecessor codes rather than the current codes current codes describing LITT from the Radiation Therapy section for considering potential MS-DRG assignments. CMS reviewed the potential assignments and designations that would align with the assignments and designations of the potential LITT procedure codes describing Destruction of the respective anatomic body site. The potential new

[6] The request, related meeting materials, and a recording of the discussion are available at https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.
[7] In ICD-10-PCS, the root operation Destruction is defined as physical eradication of all or a portion of a body part by the direct use of energy, force, or a destructive agent.

procedure codes and associated MS-DRG assignments were summarized in a table in the proposed rule.

In the final rule, CMS notes that the proposal to reclassify LITT procedures of the brain, brain stem and other anatomic sites in ICD-10-PCS that was discussed at the March 2022 ICD-10 C&M Coordination meeting was approved and the new codes were made publicly available on May 26, 2020. The new procedure codes effective October 1, 2022 describing LITT of the brain and other anatomical cites are displayed in Table 6B. CMS finalizes that procedure codes describing LITT of brain (root operation Destruction), are assigned to MS-DRGs 025,026, and 027 for FY 2023.

Commenters were appreciative that the proposal to reclassify LITT procedures in ICD-10-PCS were approved and finalized. Commenters indicated it is appropriate to utilize procedure codes with the root operation Destruction as the predecessor codes for MS-DRG assignment of the new LITT procedure codes for all the anatomic body sites.

ii. Request to reassign current ICD-10-PCS procedure codes that identify LITT of the brain and brain stem (D0Y0KZZ and D0Y1KZZ)

CMS also summarized its analysis of claims data from the September 2021 update of the FY 2021 MedPAR file for MS-DRGs 023-027 and MS-DRGs 040-042 for cases reporting LITT of the brain or brain stem. Based on this analysis of the FY 2021 MedPAR claims data for cases reporting LITT of brain or brain stem, CMS agreed with the requestors that the average costs of these cases are higher as compared to the average costs of all cases assigned to MS-DRGs 040 – 042. CMS also believed that other factors, including the reporting of secondary MCC and CC diagnoses, may be contributing to the higher average costs of these cases. CMS' clinical advisors continue to maintain that LITT is a minimally invasive procedure. CMS also recognized that craniotomy and LITT share common procedure characteristics including the use of an operating room, risk of immediate intracranial bleeding or infection, and tissue being destroyed or excised. CMS concluded that cases reporting LITT of brain or brain stem are better aligned with MS-DRGs 025 - 027.

In the event that the proposed reclassification of LITT procedures and the corresponding new procedure codes are not finalized, CMS proposed to reassign the existing procedure codes describing LITT of the brain or brain stem from MS-DRGs 040 – 042 to MS-DRGs 025 – 027 for FY 2023. CMS proposed to maintain the MS-DRG assignments for the existing procedure codes describing LITT of other anatomical sites as finalized in the FY IPPS PPS final rule. CMS noted it did not receive any comments or requests to reconsider those assignments. As the proposed reclassification of the LITT procedures and the corresponding new procedure codes was approved, CMS is not finalizing the proposed reassignment for FY 2023.

CMS intends to more fully evaluate the logic procedures involving craniotomy, as well as the overall structure of MS-DRGs 023 – 027. CMS has begun to evaluate procedure performed using an open craniotomy versus a percutaneous burr hole. It is also reviewing the indications for these procedures (e.g., malignant neoplasms vs. epilepsy) to consider if it would be better to restructuring the current MS-DRGs to recognize the clinical distinctions of patient populations.

CMS notes that some commenters did not think restructuring of the craniotomy MS-DRGs was necessary and other commenters supported CMS evaluating these DRGs. **CMS continues to seek comments on other factors that should be considered in the potential restructuring of these MS-DRGs**. Comments may be submitted by October 20, 2022 via the MEARIS.

b. Vagus Nerve Stimulation

CMS received a request to review the MS-DRG assignment for cases that identify patient who receive an implantable vagus nerve stimulation system for heart failure.[8] The requestor stated that cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator with a principal diagnosis code describing epilepsy, treatment resistant depression, or obstructive sleep apnea are assigned to MS-DRGs 040 - 042 (Peripheral Cranial Nerve and Other Nervous System Procedures). When the same procedure codes describing the insertion of a neurostimulator lead onto the vagus nerve and the insertion of a stimulator generator are reported with the principal diagnosis of heart failure, the cases are assigned to surgical MS-DRGs 252 – 254 (Other Vascular Procedures). The requestor stated the treatment of autonomic nervous system dysfunction is the underlying therapeutic objective of cranial nerve stimulation for heart failure and therefore these cases should be reassigned to MS-DRGs 040 – 042 in MDC 01.

In the proposed rule, CMS summarized the analysis provided by the requestor which is based on analysis of Medicare claims in the pivotal clinical trials. CMS' analysis confirmed that a procedure code describing the insertion of a neurostimulator lead onto the vagus nerve and a procedure code describing the insertion of a stimulator generator when reported with a principal diagnosis for heart failure group to surgical MS-DRGs 252 – 254. CMS summarized its analysis of claims data from the September 2021 update of the FY 2021 MedPAR file for MS-DRGs 252 – 254 to identify relevant cases. CMS did not find any cases reporting these procedures with either a principal or secondary diagnosis of heart failure. CMS concluded there was insufficient claims data in the MedPAR file to assess the resource use of these cases. CMS' clinical advisors noted that the concept of clinical coherence requires that the patient characteristics included in the definition of each MS-DRG relate to a common organ system or etiology. They did not think it would be appropriate to move these cases into MDC 01 because it would inadvertently cause cases reporting these same MDC 05 diagnoses with a circulatory system procedure to be assigned to an unrelated MS-DRG.

CMS finalizes its proposal not to reassign cases reporting a procedure code describing the insertion of a neurostimulator lead onto the vagus and a procedure code describing the insertion of a stimulator generator with a principal diagnosis of heart failure from MS-DRG 252 – 254 to MS-DRGs 040 – 042. Commenters supported this proposal.

During its review of the stimulator generator insertion procedures assigned to these MS-DRGs, CMS identified 24 procedure codes (listed in the proposed rule) that describe the insertion of a

[8] For FY 2023, the requestor also submitted a new technology add-on payment application for the VITARIA System, an active implantable neuromodulation system that uses vagus nerve stimulation to deliver autonomic regulation therapy to patients with moderate to serve heart failure.

simulator, differentiated by device type (e.g., single array or multiple array) that do not exist in the logic for MS-DRGs 252 - 254. For FY 2023, CMS finalizes its proposal to add these 24-ICD-PCS codes to MS-DRGs 040 – 042. Commenters supported this proposal.

During its analysis of the request, CMS also examined the GROUPER logic for case assignment of MS-DRG 041. This grouper language contains code combinations or "clusters" representing the insertion of a neurostimulator lead and the insertion of a stimulator generator differentiated by device type, approach and anatomical site placement. CMS found that 108 ICD-10-PCS code clusters describing the insertion of a stimulator generator that are not differentiated by device type and a neurostimulator lead were inadvertently excluded and do exist in the logic for MS-DRG 041. CMS' clinical advisors supported the addition of the 108 procedure code clusters to the GROUPER logic list referred to as "Peripheral Neurostimulators" for MS-DRG 041. For FY 2023, CMS finalizes its proposal to add the 108 ICD-10 PCS code clusters listed in Table 6P.3a that describe a stimulator generator, that is not differentiated by device type, and a neurostimulator lead to MS-DRG 041.

4. MDC 02 (Diseases and Disorder of the Eye): Retinal Artery Occlusion

CMS received a request to reassign cases reporting diagnosis codes describing central retinal artery occlusion (CRAO), and the closely allied condition involving branch retinal artery occlusion, (BRAO) from MS-DRG 123 (Neurologic Eye Disorders) in MDC 02 to MS-DRGs 061 – 063 (Ischemia Stroke) in MDC 01 (Diseases and Disorders of the Nervous System). The requestor believed that the current mapping of diagnoses for CRAO and BRAO to MS-DRG 123 is inappropriate because CRAO and BRAO are forms of acute ischemic stroke. In addition, the requestor stated new evidence outlines treatment of patients with CRAO with acute stroke protocols includes treatment with intravenous thrombolysis (IV tPA) or hyperbaric oxygen therapy (HBOT). BRAO is less commonly treated with IV tPA but also requires an urgent and diagnosis stroke workup. The requestor stated that patients with CRAO or BRAO more closely resemble the resources for patients mapped to MS-DRGs 061 – 063.

In the proposed rule, CMS summarized its review of this request. Based on this data analysis, CMS did not believe that the small subset of patients with a diagnosis of CRAO or BRAO receiving a thrombolytic agent or HBOT warranted a separate MS-DRG or reassignment. CMS' clinical advisors agreed. The clinical advisors also believed that CRAO and BRAO describe ischemia affecting the retina and these diagnosis codes were appropriately assigned to MDC 02. CMS also reviewed claims data to consider the option of adding another severity level to MS-DRG 123 (Neurological Eye Disorders) and assigning case with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent to the highest level. This option would involve modifying the current base MS-DRG to a two-way severity level split or to a three-way severity level split of "with MCC or thrombolytic agent, with CC, and without CC/MCC." CMS applied the five criteria to determine if it would be appropriate to subdivide cases currently assigned to MS-DRG 123 into severity levels. This analysis indicated that the current base MS-DRG 123 maintains the overall accuracy of the IPPS and that claims data did not support a three-way or two-way severity level split for MS-DRG 123.

CMS also explored reassigning cases with a principal diagnosis of CRAO or BRAO that receive the administration of a thrombolytic agent to other MS-DRGs within MDC 02. This review did not support reassignment of these cases to any other medical MS-DRGs because these cases would not be clinically coherent with the cases assigned to these MS-DRGs.

Based on the various data analysis performed, for FY 2023, CMS did not propose any MS-DRG changes for cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or HBOT.

Some commenters supported CMS' decision to not propose any MS-DRG changes; other commenters opposed or expressed concerns with the decision not to propose any MS-DRG changes for these cases. Commenters stated that from a pathophysiologic perspective, CRAO is the same process as a stroke of the brain and that although the retina is located within the eye, it is a core component of the central nervous system. Commenters believed that acute CRAO is a medical emergency that is equivalent to an acute cerebral ischemic stroke. CMS' clinical advisor reviewed these issues and noted that in ICD-10, the body or organ system is the axis of the classification. The clinical advisors agree that the retina is similar to the brain in terms of cellular and functional elements, but it is part of the eye and should be classified with other eye conditions. The clinical advisors also noted that the diagnosis of cerebral ischemia may or may not involve visual impairment.

CMS finalizes its proposal to maintain the current assignment of cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy.

5. MDC 04 (Diseases and Disorders of the Respiratory System): Acute Respiratory Distress Syndrome (ARDS)

A requestor asked CMS to reassign cases reporting diagnosis code J80 (ARDS) as the principal diagnosis form MS-DRG 204 (Respiratory Signs and Symptoms) to MS-DRG 189 (Pulmonary Edema and Respiratory Failure). CMS reviewed this request and for FY 2023, it proposed to reassign cases reporting ARDS (code J80) as a principal diagnosis form MS-DRG 204 to MS-DRG 189.

After reviewing comments, effective FY 2023, CMS finalizes its proposal to reassign cases reporting ARDS (code J80) as a principal diagnosis from MS-DRG 204 to MS-DRG 189.

6. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Percutaneous Transluminal Coronary Angioplasty (PTCA) Logic

In the proposed rule, CMS discussed a replication issue from the ICD-9 based MS-DRGs to the ICD-10 based MS-DRG for procedure code 02UG3JE (supplemental mitral valve created from left atrioventricular valve with synthetic substitute, percutaneous approach). Procedure code 02UG3JE is not clinically consistent with a PTCA procedure but it was assigned to the list for

PTCA procedures in the GROUPER logic in the transition from ICD-9 to ICD-10 based MS-DRGs.

After reviewing comments, for FY 2023, CMS finalizes its proposal to remove procedure code 02UG3JE from the list for PTCA procedures in the GROUPER logic for MS-DRGs 231 and 232. CMS also finalizes its proposal to maintain the MS-DRG assignment for procedure code 02UG3JE to MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures). N

b. Neuromodulation Device Implant for Heart Failure (Barostim™ Baroreflex Activation Therapy)

The BAROSTIM NEO System is the first neuromodulation device system designed to trigger the body's main cardiovascular reflex to target symptoms of heart failure. The system consists of an implantable pulse generator (IPG) that is implanted subcutaneously in the upper chest below the clavicle, a stimulation lead that is sutured to either the right or left carotid sinus, and a wireless programmer system that non-invasively programs and adjusts BAROSTIM NEO therapy via telemetry. The BAROSTIM NEO System was approved for new technology add-on payments for FY 2021. For FY 2023, CMS finalizes its proposal to discontinue the new technology add-on payment.

CMS received a request to (1) reassign the ICD-10 PCS procedure codes for the implantation of the BAROSTIM NEO System from MS-DRGs 252 – 254 (Other Vascular Procedures) to MS-DRGs 222 – 225 (Cardiac Defibrillator Implant) and (2) reassign the procedure code that describes the placement of a BAROSTIM NEO IPG alone from MS-DRGs 252 – 254 to MS-DRGs 245 (AICD Generator Procedures). In the proposed rule, CMS summarized the information and analysis provided by the requestor. The requestor acknowledged there are very few cases within the publicly available Medicare inpatient claims data for implantation of a BAROSTIM NEO system. The requestors analysis revealed fewer than 11 cases in the combined FY 2019 and FY 2020 MedPAR data, a time period when the system was only implanted as part of a controlled clinical trial. The requestor stated that CMS should not use this data to determine initial MS-DRG assignments, especially for devices that have an FDA Breakthrough Designation. Instead, CMS should use available information and expert knowledge to make initial MS-DRG assignments. The requestor stated that when the new technology add-on payments expire, inpatient admissions for implantation of the BAROSTIM NEO system will be paid less than the same procedure done in the outpatient setting.

In the proposed rule, CMS summarized its review of this request. CMS first examined the September 2021 update of the FY 2021 MedPAR file for MS-DRGs 252 – 254 to identify cases reporting a diagnosis of heart failure and procedures codes describing the implantation of the BAROSTIM NEO System. Only three cases reported procedure codes describing the implantation of a BAROSTIM NEO System; the claims data indicated a wide variance with regard to the length of stay and average costs for the three cases. CMS' clinical advisors also expressed concerns about the requestor equating the implantation of a BAROSTIM NEO System to the placement of implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy defibrillators (CRT-D) and cardiac contractility modulation (CCM) devices as these

devices all differ in terms of technical complexity and anatomical placement of the electrical leads. CMS concluded it does not have sufficient claims data to evaluate any proposed changes to the current MS-DRG assignment.

CMS also evaluated the request to reassign the procedure code that describes the placement of a BAROSTIM NEO IPG. This analysis found 12 cases in MS-DRG 252 and 4 cases in MS-DRG 253. CMS concluded it does not have sufficient claims data to evaluate any proposed changed to the current MS-DRG assignment.

For FY 2023, CMS proposed to maintain the assignment of cases reporting procedure codes that describe the implantation of a neuromodulation device and cases reporting a procedure code describing placement of a stimulator generator alone in MS-DRGs 252 – 254. Commenters supported this proposal. A commenter opposed this proposal for many reasons including the negative impact of the COVID-19 pandemic limiting uptake of this new technology and the fact that clinical trials were done without a charge for the device. The commenter stated that the few cases in the MedPAR data files is not a reason to allow an overly mispriced MS-DRG assignment. The commenter provided other alternatives including creating a new MS-DRG for these procedures.

In response to the commenter's feedback, CMS confirms that the claims data analysis included cases reporting a diagnosis of heart failure as either a principal or secondary diagnosis. In response to the general comments about the assignments of the BAROSTIM NEO System, CMS notes that the goals of reviewing the MS-DRG assignments of particular procedures are to better clinically represent the resources involved in caring for these patients in an inpatient hospital setting and to enhance the overall accuracy of the system. CMS reviews its established procedures for making initial MS-DRG assignments for new diagnosis and procedure codes. For FY 2023, CMS finalizes its proposal to maintain the assignment of cases reporting procedure codes that describe the implantation of a neuromodulation device and cases reporting a procedure code describing placement of a stimulator generator alone in MS-DRGs 252 – 254. CMS will continue to analyze future claim data to analyze this issue.

During its analysis of this request, CMS examined the GROUPER logic for case assignments to MS-DRGs 222 – 227 and found two diagnosis codes describing heart failure (I97.130 and I97.131) that are not currently in the listed principal diagnoses in the GROUPER logic for MS-DRGs 223 and 224. After reviewing comments, for FY 2023, CMS finalizes its proposal to modify the GROUPER logic to allow cases reporting diagnosis codes I197.130 or I97.131 as a principal diagnosis to group to MS-DRGs 222 and 223 when reported with qualifying procedures.

c. Cardiac Mapping

CMS identified a replication issue from the ICD-9 based MS-DRGs to the ICD-10 based MS-DRGs for procedure code 02K80ZZ (Map conduction mechanism, open approach). CMS summarized its review of this issue in the proposed rule. For FY 2023, CMS proposed the reassignment of procedure code 02K80ZZ from MS-DRGs 246 – 251 to MS-DRGs 273 and 273 (Percutaneous and Other Intracardiac Procedures).

Commenters both supported and opposed this proposal. Commenters raised concerns about the analysis and recommended assigning code 02K80ZZ to MS-DRGs 228 and 229 (Other Cardiothoracic Procedures) instead of MS-DRGs 273 and 274. In response to comments indicating code 02K80ZZ is designated as a non-OR procedure and does not affect MS-DRG assignment, CMS states that each procedure that is designated as a non-O.R. procedure is further classified as either not affecting the MS-DRG assignment or affecting the MS-DRG assignment (referred to as non O.R. procedure affecting the MS-DRG). CMS refers commenters to Appendix E of the IPPS files which indicates 02K80ZZ is a non O.R. affecting the MS-DRG code. In response to comments about the data analysis, CMS refers the reader to Table 6P.1e associated with this final rule which indicates there were no cases reported with procedure code 02K80ZZ assigned to MS-DRGs 246-251. In addition, CMS' clinical advisors continue to believe that this procedure code should be grouped with other procedure codes that describe cardiac mapping that are assigned to MS-DRGs 273 and 274.

After reviewing comments, CMS finalizes its proposal to reassign procedure code 02K80ZZ from MS-DRGs 246-251 to MS-DRGs 273 and 274 in MDC 05 for Version 40.

d. Surgical Ablation

In the FY 2022 IPPS PPS final rule, CMS discussed a request to review the MS-DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation.[9] For FY 2022, CMS finalized a revision of the surgical hierarchy for the MS-DRGs in MDC 05 to sequence MS-DRGs 231-236 (Coronary Bypass) above MS-DRGs 228 and 229 (Other Cardiothoracic Procedures). Under this revision, when a procedure describing a CABG and a procedure describing an open surgical ablation are present, the GROUPER logic would assign the coronary artery bypass (CABG) surgical class because a CABG would be sequenced higher in the hierarchy than an open surgical ablation.

CMS received a request to again review the MS-DRG assignment of cases involving open concomitant surgical ablation procedures. The requestor believed that the average hospital costs for surgical ablation for atrial fibrillation demonstrated a cost disparity compared to all procedures within their respective MS-DRGs. In the proposed rule, CMS discussed why it believed more time was needed before considering to again review this issue. In addition, CMS' clinical advisors believed that in open concomitant surgical ablation procedures, the CABG, MVR, and AVR components of the procedure are more technically complex than open surgical ablation procedures.

Some commenters supported CMS' decision to allow additional time for the claims data to reflect the policies finalized in FY 2022; other commenters opposed CMS' decision. In response to commenters suggesting that Medicare cover both aortic valve replacement surgery and surgical treatment for atrial fibrillation, CMS discusses the differences between GROUPER logic and coverage policies. Cases will group according to the GROUPER logic, regardless of any coding guidelines or coverage policies. The Medicare Code Editor (MCE) and other payer-specific edits identifies inconsistencies in the coding guidelines or coverage policies. CMS notes

[9] 86 FR 44836 through 44848

this separation of MS-DRG grouping and data editing allows stability of the MS-DRG GROUPER even when coding and coverage policies change.

Some commenters discussed that the FY 2022 policy does not address the increased costs of cases describing concomitant surgical ablation procedures performed with open valve procedures assigned to MS-DRG 216-221. Many commenters urged CMS to either (1) assign the cases to a different family of MS-DRGs or (2) assign these cases to the requested MS-DRGs 216 and 217. Based on the information in Tables 6P.1.c and 6P1.d associated with this final rule, CMS states the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS-DRGs but there is variation in the volume, length of stay, and average costs of the cases. Cases reporting an open concomitant surgical ablation code combination are predominately found in the higher severity level MS-DRGs of their base MS-DRG assignment. In addition, CMS notes that the total number of cases in MS-DRG 218 is below 500, and that when the NonCC subgroup criteria are applied, it may consider consolidating these MS-DRGs into two severity levels. CMS continues to believe additional time is necessary to evaluate this issue and to determine the impact of patient's co-morbid conditions or other factors contributing to the increased length of stay and costs.

In response to commenters' recommendation that a mechanism is needed for differential payment when procedures are performed concomitantly, CMS agrees this topic requires additional analysis across the MS-DRG classification as concomitant procedures may affect resource consumption. **CMS requests recommendations on possible mechanisms to address concomitant procedures and how CMS can mitigate any unintended negative payment impacts to providers providing concomitant procedures**. Recommendations should be submitted via the MEARIS. CMS notes it will consider these comments for possible proposals in future rulemaking.

Standalone Percutaneous Endoscopic Surgical Ablation. Some commenters raised concerns that the downward payment trend for MS-DRGs 228 and 229 (Other Cardiothoracic Procedures) has resulted in hospitals being undercompensated for the costs of furnishing standalone hybrid percutaneous endoscopic surgical ablation procedures for atrial fibrillation. Commenters proposed two possible remedies: (1) CMS use its statutory authority to not reduce the relative weight and payment for MS-DRGs 228 and 229, or (2) assign these procedures to MS-DRG 229. CMS notes that it did not receive this request for consideration in the proposed rule but cases reporting these procedure codes were discussed in the FY 2022 IPPS final rule (86 FR 44844-44848). CMS does, however, acknowledge the reduction in the proposed FY 2023 relative weights for MS-DRGs 228 and 229. CMS expects that when MS-DRGs are restructured the relative weights of the MS-DRGs will change. CMS discusses the changes in these MS-DRGs since 2017.

After consideration of comments, for FY 2023, CMS finalizes its proposal not to make any changes for cases involving the open concomitant surgical ablation procedures or for cases describing standalone percutaneous surgical ablation. CMS will continue to evaluate this issue in future rulemaking.

7. MDC 06 (Diseases and Disorders of the Digestive System): Appendicitis

CMS received a request to reconsider the MS-DRG assignment for diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess). In the proposed rule, CMS noted this topic has been previously discussed in both FY 2019 and FY 2021 rulemakings and summarized its previous decisions.[10] CMS concurred with commenters that the expansion of diagnosis codes K35.2 and K35.3 (effective October 1, 2018) significantly changed the scope and complexity of these diagnosis codes. CMS stated that NCHS' staff acknowledged this issue and confirmed they would consider review of these codes.
Based on this new request, CMS discussed this issue again with the CDC NCHS staff. The NCHS staff included these codes describing appendicitis for discussion at the March 8-9, 2022 ICD-10 Coordination and Maintenance Committee meeting and proposed six new codes listed in a table in the final rule. The deadline for submitting public comments to this proposal is May 9, 2022.

After considering public comments, for FY 2023, CMS is maintaining the current structure of MS-DRGs 338-343 and the MS-DRG assignment of diagnosis code K35.02. CMS continues to believe it is appropriate to delay any modifications until the NCHS staff finalize code updates.

8. MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Laparoscopic Cholecystectomy with Common Bile Duct Exploration

CMS received a request to review the MS-DRG assignment when a common bile duct exploration with a gallstone removal using a laparoscopic approach (procedure code 0FC94ZZ) is reported with a laparoscopic cholecystectomy. CMS reviewed the procedure code 0FC94ZZ and found it is designated as a non-O.R. procedure; the GROUPER logic does not recognize this procedure for purposes of MS-DG assignment. In addition, CMS analyzed the September 2021 update of the FY 2021 MedPAR data file for cases reporting procedure code 0FC94ZZ in MS-DRGs 417 – 419 (Laparoscopic cholecystectomy without common bile duct exploration (CDE)) and MS-DRGs 411 – 413 (Laparoscopic cholecystectomy with CDE). Based on these results and input from clinical advisors, for FY 2023, CMS proposed to redesignate procedure code 0FC94ZZ from a non-O.R. to a O.R, procedure and add it to the logic list for common bile duct exploration in MS-DRGs 411 – 413.

After consideration of comments, for FY 2023, CMS finalizes its proposal to redesignate procedure code 0FC94ZZ from a non-O.R. procedure to an O.R. procedure and to add it to the logic list for CDE procedures in MS-DRGs 411-413.

CMS notes that the logic for MS-DRGs 414 – 416 (Cholecystectomy Except by Laparoscope without CDE) is specifically defined for open cholecystectomy procedures without a CBE. CMS believes that it might be appropriate to further refine this family of MS-DRGs to Open Cholecystectomy with or without CDE and Laparoscopic Cholecystectomy with or without CDE. **CMS continues to request feedback on this and any alternative recommendations via MEARIS by October 20, 2022 for future consideration**.

[10] 83 FR 41230, 85 FR 32500 through 32503, and 85 FR 58484 through 58488.

9. MDC 10 (Diseases and Disorders of the Endocrine System): Eladocagene Exuparvovec Gene Therapy

CMS received a request to reconsider its redesignation of procedure code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach) from a non-O.R. procedure to an O.R. procedure and reassign from MS-DRGs 628 – 629 (Other Endocrine, Nutritional and Metabolic O.R. procedure) to MS-DRGs 987 – 090 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis). Eladocagene exuparvovec is gene therapy for the treatment of aromatic L-amino acid decarboxylase (AADC) deficiency (ICD-10 diagnosis code E70.81), a rare genetic and fatal condition.

In the proposed rule, CMS summarized it analysis of all MS-DRG claims data from the September 2021 update of the FY 2021 MedPAR file and found only 1 case reporting the administration of this therapy in MS-DRG 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms). For FY 2023, CMS proposed to maintain the current MS-DRG assignments.

Some commenters agreed with CMS' proposal but urged CMS to consider appropriate MS-DRG assignment and payment for this therapy. A few commenters disagreed with the proposal and requested CMS consider creating a new MS-DRG for neurosurgical gene therapy. After consideration of comments, for FY 2023, CMS is maintaining the current MS-DRG assignment for cases reporting the administration of eladocagene exuparvovec. CMS acknowledges the complexities related to classifying cases that are represented by low volumes in the claims data and will continue to explore appropriate mechanisms to address therapies for rate diseases.

10. MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period): MS-DRG 795 Normal Newborn

CMS received a request to review the MS-DRG assignment of newborn encounters with diagnosis codes describing contact with and (suspected) exposure to COVID-19 when the condition is ruled out after clinical evaluation and negative workup. The requestor stated these cases appeared to be assigned to MS-DRG 794 (Newborn with Other Significant Problems) and should be assigned to MS-DRG 795 (Normal Newborn).

In the proposed rule, CMS summarized the related diagnosis codes and the related GROUPER logic. CMS identified 13 ICD-10-CM diagnosis codes (see table in the proposed rule) that should be reassigned to MS-DRG 795. CMS noted that patients exposed to communicable disease that are worked up or treated prophylactically or both, and for whom it is later determined based on study results to not have the communicable disease, are distinct from patients with signs or symptoms of a disease and diagnosed with that communicable disease. CMS proposed to add the 13 diagnosis codes that describe contact with and (suspected) exposure to communicable diseases to the "only secondary diagnosis" list under MS-DRG 795.

Commenters supported this proposal; a few commenters opposed this proposal because they believe newborns exposed to communicable diseases often require care and treatment than normal newborns. CMS' clinical advisors agree that patients exposed to communicable diseases

can require workup or prophylactic treatment, but they continue to believe these patients are distinct from patients with identified signs or symptoms of a suspected problem or diagnosed with communicable disease. After reviewing comments, CMS finalizes its proposal to add the 13 diagnosis codes. CMS also agrees that the newborn MS-DRGs warrant additional analysis in future rulemaking.

During the review of the GROUPER logic, CMS identified three diagnosis codes for extremely low birth weight newborn and extreme immaturity of newborn (P07.00, P07.20, and P07.26) that were not included in the logic for MS-DRG 790 (Extreme Immaturity or Respiratory Distress Syndrome Neonate); this information is presented in a table in the proposed rule. For FY 2023, CMS proposed to reassign ICD-10-CM diagnosis codes P07.00, P07.20, and P07.26 to MS-DRG 790. After reviewing comments, for FY 2023, CMS finalizes this proposal.

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

a. Adding Procedure and Diagnosis Codes

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.

The reader is referred to the final rule for a discussion of the following:

- Embolization of Portal and Hepatic Veins and
- Percutaneous Excision of Hip Muscle

After reviewing comments, CMS finalizes its proposals related to both of the above topics.

12. 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. 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. CMS notes these proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes.

In the FY 2020 IPPS proposed rule, CMS discussed its 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. Given the ongoing PHE, CMS believes it may be appropriate to allow additional time for the claims data to stabilize before selecting the timeframe for this analysis. CMS will provide more details on the methodology for conducting this review in future rulemaking.

Commenters supported CMS' plan to conduct the comprehensive review of the ICD-10-PCS codes for determining O.R. or non-O.R. designation. Other commenters stated the designation of O.R. versus non-O.R. may no longer be the most critical differentiator between resource-intensive procedures for MS-DRG purposes and discussed the complex and resource-intensive procedures performed by hospitals that do not involve the use of an operating room (e.g., CAR T -cell therapy) and that some procedures performed in interventional radiology suites and cardiac catheterization labs can utilize more advanced equipment and supplies than traditional operating rooms. Commenters also recommended other factors that CMS should consider for resource utilization, including the administration of certain complex drugs/biologics or therapies that demonstrate higher costs and resource utilization.

CMS appreciates this feedback and notes it will explore additional means of eliciting additional opportunities for comments on this issue. CMS has already convened an internal workgroup of clinicians, coding specialists, and other policy analysts to begin to evaluate this topic.

For review of requests for FY 2023 consideration, CMS' clinical advisors considered the following for each procedure:

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

In addition, cases that contain O.R. procedures will map to MS-DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis) or MS-DRGs 987, 988, or 989 (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 the requests were not discussed in the proposed rule; CMS will consider these requests as part of its comprehensive review of procedure codes. The reader is referred to the final rule for a discussion of the requests listed below.

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

- Diagnostic and therapeutic endoscopic procedures performed on thoracic and abdominal organs (CMS notes that there are over 19,000 ICD-10-PCS codes that describe these procedures and it will include these codes in the planed comprehensive review.)
- Open drainage of subcutaneous tissue and fascia

After reviewing comments, CMS finalizes its proposals related to both of the above topics.

13. Changes to the MS-DRG Diagnosis Codes

Under the IPPS MS-DRG classification, CMS developed a standard list of diagnoses that are considered CCs. In the FY 2008 IPPS final rule[11], CMS described its process for establishing three different levels of CC severity into which it would subdivide the diagnoses codes: MCC, a CC, or a non-CC.

In the FY 2020 IPPS proposed rule, CMS proposed changes to the severity level designations for 1,492 ICD-10-CM diagnosis codes. Many commenters expressed concern with CMS' proposal and recommended that CMS conduct further analysis. In the FY 2020 final rule, CMS postponed adoption of the proposed comprehensive changes in the severity level designations to allow further opportunity to provide additional information to the public on the methodology utilized and clinical rationale for its proposals.[12] CMS developed nine guiding principles as meaningful indicators of expected resource use by secondary diagnosis:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and ability.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions,
- Reflects systemic impact.
- Post-operative condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

CMS plans to continue comprehensive CC/MC analyses using a combination of the prior mathematical analysis of claims data in combination with the guiding principles. CMS continues to invite comment regarding these principles, as well as other possible ways it can incorporate meaningful indicators of clinical severity. CMS encourages commenters to provide a detailed

[11] 72 FR 47152 through 47171
[12] 84 FR 42150 through 42152

explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code. For FY 2024, comments can be sent via the MEARIS by October 20, 2022.

Commenters agreed with CMS' decision not to propose any further changes to the designation of any ICD-10-CM diagnosis codes and recommended that because the new MCE edit was recently implemented on April 1, 2022, CMS should allow one to two full years of data availability before proposing any additional changes.

CMS received several requests to change the severity level designations of specific ICD-10-CM diagnosis codes. CMS will consider these individual requests as it continues its comprehensive CC/MCC analysis. CMS will provide more details in future rulemaking.

a. Request for Information on Social Determination of Health Diagnosis (SDOH) Codes

CMS believes that reporting SDOH Z codes in inpatient claims data could enhance coordination within hospitals across their clinical care and discharge planning teams, including post-acute partners. CMS notes that stakeholders have identified several reasons for not reporting Z codes, including the fact they are not required and patients are not willing to discuss these issues.

CMS describes the subset of Z codes that describe the SDOH. The 96 SDOH diagnosis codes that describe the social determinants of health in categories Z55-65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances) are included in Table 6P.5a. This table also includes data describing the impact on resource use when reported as a secondary diagnosis for all these 96 ICD-10-CM Z codes. CMS discusses how the impact of SDOH Z codes can increase hospital resource utilization during inpatient care and provides examples related to homelessness.

In the proposed rule, CMS sought comments on the following questions:

- How the reporting of certain Z-codes – and if so, which Z codes[13] - may improve the ability to recognize severity of illness, complexity of illness, and utilization of resources under the MS-DRGs?
- Whether CMS should require the reporting of certain Z codes – and if so, which ones – should be reported on hospital inpatient claims to strengthen data analysis?
- The additional provider burden and potential benefits of documenting and reporting of certain Z codes, including potential benefits to beneficiaries?
- Whether codes in category Z59 (Homelessness) have been underreported and if so, why? CMS was interested in hearing the perspective of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. CMS was also interested in how factors such as hospital size and type might impact a hospital's ability to develop standardized consistent protocols to better screen, document and report homelessness.

[13] https://www.cms.gov/files/document/zcodes-infographic.pdf.

CMS was also interested in comments on ways the MS-DRG classification could be useful in addressing the challenges of defining and collecting accurate and standardized self-identified socioeconomic information for the purposes of reporting, measure stratification, and other data collection efforts. CMS was interested in learning about the potential benefits and challenges associated with the collection of SDOH data in the inpatient setting.

CMS presents a summation of the comments it received. Highlights of these comments are summarized below; for additional details the reader is referred to the preamble in the final rule.

Many commented supported CMS' efforts for stressing the importance of SDOH on patients and efforts to encourage reporting of SDOH on claims forms. Commenters believed this information would enhance coordination within hospitals across clinical teams and discharge. Some commenters believed this was important information but raised concerns that the collection of this data may place significant burden on facilities and providers. Commenters stated assigning SDOH codes can be time-consuming and labor-intensive. Many commenters stated there was a lack of standard, nationally accepted definitions of the SDOH Z codes. Commenters also identified the lack of national data and exchange standards for capture of the Z codes and reporting of SDOH Z codes might necessitate changes to the claim form.

Commenters recommended CMS consider reimbursement incentives for documenting and reporting SDOH Z codes. Many commenters agreed that Z59 (Homelessness) is underreported and that increasing the severity level of cases that include homelessness from a NonCC to a CC could prompt more reporting. Commenters encouraged CMS to examine other SDOH Z codes that also increase the severity level of care provided; suggestions included food insecurity, extreme poverty, and underemployment. Other commenters expressed concerns about the proposal and stated that some SDOH diagnoses could impact MS-DRG assignment due to additional efforts for discharge planning but they believed that generally SDOH diagnoses should have limited impact on the severity of illness. Commenters thought the SDOH have greater impact on risk adjustment for population-based initiatives, such as readmissions program. A commenter also raised concerned that increasing the severity level of a MS-DRG due to homelessness could potentially lead to fraudulent or abusive coding.

Several commenters did not believe CMS proposed a clear, compelling, or significant benefit to patients as a result of collecting this data. Commenters cautioned that hospitals often do not have solutions to mitigate or eliminate these risks and CMS should not pursue an imitative that is collecting data on non-medical information. Other commenters were concerns that individuals are often hesitant to disclose this information and the information may "follow" a patient for too many years and not be updated.

Many commenters believed the most important immediate action CMS could take to increase the use of SDOH Z codes is finalize the "Screening for Social Drivers of Health" and "Screen Positive Rate for Social Drivers of Health" measures proposed for the IQR Program. As discussed below in section IX.E., CMS adopts both these measures beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period.

CMS notes these comments will provide additional information as it evaluates whether to develop a proposal in future rulemaking to change the severity level designation of the diagnosis codes describing homelessness from NonCC to CC and whether other SDOH as described by Z codes, are also appropriate candidates to be proposed for designation as CCs.

b. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2023

The following tables identify the additions and deletions to the diagnosis code MCC and CC severity levels:

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

c. CC Exclusions List for FY 2023

CMS created the CC Exclusions List to preclude coding of CCs for closely related conditions; to preclude duplicative or inconsistent coding from being treated as CC's; and to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.
The following tables identify the FY 2023 additions and deletions to the CC Exclusion list:

- Table 6G.1 - Secondary Disorders Order Additions to the CC Exclusion List;
- Table 6G.2 - Principal Disorders Order Additions to the CC Exclusion List;
- Table 6H.1 - Secondary Disorders Order Deletions to the CC Exclusion List;
- Table 6H.2 - Principal Disorders Order Deletions to the CC Exclusion List; and
- Table 6K - Complete List of CC Exclusions.

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

The following tables identify new, revised and deleted diagnosis and procedure codes for FY 2023:

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

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

15. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedures, and demographic information are entered into the Medicare claims processing systems and subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS-DRG. The link to the MCE manual file, along with the link to the mainframe and compute software for the MCE Version 38 (and ICD-10 MS-DRGs) are posted on the CMS website at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

CMS did not receive any specific MCE requests by the November 1, 2022 deadline. The interested reader is referred to the final rule for discussion of the following edits:

- External causes of morbidity codes as principal diagnosis
- Age conflict edit
- Sex conflict edit
- Unacceptable principal diagnosis edit
- Unspecified codes

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 continues to encourage **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 the MEARS by October 20, 2022.

16. 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 CMS finalizes for FY 2023, it is maintaining the existing surgical hierarchy for FY 2023.

17. 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 submit questions and comments to: nchsicd10cm@cdc.gov.
- For procedure codes submit questions and comments to: ICDProcedureCodeRequest@cms.hhs.gov.

The official list of ICD-10-CM and ICD-10-PCS codes can be found at https://www.cms.gov/Medicare/Coding/ICD10/index.html.
CMS discusses new diagnosis codes describing conditions related to COVID-19 and new procedure codes related to COVID-19 (see tables in the final rule).
CMS notes that for FY 2022, there are 72,750 diagnosis codes and 78,229 procedure codes. For FY 2023, there are 73,639 diagnosis codes and 78,496 procedure codes.

18. Replaced Devices Offered without Cost or with a Credit

In the FY 2008 final rule with comment period[14], 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,[15] 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 2023, CMS finalize its proposal to add any MS-DRGs to the policy for replaced devices offered without cost or with a credit. The table below, reproduced from the final rule, lists the existing MS-DRGs subject to this policy

[14] 72 FR 47246 through 47251
[15] 76 *FR* 51556 and 51557

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	140	Major Head and Neck Procedures with MCC
MDC 03	141	Major Head and Neck Procedures with CC
MDC 03	142	Major Head and Neck Procedures without CC/ MCC
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC
MDC 5	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC
MDC 5	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC
MDC 5	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC
MDC 5	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC
MDC 5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC
MDC 5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC
MDC 5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC
MDC 5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC

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	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
MDC 8	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
MDC 8	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

19. Other Policy Issues: Comment Solicitation on Possible Mechanisms to Address Rare Diseases and Conditions Represented by Low Volume within the MS-DRG Structure

CMS reviews the provisions of the Orphan Drug Act (ODA) and the process used by the FDA to identify a drug for the treatment of a rare disease or condition called "orphan-drug designation". The sponsor of a drug with orphan drug designation may be eligible for certain financial incentives, such as tax credits and potentially seven years of market exclusivity after approval. CMS discusses stakeholders concerns that one significant barrier to patients is the limited hospital formulary coverage for potentially high-cost therapeutics for rare diseases.

In the proposed rule, CMS described three requests it previously received related to the MS-DRG classification or rare diseases and conditions represented by low volumes in the claims data. CMS summarized prior rulemaking requests and decisions for Panhematin[16] used in treating acute porphyria attacks ANDEXXA[17] used to rapidly reverse the anticoagulation effects of two direct oral anticoagulants (apixaban and rivaroxaban) when needed for life-threatening or uncontrolled bleeding; and Zulresso[18] used for postpartum depression in adults.

In the proposed rule, CMS solicited feedback on mechanisms it can explore to address concerns relating to payment with rare diseases and conditions represented by low volume in Medicare claims data. CMS was also interested in comments on ways it may potentially improve access to treatment for postpartum depression. CMS was interested in how factors such as hospital size and type might impact a hospital's ability to develop protocols to better address these conditions. Many commenters appreciated CMS' attention to these important issues. Most commenters provided recommendations and suggested CMS explore a variety of mechanisms including a permanent payment approach which combined the MS-DRG "fixed price" with continued partial payment for the actual cost of treatment per stay; creating new MS-DRGs for low-volume therapies or for orphan conditions with more flexible cost outlier funding; creating new MS-DRGs for cell and gene therapies. For the specific administration of Zulresso® (brexanolone), commenters stated that if Medicare commits to creating MS-DRGs around the Medicare population giving birth, the impacts of these policies would be far-reaching and would service as the foundation for commercial and Medicaid populations.

CMS appreciates these comments and will take them into consideration for future policy development.

C. Recalibration of the MS-DRG Relative Weights

The Secretary is required by statute to revise the MS-DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. CMS ordinarily uses the MedPAR file (fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year) from the 2nd year preceding the rate setting year (e.g., FY 2021 for FY 2023). It also uses Medicare cost report data from the 3rd year preceding the rate setting year (e.g., FY 2020 for FY 2023).

[16] 77 FR 53311, 79 FR 49901, and 83 FR 41200
[17] 86 FR 44869
[18] 85 FR 32672 through 32676 and 85 FR 58709 through 58715

However, CMS used FY 2019 MedPAR data and FY 2018 HCRIS data to set the relative weights for FY 2022 because of concerns about using utilization data affected by the COVID-19 pandemic (some FY 2019 cost reports will end in FY 2020 during the COVID-19 pandemic). For FY 2023, CMS proposed to revert to its traditional practice of using claims data from the 2nd year preceding the payment year (FY 2021) and cost reports from the 3rd year preceding the payment year (FY 2020) indicating that it believes these data will be more representative of FY 2023 than the older data that preceded the pandemic.

In developing relative weights for FY 2023, CMS will use:

- FY 2021 MedPAR data: Bills received through March 31, 2022 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 (MA) claims and claims from facilities currently classified as CAHs are excluded. CMS used data from approximately 7,444,003 million Medicare discharges regrouped using the FY 2023 MS-DRG classifications.
- FY 2020 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2020 cost reporting periods, using the March, 2022 update of the FY 2020 HCRIS.

For FY 2023, CMS did not propose any changes to its methodology for determining CCRs and will calculate MS-DRG weights using national averages for the 19 CCRs. Accompanying the final rule, CMS posted the version of the HCRIS cost report data file which it used to calculate the 19 CCRs for FY 2023, available at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2023-ipps-final-rule-home-page#DataFiles. (Select file #4 under FY 2023 Final Rule Data files, "FY 2023 Final Rule: HCRIS Data File (ZIP)".)

National Average CCRs. The FY 2023 final CCRs in comparison to the final FY 2022 CCRs are shown in the following table.

Group	FY 2022 CCR	Final FY 2023 CCR
Routine Days	0.422	0.422
Intensive Days	0.345	0.341
Drugs	0.187	0.184
Supplies & Equipment	0.297	0.311
Implantable Devices	0.293	0.281
Inhalation Therapy	0.147	0.150
Therapy Services	0.288	0.283
Anesthesia	0.071	0.072
Labor & Delivery	0.359	0.366
Operating Room	0.167	0.165
Cardiology	0.094	0.094
Cardiac Catheterization	0.100	0.104
Laboratory	0.106	0.107
Radiology	0.136	0.137
MRIs	0.070	0.071

Group	FY 2022 CCR	Final FY 2023 CCR
CT Scans	0.034	0.034
Emergency Room	0.147	0.155
Blood and Blood Products	0.270	0.255
Other Services	0.344	0.359

One commenter requested that CMS create a dedicated cost center line for cell and gene therapy product cost information, which would enable the agency to create a 20th cost center that is separate from the drugs/pharmacy cost center. Another commenter requested that CMS study standardizing only the labor portion for each of the 19 cost centers to determine whether that improves the explanatory power of the MS-DRGs. CMS may consider these requests in future rulemaking.

Relative Weight Calculation for CAR-T cell Therapy (MS-DRG 018). In some cases, CAR-T cell therapy patients may be part of a clinical trial where the high-cost therapy product is furnished to the hospital at no cost. Beginning with FY 2021, CMS adopted a differential payment for these cases to recognize hospitals' lower costs. CMS also excluded CAR-T cases billed with a clinical trial indicator or less than $373,000 in drug costs—the average sales price of the two CAR-T cell products approved to treat relapsed/refractory diffuse large B-cell lymphoma—from the relative weight calculation.

CMS proposed to adopt these same policies for FY 2023. Several commenters supported CMS' proposed policies indicating that analysis of CAR T-cell claims data from FY 2021 through the first quarter of FY 2022 shows significant improvement in patient access to CAR-T. Commenters requested that CMS reevaluate the clinical trial threshold annually while other commenters expressed concern that Medicare's payment for CAR-T cases is less than costs and payment should be increased to at least result in recoupment of the cost of the CAR-T product.

With regard to the clinical trial threshold, CMS' responds that it continues to monitor the data and may engage in future rulemaking on this issue. CMS responds to the comment regarding inadequate payment by referring readers to a prior response on this issue in the FY 2022 IPPS final rule (86 FR 44965).[19]

Some commenters were concerned about the proportion of statistical outliers removed from the MS-DRG 018 relative weight calculation compared to other MS-DRGs. CMS examined the cases referenced by the commenter and found that they were appropriately removed as statistical outliers as they had very high charges and short lengths of stay (daily charges in excess of $1.2 million relative to the average daily charge of $114,000 for MS-DRG 018).

Several commenters objected to mapping revenue codes 087X for cell and gene therapy services furnished by hospital staff to the drug cost center. Commenters stated that if CMS finalizes this proposed mapping, it will be inconsistent with the mapping of revenues and expenses that

[19] The response indicates the IPPS is a prospective payment system designed to provide incentives for efficient care. It is not a cost-reimbursement system although payment should be sufficient to adequately compensate hospitals for the cost of providing necessary care to Medicare beneficiaries.

hospitals are required to adhere to in their cost reports. One commenter requested that CMS allow providers to bill for cell collection and cell processing services on the day that the services are rendered rather than adding them to the inpatient claim.

CMS disagreed with these comments stating that cell collection and processing activities are part of the steps required to manufacture the drug, and thus assignment to the drug cost center accurately allocates these costs. The response further indicated that CMS is unsure which cost report instructions the mapping would be in conflict with. CMS does not believe that separate payment is necessary for the various steps required to collect and prepare the genetically modified T-cells.

One commenter requested that CMS consider allowing hospitals to use expanded access condition code 90 instead of the remarks field, which would remove a layer of manual work required by the MACs and decrease the opportunity for errors. CMS agrees. Effective October 1, 2022, providers should submit condition code 90 to identify expanded access claims that group to MS-DRG 018, rather than the remarks field.

For FY 2023, CMS estimated that the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($61,540) were 21 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($293,546). Accordingly, CMS is adjusting the transfer-adjusted case count for MS-DRG 018 by applying an adjustor of 0.21 to clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS-DRG 018 in calculating the national average cost per case and the relative weights. CMS will apply this same adjustor for the applicable cases that group to MS-DRG 018 for purposes of budget neutrality and outlier simulations.

Averaging of Relative Weights for FY 2023. Using the FY 2021 claim data, CMS has observed that COVID-19 cases are increasing the relative weights for the MS-DRGs where these cases are grouped. For instance, MS-DRG 870 (Septicemia or Severe Sepsis with MV >96 hours) has a 9 percent higher relative weight including COVID-19 cases relative to excluding them.

As CMS believes there will be fewer COVID-19 cases in FY 2023 than FY 2021, CMS proposed to determine the relative weight for the MS-DRGs where COVID cases are grouped by averaging the relative weights calculated with and without COVID-19 cases. By averaging the relative weights, CMS believes the result will reflect a more accurate estimate of the relative resource use for the cases treated in FY 2023 than if no special adjustment were made.

As an example, CMS indicates that the proposed rule relative weight for MS-DRG 871 (Septicemia or Severe Sepsis Without MV >96 Hours with MCC) was 1.9549 compared to 1.9544 without any special intervention.

Several commenters supported CMS' proposal while others suggested alternative approaches to setting the relative weights for MS-DRGs involving COVID cases including using FY 2019 claims or some other alternate blend with FY 2021 claims. Some commenters expressed concern about policies that may limit the reimbursement for COVID-19 cases. One commenter

recommended that CMS differentiate patients who test asymptomatically for COVID-19 from those whose COVID-19 infection is causing clinical symptoms to worsen.

CMS disagrees with blending other data sources or taking additional steps to control for variability in the FY 2023 relative weights. After reviewing the latest CDC hospitalization data, CMS continues to believe that it is reasonable to assume that some Medicare beneficiaries will be hospitalized with COVID-19 at IPPS hospitals in FY 2023, but that there will be fewer COVID 19 hospitalizations compared to FY 2021. With respect to the commenters' concerns about policies that may limit reimbursement for COVID-19 cases, CMS responds that the relative weights calculated using the averaging methodology for FY 2023 are higher than the FY 2022 relative weights for these MS-DRGs. CMS responds to the comment about differentiating between symptomatic and asymptomatic COVID-19 cases that it is not feasible absent coding to distinguish these types of patients.

After consideration of comments received, CMS is finalizing its proposal to determine the FY 2023 MS-DRG relative weights by averaging the relative weights as calculated with and without COVID–19 cases in the FY 2021 data.

Cap on Relative Weight Reductions. In past years, CMS has selectively limited reductions in the relative weight for specific MS-DRGs in order to facilitate payment stability. These policies were adopted as one-time measures in response to concerns raised in the public comments about large reductions in specific MS-DRGs. For FY 2022, CMS considered the comments on prior rulemaking as part of proposing a broader policy to limit reductions in relative weights.

CMS cited its statutory authority under sections 1886(d)(4)(B) and (C) and section 1886(d)(5)(I)(i)[20] of the Social Security Act (the Act) to propose a permanent 10 percent annual cap on the reduction in a MS-DRG's relative weight beginning with FY 2023. CMS proposed to adopt this policy budget neutral consistent with section 1886(d)(4)(C)(iii) of the Act, which requires changes to the relative weights not increase or decrease aggregate payments.

While CMS considered reduction limits of 20 percent and 5 percent, it proposed the 10 percent cap to mitigate the financial impact resulting from significant fluctuations in the relative weights, particularly for low volume MS-DRGs, without the larger budget neutrality adjustment associated with a smaller cap. The proposed policy affected 27 MS-DRGs, based on the FY 2021 claims data used for the proposed rule.

The proposed 10 percent cap on reductions to an MS-DRG's relative weight would apply only to a given MS-DRG with its current MS-DRG number. In cases where CMS creates new MS-DRGs or modifies the MS-DRGs as part of its annual reclassifications resulting in renumbering of one or more MS-DRGs, CMS proposed that the limit would not apply.

[20] Section 1886(d)(4)(B) and (C) of the Act provides the Secretary with authority to "assign an appropriate weighting factor" to each MS-DRG and "adjust… weighting factors annually." Section 1886(d)(5)(I)(i) of the Act provides authority for "exceptions and adjustments to the payment amounts under section 1886(d) of the Act" as the Secretary deems appropriate.

Public comments generally supported CMS' proposal to establish a cap on reductions to the MS-DRG relative weight. There were many comments for alternative caps (5 percent or 5 percent for one year followed by 10 percent) as well as comments that the cap should be applied without budget neutrality. Some comments said the cap should be temporary until the data stabilizes post-PHE. Another commenter requested that the cap apply to increases in the MS-DRG relative weight as well as reductions.

CMS responded that it believes the cap policy must be adopted budget neutral consistent with the requirements of section 1886(d)(4)(C)(iii) of the Act, which specifies that the annual DRG reclassification and recalibration of the relative weights be made in a manner that ensures that aggregate payments to hospitals are not affected.

With respect to a lower or different cap than 10 percent, CMS reiterates its proposed rule rationale that on balance, a 10 percent cap would promote predictability and mitigate financial impacts resulting from significant fluctuations in the relative weights, particularly for low volume MS–DRGs, without the larger budget neutrality adjustment associated with a smaller cap. Declines in relative weight between 5 and 10 percent is not unusual or necessarily related to the first use of the PHE data. For this reason, CMS believes the cap should be permanently adopted at 10 percent.

After consideration of comments received, CMS is finalizing the proposed permanent 10 percent cap on the reduction in an MS-DRG's relative weight in a given fiscal year and the associated budget neutrality adjustment to the standardized amount. Using final rule data, 31 MS-DRGs will be affected by the 10 percent cap on reductions.

Other Issues. The relative weights are normalized by an adjustment factor so that the average case weight after recalibration is equal to the average case weight before recalibration. This process involves calculating aggregate MS-DRG relative weights for FY 2022 and FY 2023 using the FY 2021 Medicare utilization. The normalization factor equals the aggregate FY 2022 relative weights divided by the aggregate FY 2023 relative weights. The normalization factor is applied to each FY 2023 relative weight to ensure that recalibration by itself does not increase or decrease total payments under the IPPS.

For FY 2023, CMS' application of the normalization factor will be applied differently than in past years because of policies to create an average of the relative weights with and without COVID cases. Normalization will occur as follows:

Step 1: Create a set of relative weights using all applicable cases. These relative weights were normalized by an adjustment factor of 1.948410.

Step 2: Create a set of relative weights excluding cases where COVID-19 was present as a principal or secondary diagnosis. These relative weights were then normalized by an adjustment factor of 1.16445.

Step 3: Average the relative weights in steps 1 and 2. These relative weights were normalized by an adjustment factor of 1.000212.

CMS then applied the 10 percent cap on reductions to the MS-DRG relative weights. This 10 percent cap was made budget neutral through a 0.999764 (-0.02 percent) adjustment to the standardized amounts.

For very low volume MS-DRGs (less than 10 cases, 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.

D. Add-On Payments for New Services and Technologies

1. Background

Sections 1886(d)(K) and (L) of the Act establish a process for identifying and ensuring adequate payment for new medical services and technologies under the IPPS. The regulations at 42 CFR 412.87 specify three criteria for a new medical service or technology to receive add-on payments under the IPPS: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate[21]; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. Beginning with FY 2021, certain transformative new devices and Qualified Infectious Disease Products (QIDPS) may qualify for a new technology add-on payment under an alternative pathway.[22] Also, beginning with FY 2022, a drug approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway), may also qualify for a new technology add-on payment under an alternative pathway.[23]

a. New Technology Add-on Payment Criteria

Newness Criterion. 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[24]:

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.

[21] Capital costs are not included in the add-on payments for a new medical service or technology and new technology add-on payments are not made for capitol-related costs (72 FR 47307 through 47308).
[22] 84 FR 42292 through 42297; regulations at § 412.87(c) and (d)
[23] 85 FR 58736
[24] 74 FR 43813 and 43814

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 makes a determination as to whether the cost threshold and substantial clinical improvement criteria are met.

Cost Criterion. For purposes of the cost criterion, CMS includes the cost thresholds applicable to the next fiscal year, in the data files associated with the prior fiscal year. The proposed MS-DRG thresholds applicable to FY 2024 were included in the data files associated with the FY 2023 proposed rule on the CMS website.[25]

Because of the PHE, for FY 2022 rate setting, CMS used the FY 2019 MedPAR claims data instead of FY 2020 MedPAR data. Consistent with this policy, for the FY 2023 threshold values, CMS used FY 2019 claims data to evaluate whether the charges of the cases involving a new medical service or technology exceeded the cost thresholds.

For FY 2024 rate setting, CMS finalizes its proposal to use the FY 2021 MedPAR claims data for FY 2023 with certain modifications to its relative weight setting and outlier methodologies. As discussed above in section II.E, CMS finalizes its proposal to average the relative weights as calculated with and without COVID-19 cases in the FY 2021 data to determine the MS-DRG relative weights for FY 2023. For the FY 2024 threshold values, CMS finalizes its proposal to use the FY 2021 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2024. Certain steps for calculating the thresholds for new technology add-on payments use the same charge data that is used to calculate the MS-DRG weights. Thus, for purposes of calculating the FY 2024 thresholds, CMS finalizes its proposal to average the data in the steps of the calculation that uses charge data from the calculation of the MS-DRG weights.

The finalized threshold for applications for new technology add-on payments for FY 2024 are presented in a data file, along with the other data files associated with the FY 2023 final rule.

Substantial Clinical Improvement Criterion. Under the third criterion, a medical service or technology must represent an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS final rule[26], CMS codified at §412.87(b) the following aspects of how it evaluates substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

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

[25] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.
[26] 84 FR 42288 through 42292

    - 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.
- 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.
- The medical condition diagnosed or treated may have a low prevalence among Medicare beneficiaries.
- 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 reiterates that although it is affiliated with the FDA, it does not use FDA criteria to determine what drugs, devices or technologies qualify for new technology add-on payments. CMS states its criteria do not depend on the standards of safety and efficacy used by the FDA but on the demonstration of substantial clinical improvement in the Medicare population, particularly patients over age 65 years.

b. Alternative Inpatient New Technology Add-on Payment Pathway.

Alternative Pathway for Certain Transformative New Devices. If a medical device is part of FDA's Breakthrough Devices Program and received FDA marketing authorization (has been approved or cleared by, or had a De Novo classification request granted by FDA), it will be considered new and not substantially similar to an existing technology and will not need to meet the substantial clinical improvement requirements. The new device will still need to meet the cost criterion. In the FY 2021 final rule, CMS clarified that a new medical device must receive

marketing authorization for the indication covered by the Breakthrough Devices Program designation.

Alternative Pathway for Certain Antimicrobial Products. Beginning with FY 2021, if a new medical product is designated by the FDA as a QDIP and received FDA marketing authorization, it will be considered new and not substantially similar to an existing technology and will not need to meet the substantial clinical improvement requirements. Beginning with FY 2022, a drug approved under FDA's LPAD pathway, will be considered new and not substantially similar to an existing technology and will not need to meet the substantial clinical improvement requirements. These new products will still need to meet the cost criterion. For the new technology add-on payment under these alternative pathways, the product must receive marketing authorization for the indication covered by the QDIP or LPAD designation.

c. Additional Payment for New Medical Service or Technology

In the FY 2020 IPPS final rule[27], CMS finalized an increase in the new technology add-on payment percentage. Specifically, for a new technology, other than a medical product designated as a QIDP or approved under the LPAD pathway, beginning with discharges on or after October 1, 2019, Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed the full DRG payment, including payments for IME and DSH but excluding outlier payments); or (2) 65 percent of the difference between the full DRG payment and the hospital's estimated cost for the case.

For medical products designated as a QIDP or approved under the LPAD pathway, Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed the full DRG payment, including payments for IME and DSH but excluding outlier payments); or (2) 75 percent of the difference between the full DRG payment and the hospital's estimated cost for the case.

Unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS-DRG payment plus 65 percent (or 75 percent for a QDIP or LPAD) of the estimated costs of the new technology or medical service. CMS notes that add-on payments for new medical services or technologies are not subject to budget neutrality.[28]

d. Evaluation of Eligibility Criteria for New Services or Technology Applications

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 FY that the application is being considered. In the FY 2021 IPPS final rule, CMS clarified that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug

[27] 84 FR 42297 through 42300

[28] Section 503(d)(2) of Pub. L. 101-173 provides there will be no reduction or adjustments in aggregate payments under the IPPS due to add-on payments for new technologies.

Application (NDA)) by July 1 of the year prior to the beginning of the FY that the application is being considered.

In the FY 2021 IPPS final rule, CMS finalized its proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products that otherwise meet the new technology add-on payment alternative pathway but do not receive FDA approval by July 1.[29] Antimicrobial products that would otherwise meet the applicable add-on payment criteria would begin receiving the new technology add-on payment, effective for discharges the quarter after the date of FDA marketing authorization instead of waiting to re-apply for the next fiscal year, provided FDA marketing authorization is received by July 1 of the year for which the applicant applied for new technology add-on payments.

e. New Technology Liaisons

CMS has established a team of technology liaisons to serve as an initial resource to stakeholders to help assist with navigating the different CMS pathways for coverage, coding, and payment. CMS encourages stakeholders to first review resources available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. Additional questions can be sent to the new technology liaison team at MedicareInnovation@cms.hhs.gov.

f. Application Information for New Medical Services or Technologies

For FY 2024, complete application information, along with final deadlines for submitting an application, will be posted as it becomes available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. This web site will also post the tracking forms completed by each applicant and will be available before the publication of the proposed rule for FY 2024.

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

The Secretary is required to obtain public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of the proposed rule discussing these services or technologies.[30] On December 14, 2021, CMS held a town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" relating to pending new technology applications. In their evaluation of individual applications, CMS considered the presentations made at the town hall meeting and written comments received by December 27, 2021. Where applicable, CMS summarized comments at the end of each discussion of the individual applications in the proposed rule. Comments that were unrelated to the "substantial clinical improvement" criterion were not summarized in the proposed rule.

[29] 85 FR 58739 through 58742
[30] Section 1886(d)(5)(K0(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108-73.

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

Section "X" codes are ICD-10-PCS codes used to identify new medical services and technologies. Information regarding "X" codes can be found on the CMS web site at https://www.cms.gov/medicare-icd-10/2021-icd-10-pcs. 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.

As discussed below, CMS is not finalizing its proposal to use NDCs instead of ICD-10-PCS Section "X" codes to identify cases involving the use of therapeutic agents approved for new technology add-on payments.

4. New COVID-19 Treatment Add-on Payment (NCTAP)

In response to the PHE, CMS established NCTAP under the IPPS for COVID-19 cases meeting certain requirements.[31] CMS believed that for drugs and biological products authorized for emergency use or approved by FDA for the treatment of COVID-19 it was appropriate to mitigate any financial disincentives for hospitals to provide new COVID-19 treatments during the PHE. In the FY 2022 IPPS PPS final rule, CMS finalized that effective for discharges occurring on or after November 2, 2020 and until the end of the FY in which the PHE ends, CMS established the NCTAP to pay hospitals the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID-19. CMS also finalized that for a drug or biological product eligible for NCTAP that is also approved for new technology add-on payments it will reduce the NCTAP for an eligible case by the amount of any new technology add-on payment.

Additional information about NCTAP, including eligible drugs and biologicals, is available at https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap.

5. FY 2023 Status of Technologies Approved for FY 2022 New Technology Add-On Payments

CMS discusses the proposed FY 2023 status of 37 technologies approved for FY 2022 new technology add-on payments, including 2 separate add-on payments for different indications for RECARBIO and FETROJA. Because of the COVID PHE, CMS also included a 1-year extension of new technology add-on payments for FY 2022 for 13 technologies.[32]

Conditional approval of CONTEPO. CMS conditionally approved CONTEPO for FY 2022 new technology add-on payments under the alternative pathway for certain antimicrobial products, subject to the technology receiving FDA marketing authorization by July 1, 2022. In the proposed rule, CMS discussed the options available for new technology add-on payments

[31] 85 FR 71155

[32] CMS extended the new technology add-on payments using its authority under section 1886(d)(5)(I) of the Act.

available for CONTEPO based upon the status of FDA marketing authorization. In addition, CMS noted the applicant did not submit a new technology add-on payment application and therefore, CONTEPO would not be eligible for approval or conditional approval new technology add-on payments for FY 2023.

Because CONTEPO did not receive FDA approval by July 1, 2022, no new technology add-on payments will be made for cases involving the use of CONTEPO for FY 2022, and CONTEPO is not eligible for new technology add-on payments for FY 2023.

a. FY 2023 Status of Technologies Approved for FY 2022 New Technology Add-On Payments

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.

Table I.F.-01 in the final rule (see table extract below) lists the 15 technologies CMS finalizes continuation of the new technology add-on payments for FY 2023 because the 3-year anniversary date of entry into the U.S. market occurs on or after April 1, 2023. Several commenters requested that CMS update the maximum new technology add-on payment amount to reflect the current Wholesale Acquisition Cost (WAC) per vial of their respective technologies; this information is reflected in the maximum new technology add-on payment amount in Table 1.F-0.1.

The applicant for ABECMA asserted that the newness period should begin on May 10, 2021, the date the first sale occurred instead of March 26, 2021, the date of FDA approval. CMS does not consider the date of first sale of a product as the indicator of entry of a product onto the U.S. market and notes the applicant did not provide information explaining any delay on the technology's availability on the U.S. market. Because CMS determined CARVYKTI is substantially similar to ABECMA, it is using a single cost for determining the new technology add-on payment based on a weighted average of the cost of these two products.

Continuation of Technologies Approved for FY 2022 New Technology Add-On Payments Still Considered New for FY 2023 Because 3-Year Anniversary Date Occurs on or After April 1, 2023

	Technology	FDA/Newness Start Date	NTAP Start Date	3-Year Anniversary Date of Entry onto US Market	Maximum NTAP for FY 2023
1	Rybrevant™	05/21/2021	10/1/2021	5/21/2024	$6,405.89
2	Cosela™	02/12/2021	10/1/2021	2/12/2024	$5,612.10
3	ABECMA®	03/26/2021	10/1/2021	3/26/2024	$289,532.75
4	StrataGraft®	06/15/2021	10/1/2021	6/15/2024	$44,200.00
5	TECARTUS®	07/4/2020	10/1/2021	7/4/2023	$259,350.00

Continuation of Technologies Approved for FY 2022 New Technology Add-On Payments Still Considered New for FY 2023 Because 3-Year Anniversary Date Occurs on or After April 1, 2023					
	Technology	**FDA/Newness Start Date**	**NTAP Start Date**	**3-Year Anniversary Date of Entry onto US Market**	**Maximum NTAP for FY 2023**
6	VEKLURY®	07/1/2020*	10/1/2021	7/1/2023*	$2,028.00
7	Zepzelca™	06/15/2020	10/1/2021	6/15/2023	$9,145.50
8	aprevo® Intervertebral BodyFusion Device	12/03/2020 (ALIF and LLIF) 6/30/2021(TLIF)	10/1/2021	12/03/2023 (ALIF and LLIF) 6/30/2024 (TLIF)	$40,950.00
9	aScope® Duodeno	07/17/2020	10/1/2021	7/17/2023	$1,296.75
10	Caption Guidance™	09/15/2020	10/1/2021	9/15/2023	$1,868.10
11	Harmony™ Transcatheter Pulmonary Valve (TPV) System	03/26/2021	10/1/2021	3/26/2024	$26,975.00
12	Intercept® (PRCFC)	05/05/2021	10/1/2021	5/05/2024	$2,535.00
13	ShockWave C2 Intravascular Lithotripsy (IVL) System	02/12/2021	10/1/2021	2/12/2024	$3,666.00
14	Fetroja® (HABP/VABP	09/25/2020	10/1/2021	9/25/2023	$8,579.84
15	Recarbrio™ (HABP/VABP)	06/04/2020	10/1/2021	6/04/2023	$9,576.51

New Technology Add-on Payment for VEKLURY. VEKLURY (remdesivir) received an EUA from FDA for the treatment of suspected or laboratory confirmed COVID-19 adults and children hospitalized with severe disease. The applicant stated that between July 1, 2020 and September 30, 2020, it entered in an agreement with the U.S. Government to allocate and distribute commercially available VEKLURY and under this agreement, the first sale of VEKLURY was July 10, 2020. The applicant also stated that a more traditional, unallocated distribution model was begun October 1, 2020. For FY 2022, CMS considered the newness period for VEKLURY began on October 22, 2020, when VEKLURY was approved by the FDA.[33] CMS stated that although an EUA is not marketing authorization for purposes of eligibility for new technology add-on payments (§412.87(e)(2)), data reflecting the costs of products that have an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance.

The applicant provided additional information related to VEKLURY's commercial availability which indicated that from May through June 2020, the entire existing supply of VEKLURY was donated worldwide and distributed to hospitals free of charge.[34] Based on this information, CMS believes that cost data may not have been available until after the donation period, when the technology became commercially available on July 1, 2020 and that the newness period for VEKLURY may more appropriately begin on July 1, 2020. CMS states that for FY 2023 the product would remain eligible for FY new technology add-on payments, regardless of whether the newness period began on May 1 (the date of the EUA), July 1 (the date the donation phase

[33] 86 FR 45104 through 45107

[34] https://stories.gilead.com/articles/an-update-on-covid-19-form-our-chairman-and-ceo

ended), or October 22 (the FDA approval) since in all these cases the 3-year anniversary date would occur after April 1, 2023.

In the proposed rule, CMS requested comments about when the newness period for products available through an EUA for COVID-19 should begin. With respect to the start of the newness period for VEKLURY, the applicant noted there was no material impact on eligibility regardless of whether CMS used the July 1, 2020 or October 22, 2020. The applicant stated that CMS' decision to use the date of FDA approval as the beginning of the newness period for VEKLURY was consistent with its longstanding policy to generally begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant asserted that using a date prior to FDA approval as the beginning of the newness period would be a departure from how CMS has traditionally determined the beginning of the newness period. The applicant urged CMS to determine the start of the newness period for VEKLURY and other products originally available under a EUA using the same policy it applies to all other products approved for new technology add-on payments, the date of FDA approval or, if later, the date of market availability in the U.S.

In response, CMS agrees with the applicant that it generally begins the newness period on the date of FDA approval or, if later, the date of availability of the product on the U.S. market, based on a documented delay. CMS disagrees, that beginning the newness period on the date of EUA issuance and prior to FDA approval would be inconsistent with its longstanding policy. CMS notes that as discussed in the FY 2022 final rule, the data reflecting the costs of the product could become available as soon as the date of EUA issuance and prior to FDA approval. CMS recognizes that there may be unique considerations for products available under an EUA prior to FDA approval and will continue to consider comments received about this issue for future rulemaking.

New Technology Add-on Payment for Caption Guidance. CMS proposes to continue new technology add-on payments for Caption Guidance for FY 2023, a technology sold on a subscription basis. CMS did not receive any comments in response to its request for comments about the appropriate method to determine a cost per case for technologies sold on a subscription basis.

Table II.F.-02 in the final rule (see table extract below) lists the 11 technologies CMS finalizes discontinuation of the new technology add-on payments for FY 2023 because the 3-year anniversary date of entry into the U.S. market occurs prior to April 1, 2023.

Discontinuation of Technologies Approved for FY 2022 New Technology Add-On Payments no Longer Considered New for FY 2023 Because 3-Year Anniversary Date Occurs Prior to April 1, 2023				
Technology		**FDA/Newness Start Date**	**NTAP Start Date**	**3-Year Anniversary Date of Entry onto US Market**
1	*Balversa™*	04/12/2019	10/19/2019	4/12/2022
2	*Jakafi®*	05/24/2019	10/1/2019	5/24/2022
3	*BAROSTIM NEO™ System*	08/16/2019	10/1/2020	08/16/2022
4	*Optimizer® System*	10/23/2019	10/1/2020	10/23/2022

Discontinuation of Technologies Approved for FY 2022 New Technology Add-On Payments no Longer Considered New for FY 2023 Because 3-Year Anniversary Date Occurs Prior to April 1, 2023				
Technology		FDA/Newness Start Date	NTAP Start Date	3-Year Anniversary Date of Entry onto US Market
5	*RECARBRIO™ (cUTI/ cIAI)*	07/16/2019 commercially available in US1/6/20	10/1/2020	1/6/2023
6	*Soliris®*	06/27/2019	10/1/2020	6/27/2022
7	*XENLETA™*	08/19/2019 commercially available in US9/10/19	10/1/2020	9/10/2022
8	*ZERBAXA®*	06/03/2019	10/1/2020	6/03/2022
9	*Azedra®*	05/21/2019	10/1/2019	5/21/2022
10	*EXALT™ Model D*	12/13/2019	10/1/2021	12/13/2022
11	*Fetroja® (Cefiderocol)* (cUTI)	11/19/2019 Commercially available in US2/24/2020	10/1/2020	2/24/2023

Many commenters were opposed to CMS discontinuing new technology add-on payments for technologies whose 3-year anniversary date occurred either prior to FY 2023 or in the first half of FY 2023 and encouraged CMS to extend new technology add-on payments through FY 2023 because of decreased utilization during the COVID-19 pandemic. CMS does not believe that case volume is a relevant consideration for making the determinization as to whether a product is "new" and it is not extending new technology add-on payments for these technologies. As discussed in the next section, CMS allowed for a 1-year extension of new technology add-on payments for FY 2022 because of the unique circumstances associated with rate setting for FY 2022 and the use of FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights.

Several commenters disagreed with CMS' proposal to discontinue new technology add-on payment for EXACT Model D Single-Use Duodenoscope while continuing payments for the Scope Duodeno through FY 2023 based on the different FDA clearance dates for the two technologies. CMS considered the products as similar technologies and the products share one add-on payment amount and are identified using the same ICD-10-PCS codes. The applicant for the EXALT Model D stated that creating a single newness date and discontinuation date for a combined new technology add-on payment is consistent with prior CMS decision making regarding similar technologies such as IMFINZI and TECENTRIQ (FY 2021 IPPS final rule) and LUTONIX and IN.PACT Admiral drug-coated balloons (FY 2016 IPPS final rule). This commenter requested that CMS discontinue the new technology add-on payments for both products, preferably at the end of FY 2023. As an alternative, the applicant recommended that CMS recalculate the maximum payment amount from the current case-weighted average of $1,715 per case to only reflect the cost of a Scope Duodeno.

In response, CMS notes that under §412.87(c) applications for a new technology add-on payment through the alternative pathway will be considered not substantially similar to an existing

technology for purposes of the new technology add-on payment under the IPPS. Thus, the comparisons to technology determined to be substantially similar through the traditional pathway is not relevant. CMS finalizes its proposal to discontinue the new technology add-on payment for EXALT Model D for FY 2023.

CMS does agree with the recommendation that the maximum new technology add-on payments should only reflect the cost of aScope Duodeno ($1,995) and finalizes the maximum new technology add-on payment for a case involving the aScope Duodeno will be $1,296.75. Cases involving the use of the aScope Duodeno will continue to be identified by the ICD-10-PCS procedure codes XFJB8A7 and XFJD8A7.

b. Status of Technologies Provided a One-Year Extension of New Technology Add-On Payments for FY 2022

Because of the COVID PHE, CMS used FY 2019 MedPAR data instead of FY 2020 MedPAR data for the development of the FY 2022 MS-DRG relative weights. For FY 2022, CMS used its authority under section 1886(d)(5)(I) of the Act to allow for a 1-year extension of new technologies for which the new technology add-on payment would have otherwise been discontinued for FY 2022.

For FY 2023, CMS believes the best available data is the FY 2021 MedPAR file and finalizes its proposal to use this data for rate setting and for developing the FY 2023 relative weights. For FY 2023, CMS believes the 13 technologies for which the 3-year anniversary date of the product's entry onto the U.S. market occurred prior to FY 2023, may now be fully reflected in the FY 2023 MedPAR data. Table II.F.-03 in the final rule (see table extract below) lists the 13 technologies CMS finalizes discontinuation of the new technology add-on payments for FY 2023.

As previously discussed, many commenters were opposed to CMS discontinuing new technology add-on payments for technologies whose 3-year anniversary date occurred either prior to FY 2023 or in the first half of FY 2023 and encouraged CMS to extend new technology add-on payments through FY 2023 because of decreased utilization during the COVID-19 pandemic. As discussed in the next section, CMS allowed for a 1-year extension of new technology add-on payments for FY 2022 because of the unique circumstances associated with rate setting for FY 2022 and the use of FY 2019 data instead of FY 2020 data to develop the FY 2022 relative weights. For FY 2023, because CMS is finalizing the use of the FY 2021 MedPAR data for FY 2023 rate setting, including for the development of FY 2023 relative weights, CMS believes the cost of these technologies are now reflected in the MedPAR data used to recalibrate the MS-DRG relative weights for FY 2023. Thus, CMS is not extending new technology add-on payment for technologies that received a one-year extension in FY 2022.

Discontinuation of Technologies Which Received a One Year Extension for New Technology Add-On Payment in FY 2022 Because the 3-Year Anniversary Date Occurred Before the Second Half of FY 2022				
Technology		**FDA/Newness Start Date**	**NTAP Start Date**	**3-Year Anniversary Date of Entry onto US Market**
1	Cablivi®	02/06/2019	10/01/2019	02/06/2022
2	Elzonris™	12/21/2018	10/01/2019	12/21/2021

Discontinuation of Technologies Which Received a One Year Extension for New Technology Add-On Payment in FY 2022 Because the 3-Year Anniversary Date Occurred Before the Second Half of FY 2022				
Technology		**FDA/Newness Start Date**	**NTAP Start Date**	**3-Year Anniversary Date of Entry onto US Market**
3	AndexXa™	05/03/2018	10/01/2018	05/03/2021
4	Spravato®	3/5/2019	10/01/2019	3/5/2022
5	Zemdri®	6/25/2018	10/01/2018	6/25/2021
6	T2 Bacteria® Panel	05/24/2018	10/01/2019	05/24/2021
7	ContaCT	02/13/2018 (Commercially available 10/01/2018)	10/01/2020	10/01/2021
8	Eluvia™ Drug-Eluting Vascular Stent System	09/18/2018 (Commercially available in US 10/04/2018)	10/01/2020	10/04/2021
9	Hemospray®	05/07/2018 (Commercially available 07/01/2018)	10/01/2020	07/01/2021
10	IMFINZI®/ TECENTRIQ®	Imfinzi: 03/27/2020; Tecentriq: 03/18/2019 Newness date is3/18/2019 for both	10/01/2020	03/18/2022
11	NUZYRA®	10/02/2018 (Commercially available 02/01/2019)	10/01/2020	2/01/2022
12	SpineJack® System	08/30/2018 (Commercially available 10/11/2018)	10/01/2020	10/11/2021
13	Xospata®	11/28/2018	10/01/2019	11/28/2021

6. FY 2022 Applications for New Technology Add-On Payments: Traditional Pathway

CMS received 18 applications for new technology add-on payments for FY 2023. Five applicants withdrew their applications prior to the issuance of this proposed rule. Subsequently, seven applicants withdrew their applications prior to the issuance of this final rule: narsoplimab, TELIVAZ (terlipressin), teclistamab, mosunetuzumab, XENOVIEW, and treosulfan. In addition, spesolimab did not receive FDA approval by July 1, 2022 and is not eligible for new technology add-on payments for FY 2023. The summary below provides a high-level discussion of the remaining five new technology assessment; readers are advised to review the final rule for more detailed information.

CMS approves four of the applications for new technology add-on payments for FY 2023:

- CARVYKTI (Ciltacabtagene autoleucel),
- DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj*)*,
- Hemolung Respiratory Assist System (Hemolung RAS), and

- LIVTENCITY™ (maribavir).

CMS does not approve the new technology add-on payment for UPLINZA® (inebilizumab-cdon) for FY 2023.

a. CARVYKTI™ (Ciltacabtagene autoleucel)

Janssen Biotech submitted an application for CARVYKTI (Ciltacabtagene autoleucel)[35], an autologous chimeric-antigen receptor T cell (CAR-T) therapy directed against B cell maturation antigen (BCMA) for the treatment of patients with multiple myeloma (MM).[36] CARVYKTI is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.

Newness. CARVYKTI was granted Breakthrough Therapy designation in December 2019 for the treatment of patients with r/rMM who have previously received a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody. FDA approved the Biologics License Application (BLA) for CARVYKTI on February 28, 2022 for the treatment of adult patients with r/rMM after four or more prior lines of therapy, including a PI, an IMiD, and an anti-CD38 monoclonal antibody. Cases reporting the use of CARVYKTI can be uniquely identified using the following ICD-10-PCS procedure codes: XW033A7 and XW043A7.

For the first criterion (same or similar mechanism of action), the applicant stated that CARVYKTI has a unique mechanism of action because it has two distinct binding domains that confer avidity to the BCMA antigen, a 4-1BB co-stimulatory domain and a CD3z signaling domain. Other CAR T-cell products have only one target binding domain. The applicant stated that ABECMA also targets BCMA, but only binds to a single BCMA domain. The applicant also discussed how the CAR T-cell's mechanism of action is different from ABECMA and the BCMA-target agent, Blenrep, a monoclonal antibody linked to a toxic drug.

For the second criterion (same or different MS-DRG), the applicant acknowledged that CARVYKTI would be assigned to the same MS-DRG as other FDA-approved CAR T-cell therapies (Pre-MDC MS-DRG 018). For the third criterion (same or similar disease or patient population), the applicant stated that ciltacabtagene autoleucel is indicated for a specific population of patients with MM having received three prior therapies. According to the applicant, Blenrep and ABECMA are indicated with at least 4 prior therapies whereas CARVYKTI has a proposed indication for the treatment of patients with 3 or more prior therapies.

In the FY 2022 proposed rule, CMS noted that CARVYKIT may have a similar mechanism of action and treat the same or similar patients as ABECMA. For FY 2022, ABECMA received approval for new technology add-on payments for the treatment of adult patients with RRMM

[35] Ciltacabtagene autoleucel refers to both JNJ-4528 and LCAR-B38M, the investigational product being studied in China.

[36] Jansen previously submitted an application for new technology add-on payments for CARVYKTI for FY 2022 under the name ciltacabtagene autoleucel but withdrew that application prior to the FY 2022 IPPS PPS final rule (86 FR 25233 through 25239).

after four or more prior lines of therapy, including PI, IMiD, and an anti-CD38 antibody. Although the number of BCMA binding domains of CARVYKIT and ABECMA differ, in the proposed rule, CMS stated it is unclear how the additional BCMA binding domain represents a change in the mechanism of action of this therapy. CMS believed that the mechanism of action for CARVYKTI may be the same or similar to ABECMA. CMS also noted that although the applicant stated the proposed indication for CARVYKTI may be for a fourth line treatment, the recent FDA approval states it is indicated for fifth line treatment.

CMS believes that CARVYKTI and ABECMA are substantially similar to each other; the newness period for CARVYKTI would begin on March 26, 2021, the date ABECMA received FDA approval. CMS was interested in information on how these two technologies may differ with respect to the substantial similarity and newness criterion.

The applicant submitted a comment addressing the concerns CMS raised in the proposed rule. The applicant highlighted several differences between CARVYKTI and ABECMA which included the number of binding, dosage, time to cytokine release syndrome (CRS), pharmacokinetic/pharmacodynamic profile, side effects, source of antibodies, and CD4/CD8 ratio. CMS does not believe these are meaningful differences in the mechanism of action of CARVYKTI from other BCMA-directed CAR T-cell therapies that bind to BCMA-expressing cancer cells.

CMS believes that CAARVYKTI and ABECMA use the same or a similar mechanism of action to achieve a therapeutic outcome, map to the same MS-DRG, and treat the same patient populations. CMS concludes that CARVYKTI is substantially similar to ABECMA; the beginning of the newness period for CARVYKTI is March 26, 2021, the date that ABECMA received FDA marketing authorization.

Consistent with its policy regarding substantial similarity (85 FR 58679) CMS will not make a determination on cost and substantial clinical improvement for CARVYKTI. Since the approval of new technology add-on payments extend to all technologies that are substantially similar, if substantially similar technologies are submitted for review in subsequent years, CMS evaluates and makes a determination on the first application and apply that determination to subsequent applications.

Cases involving the use of the CARVYKTI will be identified by ICD-10-PCS codes XW033A7 or XW043A7. Based on information provided by the applicant estimated the cost of CARVYKTI is $465,000 per patient. CMS determines the weighted average of the cost of CARVYKTI and ABECMA to determine the new technology add-on payment. CMS projects 241 cases treated with CARVYKTI ($465,000 per case) and 179 cases treated with ABECMA ($419,500 per case). For 2023, using a maximum technology add-on payment of 65 percent, the add-on payment for a case involving the use of CARVYKTI or ABECMA is $289,532.75.

b. DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj)

Jansen Biotech submitted an application for DARZALEX FASPRO, a combination of daratumumab (a monoclonal CD38-directed cytolytic antibody) and hyaluronidase (an

endoglycosidase) indicated for the treatment of light chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide and dexamethasone (CyBorD) in newly diagnosed patients. DARZALEX FASPRO is administered through a subcutaneous injection.

AL amyloidosis is a life-threatening blood disorder caused by increased production of misfolded immunoglobulin light chains by an abnormal proliferation of malignant CD38+ plasma cells. These deficient immunoglobulin light chains aggregate into amyloid fibrils that deposit in tissues and eventually result in organ dysfunction. The most frequently affected organs are the heart, kidney, liver, spleen, gastrointestinal tract and nervous system. The applicant noted that no current therapies used to treat AL amyloidosis are approved for use by FDA for this specific indication.

Newness. DARZALEX FASPRO was granted accelerated approval from FDA on January 15, 2021, for the treatment of newly diagnosed adult patients with AL amyloidosis in combination with CyBorD in newly diagnoses patient. Outside of controlled clinical trials, DARZALEX FASPRO is not indicated or recommended for the treatment of patients with AL amyloidosis with NYHA Class IIIB or Class IV cardiac disease. Prior FDA approved indications for DARZALEX FASPRO are not part of this new technology add-on payment application.[37] Cases reporting the use of DARZALEX FASPRO would be coded with ICD-10-PCS code for introduction of other therapeutic substance into subcutaneous tissue (3E012GC); the applicant submitted a request for a unique ICD-10-PCS code.

For the first criterion (same or similar mechanism of action), the applicant stated that DARZALEX FASPRO is the first drug approved by FDA for treatment of AL amyloidosis. The applicant discusses how the mechanism of action for DARZALEX FASPRO is different from other drugs used to treat AL amyloidosis. The applicant noted that the National Comprehensive Cancer Network (NCCN) Guidelines for Systemic Light Chain Amyloidosis state that both IV and SQ daratumumab can be used to treat amyloidosis,[38] IV daratumumab is not approved for the treatment of any patients with amyloidosis. The applicant stressed that DARZALEX FASPRO is the most appropriate option for the AL amyloidosis patient because the subcutaneous dosing has a negligible volume which is important in patients with AL amyloidosis who can have compromised cardiac and renal function. For the second criterion (same or different MS-DRG), the applicant stated that treatment is not expected to change the DRG assignment of a case with AL amyloidosis. For the third criterion (same or similar disease or patient population), the applicant reiterated that DARZALEX FASPRO is the first approved drug to treat patients with AL amyloidosis.

Based on its review of comments and the information included in the application, CMS concludes that DARZALEX FASPRO meets all the newness criteria. CMS considers the beginning of the newness period to begin on the date of FDA approval, January 15, 2021.

[37] DARZALEX FASPRO received FDA approval on September 26, 2019 for the treatment of adult patients with multiple myeloma as part of combination therapy in newly diagnosed patients eligible for autologous stem cell transplant, and on May 1, 2020 for the treatment of patients with multiple myeloma.
[38] NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain amyloidosis (Version 1.2022). National Comprehensive Cancer Network.www.nccn.org. Published June 2021.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS concludes that DARZALEX FASPRO meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that DARZALEX FASPRO offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant also asserted that DARZALEX FASPRO demonstrates significant improvement in a number of clinical outcomes including hematologic complete response (hemCR), prolonged survival free from major organ deterioration, and no negative impact to health-related quality of life based on patient-reported outcomes. In the proposed rule, CMS summarized the information provided by the applicant, including results from the ANDROMEDA phase 3 trial and presentations related to these trials. The applicant noted that DARZALEX FASPRO provides important advantages because the subcutaneous administration allows for a negligible volume of administration and a reduced rate of systemic administration related reactions.

In the proposed rule, CMS discussed several concerns regarding whether DARZALEX FASPRO meets the substantial clinical improvement criterion including the design of the ANDROMEDA trial and the generalizability of the ANDROMEDA population and subgroups to the Medicare population. CMS noted that during the New Technology Town Hall meeting, the applicant clarified that all subjects in the ANDROMEDA trial received DARZALEX FASPRO in the outpatient setting. CMS questioned whether the results for this outpatient population are generalizable to patients who require hospitalization. CMS also was concerned that the secondary endpoints used for the quality-of-life assessments and hematologic responses are not appropriate to measure outcomes.

The applicant and a commenter provided additional information addressing CMS' concerns. After reviewing the additional information, CMS concludes that DARZALEX FASPRO represents a substantial clinical improvement over existing technologies for the treatment of AL amyloidosis patients.

CMS finalizes DARZALEX FASPRO meets all three criteria for new technology add-on payments and approves add-on payments for FY 2023. Cases involving the use of the DARZALEX FASPRO will be identified by ICD-10-PCS codes XW01318 in combination with the ICD-10-CM code E85.81 (Light chain (AL) amyloidosis). Based on information provided by the applicant, the estimated cost per patient for DARZALEX FASPRO is $5,159.41. For 2023, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving DARZALEX FASPRO is $5,159.41.

c. Hemolung Respiratory Assist System (Hemolung RAS)

ALung Technologies submitted an application for Hemolung RAS, a technology that uses an extracorporeal circuit to remove CO_2 directly from the blood for the treatment of acute, hypercapnic respiratory failure in adults. The Hemolung RAS provides low-flow, veno-venous extracorporal CO_2 removal ($ECCO_2R$) which provides partial ventilatory lung support as an alternative or supplement to invasive mechanical ventilation (IMV). The Hemolung RAS requires continuous systemic anticoagulation to prevent blood clots in the circuit. The Hemolung

RAS is not intended to provide therapeutic levels of oxygenation. According to the applicant, Hemolung RAS does not treat a specific disease but removes CO_2 directly form the blood to treat a variety of underlying disease states such as cystic fibrosis, chronic obstructive pulmonary disease (COPD), and asthma.

Newness. Hemolung RAS received Breakthrough Device Designation from FDA in 2015 as a Class III device for treatment of COPD patients experiencing acute, refractory, hypercapnic respiratory failure. On April 22, 2020, the Hemolung RAS received an EUA to treat lung failure due to COVID-19 when use as an adjunct to noninvasive or IMV. On November 13, 2021, Hemolung RAS was classified as a Class II device under the De Novo pathway for the treatment of respiratory support by providing extracorporeal CO_2 removal from the patient's blood for up to 5 days in adults with acute, reversible respiratory failure for whom ventilation of CO_2 cannot be adequately or safely achieved using other available treatment options and continued clinical deterioration is expected. The technology became available on the market on November 15, 2021. The applicant is seeking new technology add-on payments for the FDA De Novo indication for the treatment of hypercapnic respiratory failure due to all causes in adults. Cases reporting the use of this technology would be uniquely coded with ICD-10-PCS code 5A0920Z (Assistance with respiratory filtration, continuous, $ECCO_2R$).

For the first criterion (same or similar mechanism of action), the applicant discussed how the Hemolung RAS has a different mechanism of action compared to IMV, the only existing technology used to treat this patient population. Specifically, IMV utilizes positive airway pressure to deliver oxygen and remove CO_2 from the lungs while Hemolung RAS removes CO_2 directly from the blood, independent of the lungs. The applicant also stated that extracorporeal membrane oxygenation (ECMO) is used for treating refractory hypoxemic respiratory failure and ECMO is not suitable, nor FDA-approved, for acute, hypercapnic respiratory failure.

For the second criterion (same or different MS-DRG), the applicant acknowledged that Hemolung RAS is assigned to the same MS-DRGs as existing technologies. For the third criterion (same or similar disease or patient population), the applicant stated that Hemolung RAS and IMV are both used to treat the same patient population, but Hemolung RAS is indicated for use when IMV is unable to safely or adequately remove CO_2 from the blood and continued clinical deterioration is expected.

CMS notes that the De Novo indication includes use of the product for the EUA indication, patients with respiratory failure caused by COVID-19. CMS reiterates its belief that data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance. Therefore, data reflecting the costs of Hemolung RAS could be available beginning with the EUA on April 22, 2020. CMS questions whether the newness period for Hemolung RAS for patients with COVID-19 should begin with the date of the EUA and the newness period for other causes of hypercapnic respiratory failure begins on the date of commercial availability of the De Novo classified device, November 15, 2021. CMS also notes that the new technology add-on payment is only available for cases meeting the FDA indications; cases involving pediatric patients or cases using Hemolung RAS for greater than 5 days would not be eligible for add-on payments.

The applicant provided a comment stating that the newness period for Hemolung RAS cases should begin on November 15, 2021, the date of commercial availability and not April 22, 2020, the date of the EUA. The applicant indicated it provided the Hemolung RAS free to hospitals and during the EUA period, hospitals were not seeking payment for the therapy. CMS believes that additional information about whether hospitals charged during the EUA period would be helpful. However, CMS notes that regardless of whether the beginning of the newness period was April 22, 2020 or November 15, 2021, the three-year anniversary would occur after April 1, 2023 and the technology would be considered new for FY 2023.

CMS concludes the Hemolung RAS is new for FY 2023 for use in patients with both COVID-19 and hypercapnic respiratory failure unrelated to COVID-19.

Cost. In the proposed rule, CMS summarized the analysis provided to demonstrate the technology meets the cost criterion. CMS questioned whether the analysis should have included patients who would also require a tracheostomy, which would result in inclusion of additional MS-DRGs and could impact the cost analysis.

The applicant updated the cost analysis. Based on this additional information, CMS concludes that Hemolung meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that the Hemolung RAS offers a treatment option for patients unresponsive to non-invasive mechanical ventilation (NIV), patients unresponsive to IMV, and patients ineligible for currently available treatments (failure of NIV with do not intubate (DNI) orders). The applicant also stated that the Hemolung RAS significantly improves clinical outcomes relative to other available treatments. In the proposed rule, CMS summarized the information provided by the applicant including a consensus paper discussing how $ECCO_2R$ therapy is used; numerous case studies; a pilot study done in India and Germany; a retrospective, multicenter study of patients in the US; background studies; and the Hemolung RAS Registry Program Analysis (a voluntary registry collected data from world-wide commercial use of the Hemolung RAS).

CMS discussed several concerns regarding whether the Hemolung RAS meets the substantial clinical improvement criterion. CMS was concerned that the evidence includes small, non-randomized studies without the use of comparators or controls and case studies without comparative data. CMS noted that several of the case studies include patients outside the U.S. and it is concerned that differences in treatment guidelines between these countries may affect clinical outcomes. CMS also noted that the background studies supporting substantial clinical improvement did not utilize the Hemolung RAS.

The applicant and several other commenters provided additional information addressing CMS' concerns. After reviewing the additional information, CMS concludes that Hemolung RAS represents a substantial clinical improvement over existing technologies for the treatment of hypercapnic respiratory failure in adults while avoiding intubation or facilitating extubation. **CMS finalizes Hemolung RAS meets all three criteria for new technology add-on payments and approves add-on payments for FY 2023**. Cases involving the use of Hemolung RAS will be identified by ICD-10-PCS codes 5A0920Z. CMS notes that consistent with the FDA

approval, pediatric patients or cases involving the use of Hemolung RAS for greater than 5 days, would not be eligible for new technology add-on patients. Based on information provided by the applicant, the estimated cost per patient for Hemolung RAS is $10,00. For 2023, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving Hemolung RAS is $6,500.

d. LIVTENCITY™ (maribavir)

Takeda Pharmaceuticals U.S.A. submitted an application for LIVTENCITY, an oral anti-cytomegalovirus (CMV) compound FDA approved for treatment of post-transplant patients with CMV in solid organ transplant (SOT) and hematopoietic stem cell transplant (HCT) in patients' refractory to treatment with other therapies. The applicant stated that CMV is one of the most common viral infections experienced by transplant recipients; reactivation of CMV can potentially lead to serious consequences including loss of the transplant organ and death.

Newness. LIVTENCITY was granted Breakthrough Therapy, Priority Review and Orphan Drug designations from FDA. LIVTENCITY received FDA approval for its New Drug Application (NDA) on November 23, 2021 for treatment of adults and pediatric patients (12 years or older weighing at least 35 kg) with post-transplant CMV infection/disease that is refractory to treatment with ganciclovir, valganciclovir, cidofovir, or foscarnet. LIVTENCITY became commercially available on December 2, 2021; CMS notes there was no explanation provided for this delay from FDA approval. ICD-10-PCS code for introduction of other anti-infective into mouth and pharynx (3E0DX29) can be used to identify cases; the applicant submitted a request for a unique ICD-10-PCS procedure code for LIVENCITY.

For the first criterion (same or similar mechanism of action), the applicant stated LIVENCITY targets a different gene focus than the existing therapies to treat CMS infection. The applicant compared these therapies to LIVENCITY. For the second criterion (same or different MS-DRG) the applicant stated that cases with LIVTENCITY are expected to be assigned to the same MS-DRG as therapies currently used to treat CMS infection. For the third criterion (same or similar disease or patient population), the applicant stated LIVTENCITY is approved to treat a unique patient population and there are no other existing therapies indicated to treat this population. The applicant provided additional information explaining that the delay between FDA marketing authorization and commercial availability was due to final packaging and labeling and shipping the product to specialty pharmacies and distributors.

CMS concludes that LIVTENCITY meets the newness criterion and the beginning of the newness period is December 2, 2021.

Cost. In the proposed rule, CMS summarized the analysis provided to demonstrate the technology meets the cost criterion. CMS concludes that LIVTENCITY meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that LIVTENCITY represents a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant also stated that LIVTENCITY may significantly improve clinical outcomes by improving efficacy and reducing adverse effects compared to available treatments.

In the proposed rule, CMS summarized the information provided by the applicant which included results from SOLTSTICE (a phase III, open-label randomized control trial) and two additional phase II studies. CMS discussed its concerns regarding whether LIVTENCITY met the substantial clinical improvement criterion. It was concerned that the SOLTICE study resulted in similar rates of mortality and new-onset CMV between the 2 treatment groups. CMS requested additional information from the applicant about the safeguards taken to minimize or prevent bias from the treating physician in choosing conventional therapy for patients in the investigator-assigned therapy group of the phase III trial.

The applicant and several commenters provided additional information addressing CMS' concerns. After reviewing the additional information, CMS concludes that LIVTENCITY represents a substantial clinical improvement over existing technologies because it provides a new treatment option for a patient population unresponsive to, or ineligible for, currently available treatments for CMV.

CMS finalizes LIVTENCITY meets all three criteria for new technology add-on payments and approves add-on payments for FY 2023. Cases involving the use of LIVTENCITY will be identified by ICD-10-PCS codes XW0DX38, XWOG738, or XW0H738. Based on information provided by the applicant, the estimated cost per patient for an 8-week course of LIVTENCITY is $50,000. For 2023, using a maximum new technology add-on payment of 65 percent, the add-on payment for a case involving DARZALEX FASPRO is $32,500.

e. UPLINZA® (inebilizumab-cdon)

HTI-DAC the manufacturer under the distributor Horizon Therapeutics submitted an application for UPLIZNA, an FDA-approved CD19-directed cytolytic antibody indicated for the treatment of neuromyelitis optica spectrum disorder (NMOSD) for adult patients who are anti-aquaporin-4 (AQP4) antibody positive. The applicant stated that the binding of UPLINZA to CD19+ B lymphocytes causes antibody-dependent cellular cytolysis resulting in B-cell depletion.

NMOSD is a rare, severe autoimmune disease of the central nervous system that causes damage to the optic nerve, spinal cord, and brain stem. NMOSD affects approximately 15,000 people in the U.S. with the incidence higher for women than men and prevalence approximately 2- to 3-fold higher among Blacks and Asian populations. The applicant stated that aquaporin-4 antibodies are highly specific to NMOSD and AQP4 is expressed on astrocytes in the central nervous system (CNS). A subpopulation of CD19+ B cells produce AQP4 antibodies and these cells are increased in the blood of AQP4-seropositive individuals with NMOSD. By depleting a wide range of CD19+ B cells, UPLINZA reduces the risks of relapses or attacks in NMOSD patients.

Newness. UPLIXNA was designated as a Breakthrough Therapy and received Orphan Drug designation in February 2016 for the treatment of NMOSD. UPLIZNA received FDA approval on June 11, 2020 for the treatment of NMOSD in adult patients who are AQP4 antibody positive. The applicant has submitted a request for approval of a unique ICD-10-PCS procedure code; there are two nonspecific ICD-10-PCS codes that may be used for UPLINZA infusion. The applicant stated that the only approved treatments for NMOSD are UPLIZNA, Soliris, and

ENSPRING. CMS notes that ENSPRYNG and Soliris previously submitted applications for new technology add-on payments; Soliris was approved for a new technology add-on payment.

For the first criterion (same or similar mechanism of action), the applicant stated that UPLINZA is the only treatment for NMOSD that targets B-cells and causes B-cell depletion. The applicant discusses the differences between UPOLINZA and the other available treatments, Soliris and ENSPRYNG. For the second criterion (same or different MS-DRG), the applicant stated that cases with UPLIZNA map to the same MS-DRGs as existing treatments. For the third criterion (same or similar disease or patient population), the applicant stated that UPLIZNA treats the same patient population as existing treatments, but it offers a treatment option for a subset of this patient population. Specifically, the applicant stated that UPLINZA is not associated with an increased risk of meningitis and may be used for people who are unvaccinated and/or are not able to use prophylactic antibodies. The applicant acknowledged that unvaccinated patients with NMOSD can still receive the other available treatments, but they need to have prior treatment to reduce the risk of meningitis.

In the proposed rule, CMS was concerned that UPLIZNA does not treat a different subset of patients than existing treatments. ENSPRYNG is also not contraindicated in patients with unresolved serious *Neisseria meningitidis* infections and as previously discussed in the FY 2022 IPPS PPS final rule, CMS does not consider unvaccinated individuals as a separate patient population because the vaccine is widely available.

The applicant submitted a comment reiterating that UPLIZNA is the first and only B-cell depleting monotherapy approved for NMOSD in adult patients who are anti-aquaporin-4 antibody positive and discussed the special considerations for treating patients with rare diseases. CMS agrees that UPLINZA has a unique mechanism of action when compared to existing technologies but continues to believe that UPLIZNA does not represent a treatment option for a new population.

CMS concludes that UPLINZA meets the newness criterion and that the beginning of the newness period would be June 11, 2020, the date of FDA marketing authorization.

Cost. In the proposed rule, CMS summarized the analysis provided to demonstrate the technology meets the cost criterion. CMS concludes that UPLINZA meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that UPLINZA offers a treatment option for a patient population ineligible for current treatment which includes patients at an increased risk of meningitis, patients having trouble with the frequent dosing schedule for available treatments, and patient populations impacted by health disparities. The applicant also stated that UPLINZA significantly improves clinical outcomes compared to available treatments because it reduces the risk of NMOSD attacks. CMS discusses the information provided by the applicant which includes published studies, CDC recommendations related to complement inhibitors (Soliris is a complement inhibitor), and information related to Soliris.

In the proposed rule, CMS discussed several concerns with the information presented including the lack of information demonstrating improved outcomes for UPLINZA as compared to existing

treatments. CMS reiterated it does not believe that unvaccinated patients represent a distinct patient population and notes that ENSPRYNG does not requires patients with NMOSD to have a meningococcal vaccination. In addition, CMS was not sure that treatment regimen requirements identify a separate patient population ineligible for currently available treatments and noted that ENSPRYNG has a similar treatment schedule as UPLINZA. CMS was also concerned the information on the efficacy of UPLIZNA among African American with NMOSD is limited as the cited study only included 20 African Americans.

In response to CMS' concerns, the applicant and several commenters provided additional information. After reviewing this information, CMS continues to have concerns about UPLINZA meeting the substantial clinical improvement criterion. CMS is still unclear whether UPLINZA leads to improved relapse prevention, or other improved outcomes, as compared to other treatments for NMOSD. CMS notes the applicant did not provide data comparing outcomes with Soliris and UPLINZA. CMS agrees with the applicant that substantial clinical improvement can be determined without head-to-head trials and that it evaluates every application on its own data and merits to determine whether it meets the substantial clinical improvement criterion. After review of all the information, CMS is unable to determine that UPLINZA meets the substantial clinical improvement criterion and is not approving new technology add-on payments for UPLINZA for FY 2023.

7. FY 2023 Applications for New Technology Add-On Payments (Alternative Pathways)
Under the alternative pathway for new technology add-on payments, a technology will be considered new and not substantially similar to an existing technology and will also not need to meet the requirements that it represent a substantial clinical improvement over existing technologies.

Applications for new technology add-on payments, must have FDA market authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS final rule, CMS provided for conditional approval for a technology submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) that did not receive FDA marketing authorization by the July 1 deadline for the particular fiscal year for which the applicant applied for add-on payments.[39] Antimicrobial products that would otherwise meet the applicable add-on payment criteria would begin receiving the new technology add-on payment, effective for discharges the quarter after the date of FDA marketing authorization instead of waiting to re-apply for the next fiscal year, provided FDA marketing authorization is received by July 1 of the year for which the applicant applied for new technology add-on payments.

CMS received 19 applications for new technology add-on payments under the alternative pathway. Six applicants withdrew their applications, 11 of the technologies received a Breakthrough Device designation from FDA; one has a pending Breakthrough Device designation from FDA; and one has been designated as a QIDP and is also requesting approval under the LPAD pathway from FDA. Subsequently five applicants withdrew their applications. Two technologies, Phagenyx System and Nelli Seizure Monitoring System, did not meet the July

[39] 85 FR 58737 through 58742

1 deadline for FDA approval and therefore the technologies are not eligible for consideration for new technology add-on payments.

The summary below provides a high-level discussion of the remaining six applications, 5 technologies that received a Breakthrough Device designation from FDA and 1 that was designated as a QIDP by FDA. Readers are advised to review the final rule for more detailed information.

CMS approves five of these applications for new technology add-on payments for FY 2023:

- CERAMENT® G,
- GORE® TAG® Thoracic Branch Endoprosthesis (TBE device),
- iFuse Bedrock Granite Implant System,
- Thoraflex™ Hybrid Device, and
- ViviStim® Paired VNS System.

CMS grants a conditional approval for DefenCath™ for new technology add-on payments for FY 2023, subject to the technology receiving marketing authorization by July 1, 2023.

a. Alternative Pathway for Breakthrough Devices

(1) CERAMENT® G

BONESUPPORT Inc. submitted an application for CERAMENT G, a Breakthrough Device used as a bone-void filler as adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis.[40] The applicant anticipates FDA will grant its De Novo classification request before July 1, 2023. One ICD-10-PCS procedure codes is unique to CERAMENT G administration (XWOV0P7).

CMS agrees that CERAMENT G meets the cost criterion.

CERMENT G received FDA De Novo marketing authorization on May 17, 2022 with an indication for use as a bone void filter in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the surgical treatment of osteomyelitis in defects in the extremity (Breakthrough Device designation. The newness period will begin on May 17, 2022. Based on preliminary information provided by the applicant the cost of CERAMENT G is $7,567 per procedure. The maximum new technology add-on payment for a case involving the CERAMENT G is $4,918.55 for FY 2023.

(2) GORE® TAG® Thoracic Branch Endoprosthesis (TBE device)

W.L. Gore and Associates submitted an application for GORE TAG TBE device, a modular device consisting of three components: an Aortic, a Side Branch and an optional Aortic

[40] BONESUPPORT previously submitted an application for new technology add-on payments for CERAMENT G for FY 2022 (86 FR 25368 through 25373), but the technology did not meet the July 1, 2021 deadline for FDA approval or clearance and was not eligible for new technology add-on payments for FY 2022.

Extender. Each component is pre-mounted on a catheter delivery system for delivery from a distal access site over an aortic or branch artery guidewire. The GORE TAG TBE device is used for treating thoracic aortic aneurysms, traumatic aortic transection, and aortic dissection. A combination of two existing ICD-10-PCS procedure codes can be used to uniquely identify the GORE TAG TBE device (02VW4EZ and 02VX4EA).

The GORE TAG TBE device was granted designation under the Expediated Access Pathway (EAP) by FDA on July 17, 2015 for endovascular repair of descending thoracic aortic and aortic arch for patients who have appropriate anatomy; the EAP is considered part of the Breakthrough Devices Program by FDA.[41] The applicant anticipates receiving PMA approval of the device as a Class III Device from FDA in Spring 2022 with a proposed indication for endovascular repair of lesions of the descending thoracic aorta, while maintaining flow into the left subclavian artery, in patients who have adequate iliac/femoral access, and eligible proximal aorta, left subclavian or distal landing zones (isolated lesion patients only). Because the proposed PMA indication is included within the scope of the EAP designation, CMS believes that the proposed PMA indication is appropriate for new technology add-on payment under the alternative pathway criteria.

In the proposed rule, CMS summarized the analysis provided to demonstrate the technology meets the cost criterion. CMS noted the charges removed for the technology and other charges related to the prior technology are based on length of stay in a small study conducted at a single institution. CMS questioned if these results were generalizable to the cost analysis performed and to the greater Medicare population. CMS also noted the applicant did not specify the revenue codes used to identify and remove intensive care unit charges. In addition, CMS was concerned the applicant listed two ICD-10-PCS codes (03S43ZZ and 03SQ3ZZ) in their analysis which are percutaneous procedures and questioned whether these codes are appropriate as the device currently require open surgery. CMS also questioned whether the cases identified are appropriately representative of case eligible for treatment with CORE TAG TBE.

In response to CMS' concerns, the applicant provided comments and a revised cost analysis. Based on this additional information, CMS concludes the CORE TAG TBE meets the cost criterion.

The GORE TAG TBE received marketing authorization from FDA on May 13, 2022 for the indication covered by its Breakthrough Device designation. CMS approves the CORE TAG TBE for new technology add-on payments for FY 2023. The newness period will begin on May 13, 2022. Based on preliminary information provided by the applicant the cost of GORE TAG TBE device is $42,780. The maximum new technology add-on payment for a case involving the GORE TAG TBE device would be $27,807 for FY 2023.

(3) iFuse Bedrock Granite Implant System

SI-Bone submitted an application for the iFuse Bedrock Granite Implant System, a sterile, single-use permanent implant used in conjunction with commercially available pedicle screw fixation systems as a functional element for segmental spinal fusion. The iFuse Bedrock Granite

[41] https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.

Implant System received FDA Breakthrough Device designation on November 23, 2021 for sacropelvic fixation and as an adjunct for SI joint fusion (when used with commercially available SI joint fusion promoting devices) in conjunction with commercially available posterior pedicle screw system for the treatment of a wide range of the acute and chronic deformities of the thoracic, lumbar, and sacral spine (see the proposed rule for additional treatment indications). The applicant is seeking 510(k) clearance from FDA for the same indication.

CMS agrees with the applicant that iFuse Bedrock Granite Implant System meets the cost criterion.

The iFuse Bedrock Granite Implant System received marketing authorization from FDA on May 26, 2022 for the indication covered by the Breakthrough Device designation. CMS approves the iFuse Bedrock Granite Implant System for new technology add-on payments for FY 2023. The newness period will begin on May 26, 2022. Based on preliminary information from the applicant, the cost of the iFuse Bedrock Granite Implant System is $15,120. The maximum new technology add-on payment for a case involving the use of this technology would be $9,828 for FY 2023.

(4) Thoraflex™ Hybrid Device

Terumo Aortic submitted an application for the Thoraflex, a single use medical device combining a gelatin-sealed woven polyester graft with a Nitinol self-expanding stent graft for the surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta.[42] Thoraflex received Breakthrough Device designation March 20, 2020 for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection. Approval by the FDA as a PMA for a Class III device designation is pending. The procedure using this device is identified by two ICD-10-PCS codes (X2R0N7 and X2VW0N7).

CMS agrees that the Thoraflex Hybrid Device meets the cost criterion.

The Thoraflex Hybrid Device received FDA marketing authorization from FDA on April 19, 2022 for its Breakthrough Device designation. CMS approves the Throaflex Hybrid Device for new technology add-on payments for FY 2023. The newness period will begin on April 19, 2022. Based on preliminary information from the applicant, the cost of the Thoraflex Hybrid Device is $35,000. The maximum new technology add-on payment for a case involving the use of the technology will be $22,750 for FY 2023.

(5) ViviStim® Paired VNS System

Micro Transponder submitted an application for ViviStim Paired VNS System, a vagus nerve stimulation therapy intended to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients

[42] Terumo Aortic previously submitted an application for new technology add-on payments for the Thoraflex Hybrid System for FY 2022 (86 FR 25390) but the application was withdrawn prior to the issuance of the final rule.

with moderate to severe arm impairment. The ViviStim Paired VNS System is comprised of an Implantable Pulse Generator (IPG), an implantable stimulation Lead, and an external paired stimulation controller which is composed of the external Wireless Transmitter (WT) and the external Stroke Application and Programming Software (SAPS). The applicant stated the SAPS and WT enable the implanted components to stimulate the vagus nerve during rehabilitation.

The ViviStim Paired VNS System was designated as a Breakthrough Device on February 10, 2021 for use in stimulating the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment. The ViviStim Paired VNS System received FDA premarket approval on August 27, 2021 as a Class III implantable device for the Breakthrough Device designation. The applicant stated that the technology is not commercially available due to manufacturing delays. The applicant submitted a request to the ICD-10-PCS code to identify the insertion of this technology.

CMS agrees that the ViviStim Paired VNS System meets the cost criterion.

The applicant provided a comment stating that manufacturing delays prevented market availability of the device until April 29, 2022. CMS approves the ViviStim Paired VNS System for new technology add-on payments for FY 2023; the beginning of the newness period will be April 29, 2022. The applicant anticipated the total cost of the system to the hospital to be $36,000 per patient. The applicant stated this cost represents the entire per-patient cost of the system to the hospital, the cost of the Implantable Pulse Generator and stimulation lead. The maximum new technology add-on payment for a case involving the use of the technology will be $23,400 for FY 2023.

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

DefenCath™ (solution of taurolidine (13.5 mg/mL) and heparin (1000 USP Units/mL))

CorMedix submitted an application for DefenCath, a proprietary formulation of taurolidine and heparin used as a catheter lock solution to reduce the risk of catheter-related bloodstream infections (CRBSI) from in-dwelling catheters in patients undergoing hemodialysis (HD) through a central venous catheter (CVC). The applicant stated that *in vitro* studies of DefenCath indicate broad antimicrobial activity against gram-positive and gram-negative bacteria, including mycobacteria and clinically relevant fungi. DefenCath was designated as a QIDP in 2015 for the prevention of CRBSI in patients with end-stage renal disease receiving HD through an CVC and granted FDA Fast Track status. The applicant stated it received Priority Review under FDA's LAPD for the same indication and the applicant anticipates approval before July 1, 2022.

CMS agrees that the DefenCath meets the cost criterion.

In the proposed rule, CMS noted that DefenCath was eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by the July 1 deadline, provided the technology receives FDA marketing authorization by July 1, 2023. The applicant did not provide an estimate for the cost of DefenCath and expects to provide this

information before the final rule.

In a comment, the applicant requested that CMS correct the expected date of FDA approval; the FDA approval date is expected later in the third quarter of 2022, rather than by July 1, 2022, the date stated in the proposed rule. The applicant also provided the anticipated cost of DefenCath is $5,850 per patient.

Based on the information provided by the applicant, CMS grants conditional approval for DefenCath for new technology add-on payments for FY 2023, subject to the technology receiving FDA marketing authorization by July 1, 2023. If FDA marketing authorization is received on or after July 1, 2023, no new technology add-on payments will be made for cases involving the use of DefenCath for FY 2023. Subject to the DefenCath receiving market authorization by July 1, 2023, the maximum new technology add-on payment for a case involving the DefenCath will be $4,387.50 for FY 2023 (75% of the average cost of the technology).

8. Use of National Drug Codes (NDC) to Identify Cases Involving Use of Therapeutic Agents Approved for New Technology Add-on Payment

CMS established the Section "X" New Technology codes to more specifically identify new technologies or procedures that had not historically been captured through ICD-9-CM codes, or to more precisely describe information on a specific procedure or technology than is found in the ICD-10-PCS section.[43] In the proposed rule, CMS reviewed the comments it has received from stakeholders, including representatives from hospital associations, software vendors, professional societies, and coding professional opposing the ICD-10 Section X codes for the purpose of administering the new technology add-on payment for drugs and biologics. CMS also discussed the burden associated by applicants seeking a unique "X" code and the resources required by CMS to work with applicants, prepare for the ICD-10 Coordination and Maintenance Committee meetings, provide public summarizes, and make a final decision about the code request.

CMS has used NDCs as an alternative code set when an ICD-10-PCS code was not available to uniquely identify the use of the technology. Specifically, CMS used the NDC code set to identify eligible cases for DIFICID and VABOMERE for new technology add-on payments. In addition, cases involving the use of therapeutic agents that qualify for NCTAP, which is administered similarly to the new technology add-on payment, are identified using the NCDs for these products.

CMS proposed the following policies for the use of NDCs:

- Beginning with discharges on or after October 1, 2022 (FY 2023), CMS proposed a transitional period during which the administration of therapeutic agents newly approved for new technology add-on payments would be uniquely identified using either their respective NDC(s) or ICD-10-PCS procedure codes, in combination with ICD-10-CM codes when appropriate. When necessary, CMS may require the use of additional ICD-10-PCS procedure and/or ICD-10 diagnosis codes to uniquely identify cases using these

[43] 80 FR 49434 through 49435

technologies. CMS would continue the use of existing ICD-10-PCS procedure codes to identify the administration of therapeutic agents previously approved for new technology add-on payments and that remain eligible for add-on payment for FY 2023.

- Beginning with discharges on or after October 1, 2023 (FY2024), CMS proposed the administration of therapeutic agents newly approved for new technology add-on payments beginning FY 2024 or a subsequent year would be uniquely identified only by their respective NDC(s), along with the corresponding existing ICD-10 codes required to uniquely identify the therapeutic agents, when necessary, to make the new technology add-on payments.

This proposal did not include therapeutic agents that are not assigned an NDC by FDA (e.g., blood, blood products) and are approved for new technology add-on payment; these technologies would continue to be identified based on the assigned ICD-10-PCS procedure code. In addition, a unique ICD-10-PCS procedure code would be needed to identify the use of CAR T-cell and other immunotherapies that may be assigned to Pre-MDC MS-DRG 018 because the GROUPER logic for assignment to this MS-DRG is comprised of the procedure codes describing these technologies.

A few commenters were supportive of this proposal; some suggested that if CMS finalized this policy it would need to establish a process to educate hospitals to ensure they are prepared. Some commenters discussed concerns that the proposed use of NDCs may impose new administrative burdens to hospital and indicated that the hospital pharmacy and billing IT systems may not have existing automated systems and might need to manual process claims to report NDCs. Commenters requested CMS provide additional information in rulemaking about the specific requirements for operationalizing this policy including whether changes would be needed on the claim form. Commenters also stressed that this proposal could be difficult to implement due to staffing shortages due to the COVID-19 pandemic.

After consideration of the comments, CMS is not finalizing this proposed policy. CMS needs time to evaluate and consider the issues raised by commenters and reassess this proposal in future rulemaking.

9. Proposal to Publicly Post New Technology Add-on Payment Applications

In the proposed rule, CMS discussed the information it summarizes for each new technology add-on payment application in the proposed rule. CMS tries to ensure that sufficient information is provided to facilitate public comments on whether the medical service or technology meets the new technology add-on payment criteria. CMS noted that it generally does not take into consideration information that is marked as confidential when determining the new technology add-on payment decision.

CMS has received requests from the public to access and review new technology add-on payment applications to facilitate comment on whether the new technology add-on payment criteria are met. CMS believes that public posting the applications and certain related materials online may help foster additional comments on these applications. CMS also believes that

posting the applications online, reduces the risk that CMS may have inadvertently omit or misrepresentative relevant information from summaries in the rules. As the number and complexities of the applications has increased, this process would also streamline CMS' evaluation process.[44]

Beginning with the FY 2024 application cycle, CMS proposed to post online the completed application forms and certain related materials (e.g., attachments and uploaded supportive materials) it receives from applicants. CMS also proposed to post information acquired subsequent to the application submission such as comments received after the New Technology Town Hall, updated application information, and additional clinical studies. CMS proposed it would not post cost and volume information or any material that the applicant indicates is not releasable to the public because the applicant did not own the copyright or the applicant did not have the appropriate license to make the material available to the public.

For copyrighted material, CMS proposed that on the application form, the applicant would be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public with the exception of materials by the applicant as not releasable to the public. For material included in the application that is not releasable to the public, CMS proposed that the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public. CMS planned to post this information online, along with the other posted application material.

CMS would continue its current practice to include in the proposed rule cost information when available from the applicant for use in proposing a maximum add-on payment amount and in the final rule, cost and volume information related to the maximum add-on payment amount. CMS would not include the cost and volume information for either the traditional or alternative pathway applications as part of the application materials that would be posted online.

Currently, applicants may include information marked as proprietary or trade secret information along with its new technology add-on payment application. The current application specifies that data provided by the applicant may be subject to disclosure and instructs the applicant to mark any proprietary or trade secret information so that CMS can attempt, to the extent allowed under Federal law, to keep the information protected from public view. CMS would change this instruction under its proposal to indicate that except for cost and volume information, all submitted information would be posted online.

CMS noted this proposal would not change the timeline or evaluation process for new technology add-on payments. CMS also did not expect added burdens on prospective applicants since it did not propose to fundamentally change the information collected in the application. CMS expected to make changes in the summaries that appear in the annual proposed and final rule. CMS would continue to provide sufficient information in the rules to facilitate public comments on whether a medical service or technology meets the new technology add-on payment criteria. CMS expected it would include at a high level the following information in the proposed and final rule: the technology and applicant name; a description of the technology;

[44] This proposal would also streamline the effort required from anyone summarizing these applications.

background on the disease; FDA approval/clearance status; and a summary of the applicant's assertions. CMS also expected to provide a more succinct summary regarding the applicant's assertions of how the medical service or technology meets the criteria. CMS would continue to provide discussion of concerns or issues for applications submitted under the traditional pathway. For the alternative pathway application, CMS would continue to note any concerns and as applicable, the maximum add-on payment amount, where cost information is available. In the final rule, CMS would continue to explain its decision and for approved technologies, the final add-on payment amount.

CMS states that overall commenters were supportive of this proposal. Commenters were supportive of the proposal not to include cost and volume information, but were concerned about proposals related to confidential, commercially sensitive information. Some commenters requested CMS bifurcate the application to allow a section for information that would not be posted online. Other commenters requested CMS continue the practice of allowing the applicant to mark information that was confidential such as sensitive or trade secret information. Commenters acknowledged that CMS does not generally consider confidential or proprietary information but believed that there are circumstances where the information would contribute to CMS' understanding and decision. Commenters stated if the entire application was posted online, applicants may refrain from submitting important information to support the new technology add-on payment criteria.

In response to these comments, CMS will provide a mechanism for applicants to submit confidential information, including proprietary or trade secret information, that will not be posted online. CMS emphasizes that it will be the applicant's responsibility to put confidential information in the designated areas of the application. CMS notes that it has occasionally received applications that were entirely marked as proprietary or confidential. It reiterates that it generally will not be able to consider this information when determining whether a technology meets the criteria for new technology add-on payments. CMS notes its process provides for public input which requires providing information for public review and comment.

For copyrighted material, CMS will finalize its proposal that on the application form, the applicant will be asked to provide a representation that the applicant owns the copyright or otherwise has the appropriate license to make all the copyrighted material included with its application public with the exception of materials by the applicant as not releasable to the public. For material included in the application that is not releasable to the public, the applicant must either provide a link to where the material can be accessed or provide an abstract or summary of the material that CMS can make public.

After considering comments, beginning with FY 2024 application cycle, CMS finalizes with modifications its proposal to publicly post online new technology add-on payment applications, and any additional forms, certain related information, and any additional updated application information submitted subsequent to the initial application (except certain volume, cost and other information identified by the applicant as confidential). CMS will not publicly post cost and volume information but it will continue to summarize and discuss certain cost and volume information for the proposed rule. CMS clarifies that it will post the material at the time of the proposed rule and no sooner, and that it will not post applications that are withdrawn prior to the

publication of the proposed rule.

CMS finalizes the following modifications:

- CMS will provide a mechanism for applicants to submit confidential information that would not be posted online, such as in a separate section or by identifying particular questions that would not have answers publicly posted.
- CMS may post the application and all supporting information, except for information included in a confidential information of the application, cost and volume information, and materials identified by the applicant as copyrighted and/or not otherwise releasable to the public.

Regulatory Impact Analysis
For FY 2023, CMS finalizes continuing the new technology add-on payment for 15 technologies. Based on the information provided by the applicants, CMS estimates the aggregated total FY 2023 payments for these new technology add-on payments would be approximately $620 billion dollars.

CMS approves six alternative pathway applications for FY 2023 new technology add-on payments. Based on information from the applicants, CMS estimates that the total payment for these technologies would be approximately $82 million for FY 2023.

CMS approves four applications under the traditional pathway for FY 2023 new technology add-on payments. Based on information from the applicants, CMS estimates that the total payment for these technologies would be approximately $75 million for FY 2023.

FY 2023 Estimates for New Technology Add-On Payments for FY 2023	
Category	**Estimated Total FY 2023 Impact**
Continuing New Technology Add-on Payments	$619,943,190.45
Alternative Pathway Applications	$88,454,632.50
Traditional Pathway Applications	$75,161,627.94
Aggregate Estimated Total FY 2023 Impact	**$784,559,450.89**

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 wage index. 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. All changes made to the wage index annually are required to be budget neutral.

A. Labor Market Areas

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) Core-Based Statistical Areas (CBSAs) delineations as labor market areas. CMS is currently using OMB delineations from 2015 (based on the 2010 census) updated by OMB Bulletin numbers 13-01, 15-01, 17-01, 18-04 and 20-01.

B. Worksheet S-3 Wage Data

The final rule wage index values are based on data from FY 2019 submitted cost reports. CMS did not propose any changes to the categories of included and excluded costs for FY 2023 relative to prior years. CMS' final rule calculations of the FY 2023 wage index are based on wage data of 3,136 hospitals. The data file used to construct the final wage index includes FY 2019 data submitted to CMS as of June 30, 2022.

Hospitals with cost report begin dates during FY 2019[45] may have cost reporting periods that include the COVID-19 pandemic. However, CMS reports that the COVID-19 pandemic appears to have minimal impact on the wage data used for the FY 2023 rule wage index. One commenter stated that CMS did not provide information to review CMS' conclusion that the FY 2019 wage data was unaffected by the pandemic. The commenter asked CMS to share more information as the cost of staffing has increased substantially in the past two years.

In response, CMS provided an analysis showing a minority of hospitals had FY 2019 cost reports that overlapped the period of the pandemic. And for the majority of these hospitals, only 1/3 of the cost reporting period occurs during the pandemic months of March 1 through September 30, 2020. CMS observed that changes in hospital average hourly wages were consistent between providers with cost reporting periods ending during the PHE as those with cost reporting periods ending before the PHE. The final rule refers the commenter back to its wage index average hourly wage tables for more information. CMS will continue to analyze the impact of the COVID-PHE on the wage index in future years as it uses more cost report data that will coincide with the period of the pandemic.

General wage index policies are unchanged from prior years. CMS notes that it proposed to exclude 86 providers due to aberrant wage data that failed edits for accuracy. For the final FY 2023 wage index, CMS restored the data of 23 hospitals because their data was either verified or improved. Sixty-three hospitals with aberrant data remain excluded from the FY 2023 wage index.

Commenters opposed excluding accurate and verified data stating that section 1886(d)(3)(E) of the Act does not provide the authority for CMS to delete accurately-reported wage data, and doing so is arbitrary and capricious. CMS previously responded to this comment and believes it does have the authority under section 1886(d)(3)(E) of the Act to exclude aberrant hospital data

[45] Any cost reporting period with a begin date between October 1, 2018 through September 30, 2019 would be an FY 2019 cost report. Therefore, any 12-month cost reporting period beginning on or after April 1, 2019 would overlap the pandemic.

from the wage index to help ensure that the costs attributable to wages and wage-related costs reflect the relative hospital wage level in the hospitals' geographic area.

There were also comments requesting CMS use more timely data to set the wage index, consider using alternate data sources and apply an inflation factor to reflect the increase in wages occurring since 2019. CMS responds that it is using the most recent audited surveys and data to develop the FY 2023 wage index. Use of any later data would not be audited. CMS is unclear which alternate data sources the commenters suggest CMS use. CMS states that any kind of inflation adjustment to the wage data would be made across-the-board and would not change the wage index as it is a relative measure of average hourly wages.

C. Method for Computing the Unadjusted Wage Index

For the FY 2023 wage index, CMS did not propose any changes to the steps for computing the unadjusted wage index. The final rule includes a detailed listing of these steps. CMS calculates an unadjusted national average hourly wage of $47.79 for FY 2023.

D. 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 2019 is used for the occupational mix adjustment applied to the FY 2022 through FY 2024 IPPS wage indexes.

CMS reports having occupational mix data for 97 percent of hospitals (3,035 of 3,136) used to determine the FY 2023 final rule wage index. The FY 2023 national average hourly wage, adjusted for occupational mix, is $47.71.

E. Analysis of the Occupational Mix Adjustment

CMS compares the impact of using the 2019 occupational mix survey to not using it. These results indicate that the occupational mix adjustment changes the average hourly wage by less 1 percent for nearly 50 percent of urban areas and 57.5 percent of rural areas.

F. Geographic Reclassifications

Geographic reclassification is 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 (15 miles for urban hospitals and 35 miles for rural hospitals) and have wages that are different than its own area and comparable to the wages of the requested area:

- Urban Hospitals: Average hourly wage that is at least 108 percent of other hospitals in its geographic area and 84 percent of the requested area.
- Rural Hospitals: Average hourly wage that is at least 106 percent of other hospitals in its own geographic area and 82 percent of the requested area.

The Medicare Geographic Classification Review Board (MGCRB) decides whether hospitals meet the criteria for reclassification. Geographic reclassifications are effective for 3 years but may be temporarily withdrawn or terminated. If a hospital accepts a new MGCRB reclassification, any prior ones are permanently terminated.

Under a separate process that does not involve the MGCRB, hospitals that meet specific criteria in statute may request that a CMS Regional Office treat an urban hospital as rural for purposes of IPPS payment. Unlike MGCRB reclassifications that are effective on the basis of a fiscal year, urban to rural reclassifications are effective upon the date the application was submitted to the CMS Regional Office.

Under the statute, hospitals that reclassify from urban to rural are treated as rural for all IPPS purposes. Such hospitals may apply for geographic reclassification under the MGCRB process using the more favorable rural reclassification rules. For an urban hospital that has reclassified as rural, the 106 percent criterion is applied to other rural hospitals within the same state, not to other hospitals in the area where the hospital is geographically located. This policy applies for the first time for geographic reclassifications applications to the MGCRB due September 1, 2021 effective October 1, 2022. CMS adopted this policy in response to adverse litigation against the agency in *Bates County Memorial Hospital v. Azar*.

Geographic Reclassifications. There are 383 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2023. There are 311 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2021 that will continue for FY 2023. There are 315 hospitals approved for wage index reclassification in FY 2022 that may continue for FY 2023. CMS indicates that there will be 1,009 hospitals in MGCRB reclassification status for FY 2023 (with 166 of these hospitals reclassified back to their home area).

The deadline for withdrawing or terminating a wage index reclassification for FY 2023 approved by the MGCRB is June 24, 2022 (45 days from publication of the FY 2023 proposed rule in the *Federal Register*). Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process are incorporated into the final FY 2023 wage index values. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, CMS refers readers to 42 CFR §412.273. Applications for FY 2024 reclassifications are due to the MGCRB by September 1, 2022 which is also the deadline for canceling a previous wage index reclassification withdrawal or termination.

One commenter requested that CMS allow an additional 45-day period after the final rule is published to make determinations on MGCRB withdrawals and terminations. The commenter cited the uncertainties for the FY 2023 wage index based on the proposed rule as CMS did not indicate how it planned to respond to two adverse Court decisions against CMS decided shortly before the proposed rule (*Citrus* and *Bridgeport* discussed below). *Citrus* concerned whether CMS would include an urban to rural reclassification in calculating the rural floor wage index while *Bridgeport* concerned CMS' low wage index policy.

CMS declined to provide this additional 45-day period to make withdrawal/termination determinations after the publication of the final rule indicating that the proposed rule provided sufficient information to make these determinations. For the rural floor, CMS indicates that there are only 8 states with a difference between the state rural floor (calculated without the urban to rural reclassified hospitals) and state rural wage index (calculated with the urban to rural reclassified hospitals) and the difference in these states is minimal variance. Further, if CMS were to allow an additional time period to withdraw or terminate reclassifications after the final rule, CMS would be unable to recalculate IPPS rate to maintain budget neutrality as required by law.

One commenter asked that CMS require the MGCRB not to issue determinations before February 1 as occurred in 2022 because this did not give hospitals sufficient time to provide supporting documentation or submit a request to withdraw a reclassification application based on posting of January wage index information. CMS disagreed indicating that hospitals have the option of submitting all supporting documentation with their reclassification application and may withdraw a reclassification at any time.

Method for Withdrawing, Terminating or Canceling a Previous Withdrawal or Termination of a 3-Year Geographic Reclassification. While 42 CFR §412.273 specifies the timing for withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification, it does not specify a method of submission. This issue has been a source of confusion for some hospitals.

CMS proposed to revise the regulations to specify that requests to withdraw an application or terminate an approved reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB. This provision of regulation parallels language for how initial applications are submitted to the MGCRB as clarified in the FY 2022 IPPS rule. One commenter supported CMS' proposal that it is finalizing without change.

Lugar Hospitals and Counties. A "Lugar" county is a rural county adjacent to one or more urban areas that is deemed to be part of the urban area where the highest number of its workers commute. A Lugar hospital is a hospital located in a Lugar County. A Lugar hospital is treated as reclassified to the urban area where the highest number of its county workers commute. This process is automatic and will occur with no action on the part of the hospital.

The outmigration 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. A hospital can either have a Lugar reclassification or receive the outmigration adjustment but not both. As a Lugar reclassification occurs automatically, a Lugar hospital must decline its reclassification using the same process as other hospitals to receive the outmigration adjustment (e.g., notify CMS within 45 days of proposed rule publication that it is declining its Lugar reclassification).

CMS restates the following policies with respect to how Lugar hospitals may decline their urban status to receive the outmigration adjustment:

- Waiving deemed urban status results in the Lugar hospital being treated as rural for all IPPS purposes.
- Waiving deemed urban status can be done once for the 3-year period that the outmigration adjustment is effective.
- If a Lugar hospital waives its reclassification for 3 years, it must notify CMS to reinstate its Lugar status within 45 days of the IPPS proposed rule publication for the following fiscal year.
- In some circumstances, a Lugar hospital may decline its urban reclassification to receive an outmigration adjustment that it would no longer qualify for once it is reclassified as rural. In these circumstances, CMS will decline the Lugar hospital's request to waive its urban reclassification and continue to assign it a higher urban wage index (which itself could result in the county requalifying for the outmigration adjustment based on data in the final rule).

CMS did not receive any comments on these issues. It is continuing its Lugar policies without change.

G. Outmigration Adjustment

CMS proposed to apply the same policies for the FY 2023 outmigration adjustment that it has been using since FY 2012. There were no public comments on the issue and CMS is continuing its outmigration policies without change. CMS estimates the outmigration adjustment will increase IPPS payments by $53 million to 210 hospitals in FY 2023. This provision is not budget neutral.

H. Urban to Rural Reclassification

As noted earlier, 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.

In prior rulemaking, CMS stated that urban to rural reclassifications apply to the entire hospital (that is, the main campus and its remote location(s)). Further, a main campus of a hospital cannot obtain status as an SCH, RRC, MDH, or rural independently or separately from its remote location(s), and vice versa. However, some urban hospitals operate one or more remote location(s) in a state's rural area. In light of this scenario, CMS clarified in the proposed rule that urban to rural reclassification applies to the main campus and any remote location located in an urban area (or deemed to be located in an urban), not to a remote location in a rural area as it cannot qualify for urban to rural reclassification under section 1886(d)(8)(E) of the Act.

The proposed rule indicated that CMS has not consistently reflected urban to rural reclassification status in Table 2 of the annual IPPS/LTCH PPS rulemaking for remote locations of hospitals that are located in a different CBSA than the main campus. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS' longstanding policy to assign that remote location a wage index based on its own geographic area. These hospitals also allocate wages and hours for the calculation of the wage index based on the number of FTEs at each location. In calculating wage index values, CMS identifies the allocated wage data for these remote locations in Table 2 with a "B" in the 3rd position of the hospital's CMS claim number (CCN). CMS only found one such hospital for the FY 2023 wage index.

In the circumstance described above, not all locations of a multicampus hospital will receive the same wage index. However, if a multicampus hospital applies for urban to rural reclassification, all of its urban campuses will be reclassified as rural and receive the same rural wage index. If the hospital then applies and is approved for an MGCRB reclassification, all campuses of the multicampus hospital will be reclassified and receive the same wage index. If the hospital then cancels the MGCRB reclassification, each of its campuses will then be paid the rural wage index for the state in which it is located. Even though there is only one hospital that CMS found with a "B" in the 3rd position of the CCN, CMS urges multicampus hospitals to consider the impact of canceling an MGCRB reclassification in combination with the wage index that it will be paid as a result of an urban to rural reclassification on all of its campuses. CMS received one comment supportive of these clarifications and this policy will continue unchanged.

I. Rural, Imputed, and Frontier Floors and Low Wage Index Hospital Policy

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 final rule FY 2023 wage index for 275 urban hospitals requiring a budget neutrality adjustment factor of 0.991909 (-0.81 percent) applied to hospital wage indexes.

CMS proposed to continue a policy adopted in FY 2020 to exclude the wage data of a hospital that is reclassifying from urban to rural in calculating the rural floor for a state. Such a hospital's wage data was used to calculate the rural wage index but not the rural floor wage index that applies to hospitals that are not treated as rural for IPPS payment purposes beginning with the FY 2020 wage index.

Section 1886(d)(8)(C)(iii) of the Act also precludes an urban to rural reclassification from reducing the wage index for the county where the reclassifying hospital is located from declining below the wage index for the rural area of the state. CMS also has not considered these urban to rural reclassified hospitals' effect on the wage index for applying section 1886(d)(8)(C)(iii) of the Act—e.g., the comparison of the county wage index where the hospital is geographically located and reclassifying as rural will be to the rural area wage index exclusive of the urban to rural reclassifying hospital's wage data. CMS also proposed to continue this policy for FY 2023.

There are also other provisions of statute that either automatically reclassify hospitals from a rural area to an urban area ("Lugar" hospitals) or the hospital can apply for geographic

reclassification to the MGCRB. Once a hospital reclassifies as urban to rural, it is then permitted by statute to reclassify under the MGCRB rules to another area using the more permissive rural reclassification rules.

Under section 1886(d)(8)(C)(ii) of the Act, a reclassification out of a rural area cannot result in a reduction to the rural area's wage index. The reclassifying rural hospital's wage data is included in calculating the rural area wage index if excluding it will reduce the average hourly wage for the rural area. This policy applies when a hospital has a Lugar or MGCRB reclassification out of the rural area but does not apply when an urban hospital reclassifies into the rural and then has an MGCRB reclassification out of the rural area.

CMS' policy of excluding urban to rural reclassifications from the rural floor calculation has been the subject of pending litigation. On April 8, 2022 the DC District Court (*Citrus vs. Becerra*) found that the Secretary did not have authority under section 4410(a) of the Balanced Budget Act of 1997 to establish a rural floor lower than the rural wage index for a state. This case was decided shortly before CMS released the FY 2023 proposed rule. In the FY 2023 IPPS proposed rule, CMS indicated that it would continue to evaluate the Court's decision. CMS proposed to continue the policy for FY 2023 but said it may take a different approach in the final rule, depending on public comments or developments in the court proceedings.

There were public comments supportive of CMS' policy to exclude the wage data from an urban to rural reclassification from raising the rural floor wage index. These comments stated CMS' policy precludes "manipulating the wage index…to artificially inflate the wage indexes of hospitals in the state at the expense of all other states." Others urged CMS to acquiesce to the district court's decision in Citrus reiterating the Court's finding that CMS' policy is contrary to law. Other commenters requested that CMS apply the same policy when an urban hospital reclassifies as rural and then reclassifies out of the rural area as hospitals that are geographically rural that reclassify out of the rural area—e.g., include the hospital's average hourly wage in the rural area wage index calculation unless doing so will lower the rural wage index. These commenters believe such a policy could reduce the potential for wage index manipulation.

Following its review of the Citrus decision and the public comments, CMS is not finalizing its proposal for FY 2023—CMS will calculate a rural floor wage index including the hospitals that reclassified from urban to rural and have no additional form of reclassification (MGCRB) in the calculation of the rural floor. CMS will also calculate the wage index under section 1886(d)(8)(C)(iii) of the Act inclusive of the urban to rural reclassified hospital—e.g., the wage index from the county from which a hospital reclassifies as urban to rural will be compared to the rural floor wage index inclusive of the urban to rural reclassified hospital and may be no lower than that wage index.

CMS is not changing the other aspect of the rural floor wage index calculation requested by the commenters—it will continue to exclude a dual MGCRB and urban to rural reclassified hospital's wage data from the rural floor wage index calculation when the hospital reclassifies out of the rural area. The final rule reiterates a response from an April 21, 2016 IFC (81 FR 23428 through 23438) that when a hospital has a dual reclassification, CMS believes the MGCRB reclassification would control for the wage index calculation and to determine a

hospital's payment as an urban to rural reclassification can be for other purposes (such as DSH or to become an SCH or MDH.

CMS further provides an example for how such a policy could be used to manipulate the wage index disagreeing with the commenter's assertion that such a policy would diminish opportunities for wage index manipulation. Finally, CMS believes that such a policy would be a major change that it did not propose. Absent a proposal where the policy would be subject to universal public comment, CMS is declining to the adopt such as a policy in the FY 2023 final rule.

Imputed Floor. The rural floor does not apply in all urban states as there is no rural wage index to serve as the floor. CMS adopted an imputed floor for all urban states beginning in FY 2005. The original methodology for computing the imputed floor benefited only New Jersey hospitals. Beginning in FY 2013, CMS adopted an alternative methodology for hospitals in other all urban states (Delaware and Rhode Island). CMS applied the imputed floor in a budget neutral manner necessitating a reduction in payment to all hospitals to offset its cost. CMS allowed the imputed floor—both the original and alternative methodologies—to expire after FY 2018.

The imputed floor was reestablished by section 9831 of the American Rescue Plan Act (ARPA) enacted by Congress on March 11, 2021. However, the imputed floor provision was enacted with an exemption from IPPS budget neutrality obviating the need for a reduction in payment to all hospitals to offset its cost. In addition, the ARPA provision will apply in Washington DC, Puerto Rico and in states that have rural areas but no hospitals that are being paid using a rural wage index (only hospitals in Connecticut meet this last criterion). CMS estimates the imputed floor will increase payment to 66 hospitals by $124 million.

There were public comments both supporting and opposing the imputed floor with the opposing comment acknowledging that it is a provision of law. CMS is implementing the imputed floor consistent with the statute.

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 44 hospitals will receive the frontier floor value of 1.0000 for FY 2022. As all hospitals in Nevada have a wage index of over 1.0, the provision will have no effect on Nevada hospitals. This provision is not budget neutral, and CMS estimates an increase of approximately $71 million in IPPS operating payments due to the frontier floor.

Low Wage Index Hospital Policy. CMS proposed to continue the policy to increase wage indexes below the 25th percentile by one-half the difference between the hospital's otherwise applicable wage index and the 25th percentile wage index value for FY 2023. For FY 2023, CMS proposed a 25th percentile wage index value across all hospitals of 0.8401. CMS proposed to apply a budget neutrality adjustment of -0.18 percent for this policy.

This policy has been the subject of pending litigation. On March 2, 2022 the DC District Court (*Bridgeport Hospital vs. Becerra*) found that the Secretary did not have authority under section 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy and ordered additional

briefing on the appropriate remedy. In the proposed rule, CMS said it is continuing to evaluate the court's decision which is subject to appeal. Although CMS proposed to continue this policy for FY 2023, it said it may take a different approach in the final rule, depending on public comments or developments in the court proceedings.

Public commenters both supported and opposed CMS' low-wage index policy making comments that were largely consistent with those made in prior years. Commenters supporting the policy indicated that hospitals are using the revenues from a higher wage index to raise compensation consistent with the policy's intent. However, they indicated the policy need to stay in place longer as the growth in the national average hourly wage continues to be higher than growth in compensation that these low-wage hospitals can pay to their workers.

Other commenters requested that CMS not implement the policy budget neutral with one commenter suggesting that low-wage hospitals should be exempt from the budget neutrality adjustments as it reduces payments more than it increases them for hospitals with a wage index between the 22nd and 25th percentile. There were a variety of suggestions for other ways to apply budget neutrality—some of which CMS considered and rejected when proposing this policy three years ago.

Opponents of the policy reiterated prior year arguments that CMS' does not have authority under section 1886(d)(3)(E) of the Act to establish a wage index that is inconsistent with the relative differences in labor costs that results from CMS' wage survey.

CMS' responses largely refer back to prior responses on these same comments from earlier rules on issues like budget neutrality and whether there is authority in the statute for the policy it has now been applying for three years. The final rule acknowledges that public commenters are using additional revenues from a higher wage index to raise worker compensation consistent with the intent of the policy. With respect to the Bridgeport case, CMS disagrees with the district court's conclusion and emphasizes that the decision remains subject to appeal and only applies to FY 2020.

After consideration of the comments, CMS is finalizing its low-wage index policy as proposed and will continue to apply budget neutrality for FY 2023 as it has done in past years. The 25th percentile wage index for FY 2023 is 0.8427 and CMS is adopting a budget neutrality adjustment of -0.19 percent

J. Wage Index Tables

Final rule wage index tables 2, 3 and 4 can be found at: Select #2 under FY 2023 Final Rule Tables.

K. Process for Wage Index Data Corrections

CMS has a long-established multistep, 15+ month process for 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 including all of the public use files made available during the wage index development process. All deadlines are eastern standard time. For the FY 2023 wage index timetable go to: https://www.cms.gov/files/document/fy2023-wi-time-table.pdf.

L. 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 a hospital than using the national labor-related share. Application of the 62 percent labor-related share is not subject to wage index budget neutrality.

CMS updates the labor-related share every 4 years. The labor-related share was last updated for FY 2022. CMS is currently using a national labor-related share of 67.6 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 of 67.6 percent. Consistent with the statute, CMS is not applying budget neutrality when using the lower 62 percent labor share when a hospital has a wage index less than 1.0.

There were some comments requesting that CMS rebase the labor share to account for the increase in labor costs that have occurred since the last rebasing in FY 2022 based on 2018 Medicare cost reports. Some of these comments said the rebasing should be based only on those hospitals with a wage index greater than 1.0 as other hospitals receive a labor share of 62 percent and the growth in labor costs has been higher in high wage areas than low wage areas.

CMS responded that it reviewed the most recent Medicare cost report data available for IPPS hospitals submitted as of March 2022. These data showed slight decreases in the compensation cost weight of approximately 1 percentage point less than the 2018-based IPPS market basket cost weight. If CMS rebased the labor share based on these data, the labor share would be lowered, not increased as requested by the commenter.

CMS plans to review the 2021 Medicare cost report data as soon as complete information is available and evaluate these data for future rulemaking. After consideration of the public comments, CMS is finalizing use of a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2022 for all hospitals with wage indexes greater than 1.0.

M. Permanent Cap on Wage Index Decreases

In recent years, CMS has adopted a 5 percent cap on reductions to a hospital's wage index in response to various policy changes (i.e., CMS' low wage index policy adopted beginning in FY 2020 and the adoption of revised OMB CBSA delineations in FY 2021). CMS applied a budget neutrality adjustment to the standardized amount to ensure the 5 percent cap did not result in an increase in IPPS payments. The 5 percent cap on wage index reduction was adopted ad hoc in response to specific wage index changes and not as a permanent policy.

In response to a comment solicitation in the FY 2022 IPPS/LTCH PPS proposed rule, commenters recommended CMS consider making a maximum 5 percent annual reduction to the wage index permanent. While CMS did not adopt such a suggestion for FY 2022, it recognizes significant year-to-year fluctuations in an area's wage index can occur due to external factors beyond a hospital's control that are difficult to predict. CMS indicates that predictability in Medicare payments is important to enable hospitals to budget and plan their operations. For these reasons, CMS proposed a 5 percent cap on annual reductions to hospital wage indexes effective for FY 2023.

CMS believes a 5 percent cap balances between payment stability and maintaining a smaller budget neutrality adjustment. The proposed rule indicated typical year-to-year variation in the wage index has historically been within 5 percent. Therefore, the cap would effectively mitigate instability in IPPS payments enabling hospitals to more effectively budget and plan their operations while maintaining relativity of the wage index.

The proposed rule indicated the policy would likely apply equally to all hospitals in the same labor market area, as the hospital average hourly wage data in the CBSA (and any relative decreases compared to the national average hourly wage) would be similar. While in certain circumstances this policy may result in some hospitals in a CBSA receiving a higher wage index than others in the same area, CMS believes the impact would be temporary.

Other aspects of the policy are:

- The capped wage index would be the basis for applying the 5 percent cap for the subsequent year (e.g., if the wage index were 1.00, the capped reduction would be 0.95 and any reduction for the following year would be capped at 95 percent of 0.95).
- The basis for the cap would be the final wage index applicable to the hospital on the last day of the prior fiscal year as listed in Table 2 of the IPPS rule for the prior fiscal year (except as noted below for hospitals with an urban to rural reclassification approved mid-year and newly opened hospitals).
- For a hospital obtaining an urban to rural reclassification outside of the MGCRB process, reclassifications may become effective during a fiscal year rather than at the beginning of a fiscal year. Therefore, the wage index that is being used to pay the hospital changed mid-fiscal year and may not be reflected in Table 2 of the IPPS rule. This lower rural wage index (not reflected in Table 2) would then become the base wage index that would

be subject to the 5 percent cap on wage index reductions for the following year.[46]

- A newly opened hospital would be assigned the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it would not receive a cap for that first year because it would not have been assigned a wage index in the prior year. For the following year, the hospital's wage index cap reduction would be 95 percent of its initial wage index.

CMS cites section 1886(d)(3)(E) and (d)(5)(I)(i) of the Act as its authority for this proposal. Section 1886(d)(3)(E) of the Act provides authority to adjust "for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level." This provision of law further requires that "any adjustments or updates…shall be made in a manner that assures that the aggregate payments…are not greater or less than those that would have been made in the year without such adjustment." Section 1886(d)(5)(I)(i) provides authority for "exceptions and adjustments to the payment amounts under section 1886(d) of the Act" as the Secretary deems appropriate.

Public commenters were generally supportive of CMS' proposal but indicated that the statute neither authorizes nor requires budget neutrality to offset adjustments made under section 1886(d)(5)(I)(i) of the Act. These commenters requested CMS apply the wage index reduction cap policy without budget neutrality.

CMS disagreed with these comments stating that section 1886(d)(3)(E) of the Act gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be applied in a budget neutral manner.

The final rule further states that the low wage index policy is a technical adjustment and not a policy tool to increase payments. Further, CMS argues that section 1886(d)(5)(I)(i) of the Act, similarly gives the Secretary broad authority to provide by regulation for such other exceptions and adjustments to such payment amounts under subsection (d) as the Secretary deems appropriate. CMS' longstanding policies have established transitions for large changes in the wage index that have included a budget neutrality adjustment.

MedPAC commented that there should also be a limit of 5 percent on increases to the wage index. CMS disagrees and does not believe a limit on increases is needed to assist hospitals more effectively budget and plan their operations.

A commenter did not support CMS's proposed policy approach to the wage index cap policy with regard to newly opened hospitals indicating that it will create inequity in Medicare payments for hospitals within the same market by giving nearby hospitals different wage

[46] CMS has identified hospitals that obtained an urban-to-rural reclassification during FY 2022 that will make their wage index different than the one that is in Table 2 of the FY 2022 final rule (as corrected). These hospitals are identified in column C of Table 2 of the FY 2023 IPPS final rule.

indexes. CMS disagrees and indicated that any potential difference in the wage index value hospitals in the same labor market area receive would likely be minimal and temporary.

After consideration of the public comments, CMS is finalizing the 5 percent cap on reductions in the wage index as proposed with the associated budget neutrality adjustment.

IV. Disproportionate Share (DSH) and Uncompensated Care Payments (UCP)

A. Background

Medicare makes DSH 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) or 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 Affordable Care Act (ACA) required that DSH equal 25 percent of the statutory formula and UCP equal the product of three factors:

- Factor 1: 75 percent of the aggregate DSH payments that would be made under section 1886(d)(5)(F) of the Act without application of the ACA;
- Factor 2: The ratio of the percentage of the population uninsured in a base year prior to ACA implementation to the percentage of the population uninsured in the most recent period; 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).

B. Uncompensated Care Payments

1. FY 2023 Factor 1

CMS estimates this figure based on the most recent data available. It is not later adjusted based on actual data. CMS used the Office of the Actuary's (OACT) June 2022 Medicare DSH estimates, which were based on the March 2022 update of the HCRIS and the FY 2023 IPPS final rule impact file. Starting with these data sources, OACT applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

OACT's June 2022 Medicare estimate of DSH payments for FY 2023 is $13.949 billion. This is about 4.1 percent higher than the 2023 proposed amount of $13.266 billion. **The Factor 1 amount is seventy-five percent of this amount, or $10.462 billion.** The Factor 1 for 2023 is about $27 million less than the final Factor 1 for FY 2022.

The Factor 1 estimate for FY 2023 began with a baseline of $13.814 billion in Medicare DSH expenditures for FY 2019. The table below shows the factors applied to update this baseline to the current estimate for FY 2023.

Factors Applied for FY 2020 through FY 2023 to Estimate Medicare DSH Expenditures Using 2019 Baseline

FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2020	1.031	0.862	1.038	0.9952	0.9181	12.682
2021	1.029	0.939	1.029	1.0174	1.0116	12.829
2022	1.025	0.986	0.990	1.0235	1.0241	13.138
2023	1.043	1.050	0.990	0.9793	1.0618	13.949

- The discharge factor represents the increase in the number of Medicare FFS inpatient hospital discharges (based on Medicare claims data adjusted by a completion factor). These claims include the impact of the pandemic and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage plans.
- The case-mix column shows the estimated change in case-mix for IPPS hospitals and also includes the actual and estimated impact of the pandemic.
- The "other" column shows the changes in other factors affecting Medicare DSH estimates, including the difference between the total inpatient hospital discharges (including IPPS exempt hospitals) and IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in other columns (such as the change in rates for the 2-midnight stay policy and the 20 percent add-on for COVID-19 discharges). It also includes the estimated impacts on Medicaid enrollment from the COVID-19 pandemic.

The table below shows the factors that are included in the "update" column of the table above.

FY	Market Basket Percentage	Affordable Care Act Payment Reductions	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2020	3.0	0	-0.4	0.5	3.1
2021	2.4	0	0	0.5	2.9
2022	2.7	0	-0.7	0.5	2.5
2023	4.1	0	-0.3	0.5	4.3

Comment/Response: As in past years, some commenters expressed a general concern and/or request that CMS provide greater transparency in the methodology used by CMS and OACT to calculate Factor 1. Several wanted additional detail that would allow replication of CMS' DSH calculation. In particular, commenters requested further clarification regarding how the estimate of the "Other" factor is calculated.

Many commenters also questioned the proposed rule's estimate of the "Discharge" component of the Factor 1 calculation. They cited data from external and internal studies of inpatient discharge volume that indicates that 2022 and 2023 volumes will continue to rebound and increase substantially (+16-18 percent), even though levels are expected to be lower than pre-PHE levels. Others suggested that CMS either adjust the data used in the Factor 1 calculation or exclude data from the later parts of 2021 and early 2023 due to COVID PHE impacts. Commenters also raised concerns about the "Case Mix" update factor used in the Factor 1 calculation. Specifically, some were concerned that this factor underestimates the complexity of patients returning to seek care following deferral of care during the COVID-19 PHE. Some commenters believe CMS' estimates were inconsistent with those used to develop the Medicare Advantage capitation payments; the agency expected that utilization would rebound in 2022 and that the risk scores would increase under the assumption that patients delaying medical care during the PHE would be returning to the hospital for that care.

In its response, CMS disagrees with commenters and believes that it has been transparent about the methodology and data used to estimate Factor 1. It notes that these calculations are not done in isolation and are consistent with the economic assumptions and actuary analyses used to develop the President's Budget estimates under current law. CMS notes that when updating the "Other" factor and the "Discharge" factor it used the most recently available data and believes that its assumptions are reasonable. It notes that Medicare Advantage and Medicare FFS are distinct programs and that it only used claims from the Medicare FFS program to estimate the "Discharges" and "Case-Mix" factors.

CMS finalizes its methodology, as proposed, for calculating Factor 1 for FY 2023.

2. FY 2023 Factor 2

Factor 2 adjusts Factor 1 based on the percent change in the number of individuals who are uninsured from 2013 until the most recent period for which data are available. CMS uses uninsured estimates from the National Health Expenditure Accounts (NHEA) in place of CBO data as the source of change in the uninsured population.[47]

For FY 2023, CMS estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2022 and 2023 is 8.9 percent and 9.3 percent, respectively. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates Factor 2 for FY 2023 (weighting the portion of calendar years 2022 and 2023 included in FY 2022) as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2022: 8.9 percent.
- Percent of individuals without insurance for CY 2023: 9.3 percent.

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

- Percent of individuals without insurance for FY 2023 (0.25 times 0.089) + (0.75 times 0.093): 9.2 percent

Factor 2 = 1-|((0.092-0.14)/0.14)| = 1 - 0.3429 = 0.6571 (65.71 percent)

CMS calculated Factor 2 for the FY 2023 final rule to be 0.6571 or 65.71 percent, and the uncompensated care amount for FY 2023 to be $10.461 billion x 0.6571 = $6.874 billion which is about $318 million less than the FY 2022 UCP total of about $7.192 billion; the percentage decrease is 4.4 percent. The table below shows the Factor 1 and Factor 2 estimates for FY 2022 and FY 2023.

FY 2023 Change in UCP

($ in billions)

	FY 2022	FY 2023	$ Change	% Change
Factor 1	$10.489	$10.462	-$0.027	-0.26%
Factor 2	0.6857	0.6571	-0.0286	-4.2%
UCP	$7.192	$6.874	-$0.318	-4.4%

CMS also finalizes a technical change to the regulation at §412.106 to update paragraph (g)(1)(ii) to reflect the statutory requirements governing the determination of Factor 2 for FY 2018 and subsequent fiscal years. This reference had been inadvertently omitted.

Comment/Response: The majority of commenters expressed concern about the impact of the temporary COVID-19 PHE provisions, such as the American Rescue Plan's Marketplace enhanced premium tax credits, on the uninsured rate for FY 2023. They believed that the number of uninsured will increase as these provisions expire and that CMS should account for this factor in its projections. Commenters cited various data sources and analyses from the Kaiser Family Foundation, the Urban Institute, as well as HHS' Assistant Secretary for Planning and Evaluation (ASPE). In its reply, CMS notes that its estimates take into account the expected impacts of current law including the termination of the Families First Coronavirus Response Act's continuous coverage provision for Medicaid and the conclusion of the enhanced Marketplace premium tax credits. It believes that its data sources and methodology are appropriate and reasonable as determined by OACT.

3. Factor 3 for FY 2023

a. Background & Methodology Used to Calculate Factor 3 in Prior Fiscal Years

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

For Factor 3, the statute requires the Secretary to: (1) define uncompensated care; (2) determine the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the amount for each hospital estimated to receive DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period "based on appropriate

data." In addition, it permits the Secretary to use alternative data if the Secretary determines that available alternative data are a better proxy for the costs of IPPS hospitals for treating the uninsured.

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 limit year-to-year fluctuations in Factor 3 and the resulting uncompensated care payments. It also set up CMS to transition in the following year from using low-income patient days to Worksheet S-10 to distribute uncompensated care payments. CMS also issued transmittals to improve instructions for Worksheet S-10 data.[48]

In FY 2018, CMS began transitioning to use of Worksheet S-10 by using 2 years of low-income patient days and 1 year of Worksheet S-10 data (FY 2014).[49] In FY 2019, CMS continued that transition by using 1 year of low-income patient days and 2 years of Worksheet S-10 data (FY 2014 and FY 2015).[50]

In FY 2020, CMS used a single year of data—the FY 2015 Worksheet S-10 cost report data in the methodology to determine Factor 3. It concluded that the FY 2015 Worksheet S-10 data were the best available audited data and noted that it had begun auditing the FY 2017 data in July 2019 with the goal of having that data available for future rulemaking.

In FY 2021, CMS finalized its proposal to use the most recent available single year of audited Worksheet S-10 data to determine Factor 3 for FY 2021 and subsequent years. For FY 2021, CMS used FY 2017 data to determine Factor 3. It did not finalize a methodology to determine Factor 3 for Indian Health Service (IHS) and Tribal hospitals and Puerto Rico hospitals for FY 2022 using Worksheet S-10 data as it believed further consideration and review was needed. It also finalized the definition "uncompensated care" for FY 2021 and subsequent fiscal years that it had initially adopted in FY 2018. Specifically, "uncompensated care" is defined as the amount on line 30 of Worksheet S-10, which is the cost of charity care (line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (line 29).

In FY 2022, CMS mostly continued its existing policies. This included, for example, continuing the policy it first adopted for FY 2018 of substituting data regarding FY 2013 low-income insured days for the Worksheet S-10 data when determining Factor 3 for IHS and Tribal hospitals and subsection (d) Puerto Rico hospitals that have a FY 2013 cost report. At that time, CMS believed

[48] For example, transmittal 11 provided clarification on full or partial discounts given to uninsured patients who meet the hospital's charity care or financial assistance policy. Transmittal 11 is available for download on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R11p240.pdf.
[49] 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).
[50] Medicaid inpatient days from FY 2013 and SSI days from FY 2016.

that this approach was appropriate as the FY 2013 data reflect the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid (CMS proposes to change this policy in FY 2023, as discussed below).

b. Methodological Changes for Calculating Factor 3 for FY 2023 and Subsequent Fiscal Years

Number of Years of Audited Worksheet S-10 data used to calculate Factor 3
CMS finalizes its proposal to determine Factor 3 for FY 2023 using the average of the audited FY 2018 and FY 2019 Worksheet S-10 reports instead of basing it on a single year. In addition, CMS finalizes its proposal for FY 2024 and subsequent fiscal years to use a three-year average of the uncompensated care data from the three most recent fiscal years for which audited data are available to determine Factor 3. CMS believes that these policies address concerns from stakeholders regarding year-to-year fluctuations in uncompensated care payments. Consistent with its past methodology, CMS adopts the policy that if a hospital does not have data for all three years, it will determine Factor 3 based on an average of the hospital's available data.

Comment/Response: An overwhelming majority of commenters supported CMS' proposal to calculate Factor 3 for FY 2023 based on a two-year average of audited FY 2018 and FY 2019 Worksheet S-10 data. They cited several benefits including minimizing year-to-year volatility, ensuring stability in future uncompensated care payments, and mitigating the effect of irregular trends and data anomalies. These commenters also expressed support for the proposal to use a three-year average of the most recent available audited Worksheet S-10 data for FY 2024 and subsequent fiscal years.

After consideration of comments received, CMS finalizes its proposals without modification. It notes that the number of audited hospitals continues to increase year to year end and that it expects the reliability of Worksheet S-10 will continue to improve.

IHS and Tribal Hospitals and Subsection (d) Puerto Rico hospitals that have a FY 2013 cost report
CMS finalizes its proposal to discontinue the use of low-income insured days as a proxy for the uncompensated care costs for IHS and Tribal hospitals and Puerto Rico hospitals, and will use the same data to determine Factor 3 as it uses for other hospitals. CMS notes that the low-income insured days will be 10 years old in 2023 and there is no obvious way to update the information given the different impact of state Medicaid expansions after 2013. Thus, it believes that Worksheet S-10 data will be a better proxy for the costs of these hospitals in treating the uninsured.

CMS recognizes that this new methodology for IHS/Tribal and Puerto Rico hospitals could result in significant financial disruption. To mitigate these impacts, it is adopting a new supplemental payment for IHS/Tribal and Puerto Rico hospitals beginning in FY 2023 to address this concern (this policy is discussed in detail in section IV.C of this summary).

Scaling Factor
To address the effect of calculating Factor 3 using data from multiple fiscal years, CMS finalizes its proposal to apply a scaling factor to the Factor 3 values calculated for all DSH-eligible

hospitals. This is necessary so that total uncompensated care payments to hospitals that are projected to be eligible for DSH for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Specifically, CMS proposes to adopt a policy under which it divides the expected sum of all DSH-eligible hospitals' Factor 3 values by the actual sum of all DSH-eligible hospitals' Factor 3 values and then multiplies the quotient by the uncompensated care payment determined for each DSH-eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. It notes that a similar scaling factor was used in both FY 2018 and FY 2019 when the Factor 3 calculation included multiple years of data.

CMS did not receive any comments on this proposal and finalizes it without modification.

New Hospital for Purposes of Factor 3
CMS modifies its policy that was initially adopted in FY 2020 to determine Factor 3 for new hospitals. It finalizes its proposal to define a new hospital as a hospital that does not have cost report data for the most recent year of data being used in the Factor 3 calculation. Thus, hospitals with CMS Claim Numbers (CCNs) established on or after October 1, 2019, will be subject to the new hospital policy in FY 2023.

CMS will continue its policy established in FY 2020 that if a new hospital has a preliminary projection of being eligible for DSH payments, it may receive interim empirically justified DSH payments. New hospitals, however, will not receive interim uncompensated care payments during FY 2023 because CMS will have no FY 2018 or FY 2019 uncompensated care data on which to determine those interim payments.

CMS also modifies the methodology it uses to calculate Factor 3 for new hospitals. CMS will determine Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. It will also apply a scaling factor to the Factor 3 calculation for a new hospital.

Newly Merged Hospitals
CMS continues its policy to treat hospitals that merge after the development of the final rule similar to new hospitals. Consistent with its policy adopted in the FY 2015 IPPS/LTCH PPS final rule, CMS finalizes its proposal that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. If the hospital's cost reporting period is less than 12 months, CMS will annualize its data for purposes of the Factor 3 calculation. CMS will also apply a scaling factor, as discussed previously.

In addition, CMS continues its policy that the interim uncompensated care payments for the newly merged hospital will be based only on the data for the surviving hospital's CCN available after the time of the development of the final rule. For FY 2023, this data will be the FY 2018 and FY 2019 cost reports available for the surviving CCN at the time the final rule is developed. At cost report settlement, CMS will determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2023 cost report.

Comment/Response: CMS received limited comments, but these comments were supportive. One commenter sought clarification regarding which cost report would be used in the numerator of the Factor 3 calculation for a newly merged or new hospital. In response, CMS notes that the new hospital and newly merged hospital policy are based on the start date of the hospital's cost reporting period. For a new hospital in its 2023 cost reporting period, the numerator would be based on the hospitals FY 2023 cost report.

CCR Trim Methodology
For hospitals lacking a CCR on Worksheet S-10, line 1 or hospitals that report an aberrant CCR (greater than 3 standard deviations above the national geometric mean), CMS substitutes the statewide average CCR trimmed of outlier values. Consistent with its process for trimming CCRs in FY 2022, CMS will apply the following steps (shown in table below) to determine the applicable CCR for FY 2018 and FY 2019 reports separately.

Methodology for Trimming CCRs	
Step 1	Remove Maryland hospitals and all-inclusive rate providers
Step 2	CMS will calculate a CCR ceiling by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.
Step 3	Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S-3, Part I, Line 14, Column 15.
Step 4	Assign the appropriate 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"). Under the proposed and final rule, the statewide average CCR was applied to 8 hospitals' FY 2018 reports, of which 3 hospitals had FY 2018 Worksheet S-10 data. The statewide average CCR was applied to 14 hospitals' FY 2019 reports, of which 6 hospitals had FY 2019 Worksheet S-10 data.
Step 5	For providers that did not report a CCR on Worksheet S-10, Line 1, CMS assigns them the statewide average CCR as determined in step 3.

After completing the steps above, CMS recalculates the hospitals' uncompensated care costs (Line 30) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

CMS did not receive any comments on the discussion of CCR trim methodology and is finalizing these, as proposed.

Modifications to the Uncompensated Care Data Trim Methodology
CMS finalizes its proposal to continue the trim methodology for potentially aberrant uncompensated care costs (UCC) that it finalized in the FYs 2019-2022 IPPS/LTCH PPS final rules. That is, if the hospital's UCC for FY 2018 or FY 2019 are an extremely high ratio (greater

than 50 percent) of its total operating costs, CMS finalizes that data from another available cost report will be used for the ratio calculation. For example, to calculate an estimate of the hospital's UCC for FY 2018 for purposes of determining Factor 3 for FY 2023, the hospital's UCC for FY 2018 would be trimmed by multiplying its FY 2018 total operating costs by the ratio of UCC to total operating costs from the hospital's FY 2019 cost report. CMS will apply the same approach to address potentially aberrant data in the FY 2019 cost report, by trimming based on the hospital's FY 2020 cost report. For hospitals whose FY 2018 and 2019 cost report have been audited, CMS will not apply the trim methodology.

In addition to the existing UCC trim methodology, CMS finalizes its proposal to apply a new trim specific to certain hospitals that do not have audited FY 2018 and/or FY 2019 Worksheet S-10 data. It notes that in rare cases hospitals that are not currently projected to be DSH eligible and that do not have audited data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). Thus, for FY 2023, it finalizes that in the rare case that a hospital's insured patients' charity care costs are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total UCC (line 30) is greater than 60 percent, it will exclude the hospital from the prospective Factor 3 calculation. This trim will only impact hospitals that are not currently projected to be DSH eligible. If the hospital is ultimately determined to be DSH eligible at cost report settlement, then the MAC will calculate the Factor 3 after reviewing the reported uncompensated care information.

CMS did not receive any comments on the proposed modifications and finalizes changes to uncompensated care data trim methodology, as proposed.

c. Proposals Related to the Per Discharge Amount of Interim Uncompensated Care Payments

Consistent with the policy adopted in FY 2014 and applied in each subsequent fiscal year, CMS calculates a per discharge amount of interim uncompensated care by dividing the hospital's total uncompensated care payment amount in the proposed rule year by the hospital's 3-year average of discharges. This per discharge payment amount is used to make interim uncompensated care payments to each projected DSH-eligible hospital. These interim payments are reconciled following the end of the year.

CMS modifies this calculation for FY 2023 to be based on the average of FY 2018, FY 2019, and FY 2021 historical discharge data, rather than FYs 2019, 2020, and 2021. It believes that using a 3-year average with the FY 2020 discharge data would underestimate discharges, due to the decrease in discharges during the pandemic.

To reduce the risk of overpayments of interim uncompensated care payments and the potential for unstable cash flows for hospitals and MA plans, CMS continues its voluntary process through which a hospital may submit a request to its MAC for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the fiscal year and/or once during the fiscal year. The hospital would have to provide documentation to support a likely significant recoupment – for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000. The only change that would be made would be to lower the per discharge amount either to the amount requested by the hospital or another amount

determined by the MAC. This does not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

Comment/Response: Some commenters stated that interim payments should be subject to later reconciliation based on estimates derived from actual data from the federal fiscal year. CMS does not agree and notes that the Secretary has the discretion to estimate the three factors used to determine uncompensated care payments and that administrative and judicial review of these estimates is prohibited by statute (Section 1886(r)(3) of the Act).

d. Process for Notifying CMS of Merger Updates and to Report Upload Issues

In the case of hospital mergers, CMS publishes a table on the CMS Web site, in conjunction with the issuance of each fiscal year's proposed and final IPPS rules, containing a list of the mergers known to CMS and the computed uncompensated care payment for each merged hospital. Hospitals had 60 days from the date of public display of this year's proposed rule to review the tables and notify CMS in writing of any inaccuracies.

For FY 2023, CMS again adopts the policy that after the publication of the FY 2023 IPPS/LTCH PPS final rule, hospitals will have 15 business days from the date of public display to review and submit comments on the accuracy of the table and supplemental data file published in conjunction with the final rule. [51]

CMS did not receive any comments on the notification process for mergers or data upload issues and finalizes its proposals without modification.

C. Supplemental Payment for Indian Health Service, Tribal and Puerto Rico Hospitals

Over the past several years, IHS and Tribal hospitals located in Puerto Rico have commented on the challenges they face with respect to uncompensated care due to structural differences in health care delivery and financing in these areas compared to the rest of the country.[52]

In light of these concerns, CMS finalizes its proposal to establish a new permanent supplemental payment under the IPPS for IHS/Tribal hospitals and hospitals located in Puerto Rico. CMS believes that this new supplemental payment will also mitigate the anticipated impact on IHS/Tribal hospitals and hospitals located in Puerto Rico from its policy to discontinue the use of low-income insured days as a proxy for their uncompensated care costs. The additional payment to these hospitals will be determined based upon the difference between the amount of the uncompensated care payment determined for the hospital using Worksheet S-10 data and an approximation of the amount the hospital would have received if it had continued to use low-income days as a proxy for uncompensated care.

[51] These should be submitted to the CMS inbox at Section3133DSH@cms.hhs.gov. CMS notes that this box is not intended for Worksheet S-10 audit process related e-mails, which should be directed to MACs.
[52] CMS refers readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45242 and 45243) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58824 and 58825).

CMS uses its exceptions and adjustments authority under section 1886(d)(5)(1) of the Act to establish a new permanent supplemental payment under IPPS for IHS/Tribal hospitals and hospitals located in Puerto Rico, beginning in FY 2023. CMS believes that this supplemental payment is necessary so as not to cause undue long-term financial disruptions due to its policy to discontinue the use of low-income insured days as a proxy for uncompensated care in determining Factor 3 for these hospitals.

CMS will calculate a supplemental payment by using the hospital's FY 2022 uncompensated care payment as the starting point for the calculation. It chose FY 2022 because it is the most recent year for which it used low-income insured days data in the determination of uncompensated care payments for these hospitals. The base year amount will be calculated as the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable year (for example, FY 2023 for purposes of this rulemaking) and FY 2022. For the hospitals that were not projected to be DSH eligible in FY 2022, CMS will use the uncompensated care payment that the hospital would receive, if the hospital were to be determined to be DSH eligible in FY 2022 at cost report settlement.

The percent change between the FY 2023 uncompensated care amount and final FY 2022 uncompensated care amount is projected to be -4.4 percent. To calculate each hospital's base year amount for FY 2023, CMS would multiply a hospital's FY 2022 uncompensated care amount by 0.956 (1-0.044). The hospital's supplemental payment for a fiscal year will then be determined as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year. If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, then the hospital will not receive a supplemental payment.

CMS also aligns the eligibility and payment processes for the new supplemental payment with the processes used to make uncompensated care payments.

- Eligibility to receive interim supplemental payments will be based on a projection of DSH eligibility for the applicable fiscal year.
- An average of historical discharges will be used to calculate a per discharge amount for interim supplemental payments. For FY 2023, CMS will use FY 2018, FY 2019, and FY 2021 discharge data (2020 excluded due to the effects of the pandemic).
- Per-discharge supplemental payments will be included in the outlier payment.
- The MAC will reconcile the interim supplemental payments at cost report settlement to ensure that the hospital receives the full amount of the supplemental payment that was determined prior to the start of the fiscal year.
- A pro rata supplemental payment calculation may be made if the hospital's cost reporting period differs from the Federal fiscal year.
- The MAC will make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year. A hospital that is not DSH eligible will not be eligible to receive a supplemental payment for that fiscal year.

In addition, CMS adopts the policy that IHS/Tribal hospitals and Puerto Rico hospitals that do not have a FY 2022 Factor 3 amount using the low income insured days proxy or that are new hospitals that begin participating in the Medicare program on or after October 1, 2022, will not be eligible to receive the supplemental payment.

Comments/Response: Commenters were supportive of CMS's proposal to establish a new supplemental payment for IHS and Tribal hospitals to mitigate the anticipated impact of the agency's proposal to discontinue the use of low-income insured days as a proxy to calculate uncompensated care for these hospitals. Some commenters expressed concern about the proposal to limit the new supplemental payment to existing IHS/Tribal hospitals that have a Factor 3 amount for FY 2022 determined using the low-income insured days proxy. CMS responds that it appreciates the inputs from commenters on its proposal and notes that it recognizes the unique nature of these hospitals and circumstances they face. It also notes that it is not appropriate to extend the supplement payment to include new hospitals at this time because their uncompensated care costs had not been previously determined using the low-income insured days proxy.

D. Impact

The regulatory impact analysis presented in Appendix A of the final rule includes the estimated effects of the changes to uncompensated care payments for FY 2023 across all hospitals by geographic location, bed size, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,368 hospitals that are projected to be eligible for DSH in FY 2023.

The total amount of uncompensated care payments ($6.874 billion) combined with supplement payments for IHS/Tribal hospitals and Puerto Rico hospitals ($96 million) is $6.971 billion. This is a 3.08 percent decrease from FY 2022 payments (about $221 million). Changes in FY 2023 payments are driven by a decrease in Factor 1 and Factor 2 and the establishment of the new supplemental benefit for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals.

The variation in the distribution of payments by hospital characteristics is largely dependent on a given hospital's reported uncompensated care costs used in the Factor 3 computation and whether the hospital is eligible to receive the new supplemental payment. A percent change in payments lower than negative 3.08 percent indicates that hospitals within that category are projected to experience a larger decrease compared to the average for all hospitals, and a percent change greater than negative 3.08 percent indicates the category of hospitals is receiving a smaller decrease in payments than the average for all hospitals. The table below shows impacts for selected categories of hospitals, including uncompensated care payments and supplemental payments.

Hospital Type	Dollar Difference FY 2022-FY 2023 ($ in millions)	Percent Change
All Hospitals	-$221	-3.08%
Urban	-197	-2.90
Large Urban	-73	-1.77
Other Urban	-124	-4.69
Rural	-24	-6.00
Beds: 0-99 (Urban)	-19	-6.55
Beds: 250+ (Urban)	-139	-2.80
New England (Urban)	-11	-5.91
Middle Atlantic (Urban)	-54	-6.58
South Atlantic	-38	-4.76
West North Central (Urban)	-10	-2.38
West South Central (Urban)	-32	-2.26
Pacific (Urban)	3	0.52
Puerto Rico	-6	-6.24
Major Teaching	-106	-3.88
Non-Teaching	-55	-2.82
Voluntary	-80	-1.95
Proprietary	-24	-2.37
Government	-117	-5.65

Rural hospitals are projected to receive a larger percentage decrease in UCP (6.00 percent) than urban hospitals (2.90 percent) in FY 2023 compared to FY 2022. Urban hospitals in the New England, the Middle Atlantic, the South Atlantic and Puerto Rico are the most negatively affected. Rural hospitals in all regions are expected to receive larger than average decreases, except for rural hospitals in the South Atlantic. Major teaching hospitals (100 or more residents) are the most negatively affected compared to other teaching hospitals. Government hospitals are projected to receive larger than average decreases of 5.65 percent, whereas voluntary and proprietary hospitals are projected to receive a payment decrease of 1.95 and 2.37 percent, respectively.

E. 1115 Waiver Days in the Medicaid Fraction

In the FY 2023 IPPS/LTCH PPS proposed rule, CMS proposed revisions to the regulation relating to the treatment of section 1115 demonstration days for purposes of DSH adjustment (87 FR 283898 through 28402). CMS states that due to the number and nature of the comments it received and after further consideration of the issue, it determined not to move forward with its proposal. CMS expects to revisit this issue in future rulemaking. It did not summarize the comments received in this section.

V. Other Decisions and Changes to the IPPS

A. Inpatient Hospital Update

The inpatient hospital update for FY 2023 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 total factor productivity.
- For hospitals that fail to submit quality information, the FY 2023 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 2023 inpatient hospital update will be reduced by three-quarters of the market basket update.

The IHS Global Insight, Inc. (IGI) 2nd quarter 2022 forecast (with historical data through the 1st quarter of 2022) for the hospital market basket is 4.1 percent. IGI's 4th quarter 2021 forecast of total factor productivity is 0.3 percent.

Four different scenarios that may apply to a hospital, depending on whether it submits quality data and/or is a meaningful EHR user, are shown in the following table.

FY 2023	Scenario 1: Hospital Submitted Quality Data and is a Meaningful	Scenario 2: Hospital Submitted Quality Data and is NOT a Meaningful	Scenario 3: Hospital Did NOT Submit Quality Data and is a Meaningful	Scenario 4: Hospital Did NOT Submit Quality Data and is NOT a Meaningful
Market Basket Rate-of-Increase	4.1	4.1	4.1	4.1
Adjustment for Failure to Submit Quality Data	0.0	0.0	-1.025	-1.025
Adjustment for Failure to be a Meaningful EHR User	0.0	-3.075	-0.0	-3.075
Productivity Adjustment	-0.3	-0.3	-0.3	-0.3
Applicable Percentage Increase	**3.8**	**0.725**	**2.775**	**-0.3**

For updates to the hospital-specific rate for SCHs, CMS will adopt the same four applicable percentage increases shown in the table above.

Puerto Rico hospitals are not subject to the quality reporting provisions but do receive EHR subsidies and may be subject to a penalty for not being meaningful users of EHR technology. However, the penalty for not being a meaningful user of EHR technology is slightly different than for other hospitals although transitioning to be the same reduction over 3 years in 1/3 increments.

FY 2023 is the first year that hospitals in Puerto Rico will be subject to a penalty for not being a meaningful user of EHR technology. The penalty will be 1/3 of the 75 percent reduction to the market basket in FY 2023, 2/3 of the 75 percent reduction to the market basket in FY 2024, and 100 percent of the 75 percent reduction to the market basket in FY 2025 and subsequent years.

For FY 2023, Puerto Rico hospitals that are not meaningful EHR users will be subject to a market basket reduction of 1/3 of 75 percent of 4.1 percent, or 2.05 percentage points. The productivity adjustment further reduces the update by 0.3 percentage points. The update for Puerto Rico hospitals that are not meaningful users of EHR technology will be subject to an update of 1.75 percent (4.1 percent less 2.05 less 0.3).

Many public commenters raised concerns about CMS' proposed update using the IGI forecast of the FY 2023 hospital market basket. The comments generally were in the following categories:

Accuracy/Timeliness of BLS Data: Several commenters expressed concern that the proposed market basket update was not accurately reflecting recent hospital inflation. These commenters stated that BLS' Employment Cost Index (ECI), which accounts for 53 percent of the market basket, did not accurately reflect hospitals' compensation costs after the labor market changes triggered by the PHE when compared to other data sources such data supplied by Premier Incorporated in their public comments. They urged CMS to use more recent data and to appropriately capture significant inflationary trends that may not yet be fully captured in IGI's updated market basket forecast.

CMS responded that it was using the IGI's 4th quarter 2021 forecast of the FY 2023 market basket with historical data through the 3rd quarter of 2021 when determining the proposed rule update. In the proposed rule, CMS indicated it would use later available data for forecasting the FY 2023 market basket in the final rule. Using IGI's second quarter 2022 forecast with historical data through first quarter 2022, CMS is projecting a FY 2023 IPPS market basket update of 4.1 percent (reflecting forecasted compensation price growth of 4.8 percent) and a productivity adjustment of -0.3 percentage point. This compares to a proposed rule market basket of 3.1 percent less 0.4 percentage point for productivity. CMS notes that the final FY 2023 IPPS market basket growth rate of 4.1 percent would be the highest market basket update implemented in an IPPS final rule going back to FY 1998.

Use of Contract Labor: Commenters noted that the ECI does not capture inflation in contract labor compensation that has become a higher proportion of total compensation and is both higher and growing faster than employed staff compensation according to data provided by Premier Inc. CMS acknowledges that the ECI only reflects price changes for employed staff but believes that the ECI for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care.

CMS reviewed FY 2020 Medicare cost reports and found that employed workers' hours account for 97 percent of hospital compensation hours. Further, as a fixed weight index that is periodically rebased, CMS believes the market basket appropriately controls for price increases and not changes in the mix of staff. Any shift among labor categories and its impact on the index will be accounted for when the market basket is next rebased and revised.

Use of Other Data Sources: Several commenters requested that CMS review other inflation data sources such as the Consumer Price Index and the core Personal Consumption Expenditures deflator, and that the market basket increase at least match or exceed these rates of increases. Another commenter recommended that CMS use its exceptions and adjustments authority to substitute Premier Inc. data for the IGI forecast to provide hospitals with an increased payment update in FY 2023 that accurately reflect labor cost increases. Some public commenters recommended that CMS use the Medicare cost report as the source of the market basket.

CMS responded that it disagrees with using price indices other than the market basket to update hospital rates. The indices suggested by the commenters do not reflect the increase in the prices

of goods and services purchased by hospitals. CMS indicates that the market basket has been an accepted price index since the beginning of the IPPS in 1984 and has been used as the update mechanism for other payment systems. As CMS did not propose to use other methods or data sources to calculate the final market basket update for FY 2023, it does not believe such a major change would be appropriate to undertake in the final rule.

In response to the using the cost report to update IPPS rates, CMS disagrees that cost reports would be a suitable for estimating the market basket rate of increase. Section 1886(b)(3)(B)(iii) of the Act states the Secretary shall estimate a market basket percentage increase based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in inpatient hospital services. The Medicare cost report data reflects factors that are beyond those that impact wage or price growth.

More Frequent Rebasing/Revising of the Hospital Market Basket: Some commenters expressed concern that CMS relies on a hospital market basket that was last rebased and revised using 2018 hospital cost report data. These commenters indicated that the weights may have been impacted by COVID-19. For example, they stated that during the pandemic there has been increased use of personal protective equipment, yet this utilization would not be captured in the market basket, which was rebased and revised in the FY 2022 IPPS final rule. Other commenters believe the compensation weight should be higher.

The IPPS market basket was last rebased in the FY 2022 IPPS final rule using 2018 Medicare cost reports (86 FR 45194 through 45207), the most recent year of complete data available at the time of the rebasing. CMS reviewed Medicare cost report data submitted as of March 2022, which includes data for 2019-2020. These data showed that if CMS rebased the market basket based on the latest available data, the compensation cost weight would decline by approximately 1 percentage point. The pharmaceuticals cost weight and home office cost weight would increase approximately 0.3 percentage point each.

CMS' preliminary analysis shows any rebasing done now would have a minimal impact on the market basket and it is unclear whether these trends (particularly the compensation cost weight) through 2020 are reflective of sustained shifts in the cost structure for hospitals or were temporary as a result of the PHE. CMS believes it is premature at this time to rebase and revise market basket based on data from a year later than the last time it rebased and revised. Nevertheless, CMS will continue to review this issue for future rulemaking.

Accounting for Forecast Errors: Several comments said CMS does not account for substantial forecast errors driven by an unusually fast acceleration of the inflation rate such as occurred in FY 2021. They urge CMS to use its exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to modify its methodology for FY 2023 to account for substantial forecast error in the FY 2021 and FY 2022 market baskets. A commenter cited the unprecedented nature of the pandemic and its extraordinary impact on hospital costs alongside record inflation as the basis of this one-time adjustment for forecast error correction.

CMS responds that the statute does not include a forecast error adjustment for the hospital market basket and there is no precedent to adjust for market basket forecast error in the IPPS

operating payment update. Forecast errors can be both positive and negative. For example, the FY 2020 IPPS forecast error was -1.0 percentage point, and the FY 2021 IPPS forecast error was +0.7 percentage point. CMS believes that an important goal of a PPS is predictability. For these reasons, CMS does not believe it is appropriate to include adjustments to the market basket update for future years based on the difference between the actual and forecasted market basket increase in prior years.

Productivity Adjustment: Several commenters requested that CMS use its "special exceptions and adjustments" authority under section 1886(d)(5)(I)(i) of the Act to eliminate the productivity adjustment for FY 2023 or for any year of the COVID-19 PHE. Other commenters indicated that an offset for economy-wide productivity is inappropriate for hospitals as hospitals cannot be as efficient as the overall economy. The Office of the Actuary itself acknowledged this point in a memorandum that compares private non-farm total factor productivity growth measure and a hospital-specific measure (https://www.cms.gov/files/document/productivity-memo.pdf)

CMS responds that it appreciates the commenters concerns but it is required by law to apply the productivity adjustment by 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the proposed rule, CMS is using more recent data to determine the FY 2023 productivity adjustment for the final rule. Based on IGI's second quarter 2022 forecast, CMS is using a productivity adjustment of 0.3 instead of 0.4 percentage point in the final rule.

After consideration of the comments received and consistent with its proposal, CMS is using more recent data to determine the FY 2023 market basket update for the final rule than the proposed rule. Based on more recent data available, CMS is finalizing a market basket of 4.1 percent less 0.3 percentage points for hospitals that receive the full IPPS update.

B. Rural Referral Centers (RRCs)

RRCs are hospitals that are either geographically rural or treated as rural for IPPS purposes that are subject to special rules for the DSH payment adjustment and geographic reclassification. To qualify as an RRC, a hospital must have more than 275 beds or meet case-mix, discharge and other criteria for the federal fiscal year that ends at least one year prior to the beginning of the cost reporting period for which the hospital seeks RRC status.

CMS annually revises case mix index (CMI) and discharge criteria to qualify for RRC status. For FY 2023, CMS proposed to use FY 2021 data to set the CMI criteria. Commenters supported this proposal that CMS is finalizing without change. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2022, a hospital may qualify as an RRC if the hospital is rural or treated as rural and has:

- 275 beds or more; or
- More than 5,000 discharges (3,000 for an osteopathic hospital) in its cost reporting period that began during FY 2021, and a CMI greater than or equal to the lower of 1.8262 (national urban hospital CMI excluding teaching hospitals) or the CMI for the hospital's region shown in the below table.

Census Region	CMI Value
1. New England (CT, ME, MA, NH, RI, VT)	1.49610
2. Middle Atlantic (PA, NJ, NY)	1.59950
3. East North Central (IL, IN, MI, OH, WI	1.70620
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.77709
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.68745
6. East South Central (AL, KY, MS, TN	1.67540
7. West South Central (AR, LA, OK, TX	1.87560
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.89600
9. Pacific (AK, CA, HI, OR, WA)	1.85470

The median regional CMIs in the final rule reflect the March 2022 update of the FY 2021 MedPAR containing data from bills received through March 31, 2022. A hospital seeking to qualify as an RRC should get its hospital-specific CMI value (not transfer-adjusted) from its Medicare Administrative Contractor (MAC).

C. Low-Volume Hospitals

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. The below table shows the statutory and regulatory criteria to be a low-volume hospital and how the additional payment is calculated.

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%

Absent statutory intervention, only hospitals with less than 200 total discharges will be eligible for the low-volume hospital adjustment beginning in FY 2023. As shown in the above table, the payment adjustment for a qualifying low-volume hospital will be 25 percent for each Medicare discharge.

CMS proposed to continue the past process for hospitals to apply for low-volume hospital status. Hospitals must submit a written request for low-volume hospital status to its MAC by September 1, 2022 that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. Hospitals must use the latest submitted Medicare cost report for discharge information. Use of a web-based mapping tool may be used to demonstrate that the mileage criterion has been met.

If a hospital qualified for the low-volume hospital payment adjustment for FY 2022, it may continue to receive a low-volume hospital payment adjustment for FY 2023 without reapplying. However, CMS proposed that the hospital must provide written verification to the MAC that it continues to meet the lower discharge criterion applicable for FY 2023.

If a hospital's written request for low-volume hospital status for FY 2023 is received after September 1, 2022, CMS proposed that any approval will be effective prospectively within 30 days of the date of the MAC's determination.

Several commenters requested that CMS extend the modified definition of a low-volume hospital and the payment adjustment for low-volume hospitals using its authority to make "Emergency Pandemic Declarations." CMS believes the commenter is referring to waiver authority under section 1135 of the Act. This authority does not allow CMS to waive the low-volume hospital adjustment provisions or most other payment provisions of statute.

By statute, CMS can make the low-volume payment adjustment to hospitals that have up to 800 total discharges. However, CMS used its regulatory authority to make the payment adjustment to hospitals that have up to 200 discharges. Public commenters requested that CMS increase the number of discharges a hospital may have to receive the low-volume hospital payment adjustment up to 800 consistent with the statute.

CMS performed several regression analyses to evaluate the relationship between hospitals' costs per case and discharges when the low-volume hospital provision first became effective in the 2000's. These analyses found that an adjustment for hospitals with less than 200 total discharges is most consistent with the statutory requirement to provide for additional payments where there is empirical evidence that higher incremental costs are associated with lower numbers of discharges (69 FR 49101 through 49102). CMS is not aware of any analysis or empirical evidence that would support expanding the originally established low-volume hospital adjustment policy to 800 discharges although it may redo its regression analysis in the future.

One commenter indicated that the conditions of participation require a hospital to maintain an average daily census (ADC) of 2 days and an average length of stay (ALOS) of 2 midnights to retain status as a hospital. The commenter believes the requirement that only allows a hospital to have up to 200 discharges to receive the low-volume hospital adjustment is inconsistent with the conditions of participation. CMS responds that it is not clear why a low-volume hospital payment adjustment criterion of less than 200 discharges would prevent a hospital from meeting the ADC and ALOS thresholds required for maintaining its certification and status as an inpatient facility. A hospital's ability to adhere to the inpatient hospital CoPs is not relevant to the reversion to the low-volume hospital payment requirements that were in effect prior to FY 2011.

CMS is not making any changes in its proposals in the final rule with regard to the low-volume hospital adjustment.

D. Medicare-Dependent Small Rural Hospitals (MDH)

Section 1886(d)(5)(G) of the Act provides special payments under the IPPS to a MDH through September 30, 2022. Beginning with discharges occurring on or after October 1, 2022, all hospitals that previously qualified for MDH status will no longer be eligible for this special payment methodology. While the MDH program was set to expire many times previously, it has

always been extended by Congress. Nevertheless, at this time, CMS is advising hospitals of the MDH program expiration and the potential to ameliorate the associated reduction in payment through becoming an SCH.

When the MDH program was set to expire at the end of FY 2012, CMS revised the SCH regulations to allow MDHs to apply for SCH status in advance of the expiration of the MDH program. These regulations allow SCH status to begin the day following the MDH program's expiration. In order for an MDH to receive SCH status effective October 1, 2022, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program, or by September 1, 2022. The MDH also must request that, if approved, the SCH status be effective with the expiration of the MDH program. If the MDH does not apply by the September 1, 2022 deadline, the hospital would instead be subject to the usual effective date for SCH classification, which is the date the MAC receives the complete application.

Several commenters asked CMS to extend the MDH program into FY 2023 and also change the base year that is used to determine an MDH's hospital-specific rate. CMS responded that these requests are outside of its statutory authority.

Commenters expressed support for CMS' procedural rules that allow an MDH to seamlessly become an SCH upon expiration of the MDH program. In a March 1, 2013 change request, CMS allowed for reinstatement of MDH status retroactive to October 1, 2013 except where the hospital transitioned to SCH status or cancelled an urban to rural reclassification. The commenters requested that MDHs be able to rescind SCH status and reinstate MDH status retroactive to the date the MDH program is extended as well.

CMS responded that it will consider potential mechanisms to further streamline such transitions in connection with legislative extensions of the MDH program. Under the current regulations, an MDH that applied for and was classified as an SCH in advance of the MDH expiration could request a cancellation of its SCH status and simultaneously re-apply for MDH status if the MDH program were to be extended. The MDH classification would be effective as of the date that the MAC receives the complete application.

E. Indirect and Direct Graduate Medical Education Costs

1. Background

Medicare pays hospitals for direct graduate medical education (DGME) and indirect medical education (IME) costs based on the number of full-time equivalent (FTE) residents they train. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare DGME and IME payments the hospital will receive. Since 1997, the law has limited the number of residents a hospital may count for DGME and IME (other than dental and podiatric residents) to the amount they counted in 1996.

For DGME, resident FTE counts are weighted 1.0 during the initial residency period and 0.5 beyond the initial residency period. The initial residency period is the number of years required for a resident to obtain an initial Board certification. Generally, residents are counted at 1.0 FTE

for the period of their initial residency Board certification and at 0.5 FTE when in subspecialty training. The caps that have been in place since 1997 have been on the unweighted resident counts. However, Medicare makes DGME payment based on the weighted resident count.

To address situations where a hospital's unweighted FTE count exceeds its unweighted FTE cap, CMS has been using the following formula to determine the weighted count:

$$\frac{FTE\ Cap}{Unweighted\ Count} \times Weighted\ Count\ = Weighted\ Cap\ Adjusted\ Count$$

This methodology was adopted through notice and comment rulemaking and has been in use since 1997 but recently became the subject of litigation in *Hershey v. Becerra (Hershey)*. The original rule was adopted on an interim final basis in 1997 with comment period, but the agency received no public comments and the rule was finalized as originally adopted. In the proposed rule, CMS indicates that the above formula has been applied separately for residents training in primary care and obstetrics/gynecology from residents training in all other specialties.

2. *Hershey v. Becerra*

On May 17, 2021, the U.S. District Court for the District of Columbia in *Hershey* found that the proportional reduction methodology improperly modified the weighting factors statutorily assigned to residents beyond the initial residency period. The court ordered CMS to pay the plaintiffs according to a more favorable method. CMS provided the following examples to illustrate the Court's finding:

Year 1
DGME Cap = 100 FTE
Unweighted Count = 100
Residents Weighted at 1.0 = 90 x 1.0 = 90
Residents Weighted at 0.5 = 10 x 0.5 = 5
Weighted Count = 95

Substituting the above figures into the formula yields the following weighted cap-adjusted count:

$$\frac{100}{100} \times 95\ = 95$$

As the unweighted count of residents does not exceed the DGME cap, the weighted count of residents and the weighted cap-adjusted count of residents are the same. No adjustment to the unweighted count is necessary.

Year 2

In Year 2, the hospital adds 10 residents who are beyond the initial residency period as follows:

DGME Cap = 100 FTE
Unweighted Count = 110
Residents Weighted at 1.0 = 90 x 1.0 = 90
Residents Weighted at 0.5 = 20 x 0.5 = 10
Weighted Count = 100

Substituting the above figures into the formula yields the following weighted cap-adjusted count:

$$\frac{100}{110} \times 100 = 90.91$$

For each resident above the cap added that is beyond the initial residency period, the hospital's weighted count declines. The hospital is penalized for adding residents in sub-specialty training as opposed to receiving no additional payment that would occur if each additional unweighted resident being added is not counted at all. Effectively, this results in each resident beyond the initial residency period being weighted at less than 0.5 FTE according to the court.

The court held that CMS' proportional reduction methodology is inconsistent with the statutory requirement that each resident beyond the initial residency period be weighted at 0.5 FTE. In response to the court's decision, CMS proposed to implement a modified policy applicable to all teaching hospitals, effective October 1, 2001. CMS is making the policy effective October 1, 2001 instead of October 1, 1997 because it is unaware of any open or reopenable notice of program reimbursements for the 1997-2001 period where the proportional reduction method caused a provider's payments to be lower than they would be under the proposed new policy.

CMS provided good cause to engage in retroactive rulemaking in this circumstance because:

- The court in *Hershey* struck down CMS' existing rule and the agency "has no promulgated rule governing" DGME payments to teaching hospitals over the cap for cost reporting periods beginning on or after October 1, 2001.
- Section 1886(d)(4) requires CMS to "establish rules consistent with this paragraph [establishing DGME FTE counts taking into account the initial residency period and DGME FTE caps] for the computation of the number of full-time-equivalent residents in an approved medical residency training program."
- Undertaking retroactive notice-and-comment rulemaking is in the public interest because it will permit interested stakeholders to comment on the proposed approach and allow the agency to have the benefit of those comments in the development of a final rule.

The rule indicates that CMS' new policy would cover cost reporting periods for which many Notice of Program Reimbursement have already been final settled. Consistent with 42 CFR §405.1885(c)(2), any final rule retroactively adopting a proposed new policy would not be the basis for reopening final settled NPRs.

CMS proposed the following:

- If the hospital's weighted FTE count is equal to or less than the FTE cap, no adjustment is necessary.
- If the hospital's weighted FTE count is greater than the FTE cap, CMS will adjust the weighted FTE to make the total weighted FTE count equal the FTE cap as follows:

$$\frac{Weighted\ Primary\ Care\ and\ OBGYN\ FTEs}{Weighted\ FTEs\ All\ Residents} \times FTE\ Cap$$

$$+$$

$$\frac{Weighted\ All\ Other\ FTEs}{Weighted\ FTEs\ All\ Residents} \times FTE\ Cap$$

$$= Adjusted\ Weighted\ Count$$

The rule provides detailed instructions as to how these calculations would be done on the Medicare cost report.

CMS provides examples for how the adjustment would work.

Example 1:
Unweighted Cap = 100
Unweighted Count = 120
90 FTEs within the Initial Residency Period and 30 FTEs in subspecialty training.
Weighted Count = (90 x 1.0) + (30 x 0.5) = 105
Primary Care and OBGYN = 70
Other=35

Adjusted Count =

$$\frac{70}{105} \times 100 + \frac{35}{105} \times 100 = 100$$

As the weighted count of 105 residents exceeds the unweighted cap of 100 residents, the adjustment is applied using CMS' proposed formula such that when the weighted count exceeds the unweighted cap, the result will always be the unweighted cap.

Example 2:
Unweighted Cap = 100
Unweighted Count = 102
90 FTEs within the Initial Residency Period and 12 FTEs in subspecialty training.
Weighted Count = (90 x 1.0) + (12 x 0.5) = 96

As the weighted count of 96 residents is below the unweighted cap of 100 residents, no adjustment is necessary.

Public commenters were supportive of CMS' proposal but raised legal concerns about using retroactive rulemaking to establish the proposed policy. In the view of these commenters, there is neither a necessity for CMS to be in compliance with the law nor a public interest that supports retroactive rulemaking—the two bases upon which retroactive rulemaking is authorized under section 1871 of the Act for Medicare rules.

These commenters believe CMS could obtain public comment through prospective rulemaking while addressing the past through program instruction in compliance with the order of the district court. Unlike the *Allina*[53] case where the statute was ambiguous and CMS needed to fill a statutory gap when the Court struck down CMS' rule, the statute here is clear and there is no alternative to the policy CMS proposed. Citing a number of examples, commenters observed that historically, both before and after *Allina*, CMS has implemented policy changes to resolve appeals or comply with court decisions without engaging in retroactive rulemaking.

The commenters further requested that CMS reopen all cost reports within the three-year reopening period and recalculate direct GME payments consistent with the statute. Alternatively, hospitals should be permitted to reopen their cost reports for the purpose of recalculating their direct GME payments according to the revised weighting methodology. Commenters objected to CMS' statement that under 42 CFR §405.1885(c)(2), any final rule retroactively adopting proposed new policy would not be the basis for reopening final settled NPRs (87 FR 28411). Absent reopening, CMS' proposal for retroactive rulemaking has no practical effect argued these commenters.

CMS responded that section 1886(h)(4)(A) of the Act requires "[t]he Secretary shall establish rules consistent with this paragraph for the computation of the number of full-time equivalent residents…" where "this paragraph" includes the weighting methodology for residents within and beyond an initial residency period. As the *Hershey* court stated the rule at issue was not consistent with the statute, CMS concluded that the existing rule should be modified retroactively to make it consistent with the statute.

With respect to whether there is ambiguity in the statute or a policy gap to fill through rulemaking, CMS disagrees with the commenters. The entire reason for the original rule was CMS' attempt to reconcile two potentially conflicting provisions of statute—one that required a cap on residents based on an unweighted count and the other that the required weighting residents beyond the initial residency period for determining payment. CMS believes there is more than one possible way to resolve the conflict in light of *Hershey* as the Court did not mandate a particular calculation method. Further, CMS believes retroactive rulemaking would still be needed to address the new application of the cap in the context of the 3-year averaging rules left completely unaddressed by the Court.

[53] *Azar v. Allina Health Services* was a case in which the Supreme Court held that CMS did not properly go through notice and comment rulemaking to establish a policy. The Supreme Court struck down CMS' rule. Following that decision, CMS undertook retroactive notice and comment rulemaking arguing that it needed a policy for the retroactive period where there was none as a result of the Supreme Court striking down the agency's regulation.

With respect to retroactive rulemaking being inconsistent with historical practice, CMS states the examples raised by commenters do not involve judicial decisions calling into question agency rules. Here the governing statute requires the promulgation of rules consistent with statutory requirements. As the Court stated that CMS' rules were inconsistent with those requirements for the retroactive period, CMS is engaging in retroactive rulemaking to establish rules "consistent with this paragraph" for past periods. If CMS promulgated its rule prospectively only, a necessary result would be that some hospitals would receive GME reimbursement based on a computation of FTE equivalents that was not established by rule.

CMS further argues that the public interest will be served by having past payments calculated in the same way as future payments established with the benefit of notice-and-comment rulemaking. The response indicates the alternative—for plaintiffs in *Hershey* and other judicial challenges to have their payments calculated by a different methodology than other providers—would be contrary to the public interest. CMS states its rule will allow payments to hospitals with open cost reports to be determined based on a universal and transparent formula and reduce the need for hospitals to file administrative appeals in order to obtain the benefit of the new payment formula.

Regarding the applicability of 42 CFR §405.1885(c)(2) to reopening of cost reports, CMS disagrees with the commenters noting that its rule is a "change of legal interpretation or policy by CMS in a regulation . . . made in response to judicial precedent," and thus it is "not a basis for reopening a CMS or contractor determination." CMS indicates that the rule will have retroactive effect as it will allow the revised policy to benefit hospitals with past cost reporting periods that are not yet closed or settled.

After consideration of comments received, CMS is finalizing its proposed policies. Public commenters suggested a number of technical changes to the regulations and cost reporting instructions to ensure that CMS' revised policies are accurately implemented. CMS accepted these comments and is making the suggested changes to the regulations and instructions.

3. Reasonable Cost Payment for Nursing and Allied Health Education Programs

Medicare pays for provider-operated nursing and allied health education programs on a reasonable cost basis. Under the reasonable cost payment methodology, a hospital is paid Medicare's share of its reasonable costs. Provisions of law enacted in 1999 and 2000 required that CMS include Medicare Advantage (MA) utilization in determining the Medicare share of reasonable cost nursing and allied health education payments. These additional payments for nursing and allied health education attributed to MA utilization were funded through a reduction to analogous payments made to teaching hospitals for DGME and limited to $60 million per year.

CMS uses cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year to determine each eligible hospital's share of the pool in a given year. Each hospital's payment is based on its relative share of national nursing and allied health education payments and MA utilization. For initial implementation of these provisions, CMS used

rulemaking to advise the public of key data elements that went into the calculations including total MA nursing and allied health education payments and the percent reduction needed to MA DGME payments to fund the nursing and allied health education MA payments. In that rulemaking, CMS indicated it would use the annual IPPS rulemaking process to inform the public of this same information annually. However, CMS has used a sub-regulatory process (change requests) for subsequent years.[54]

For 2020 and future years, CMS proposed to use the annual IPPS rule to advise the public of key information that is used to determine nursing and allied health education MA payments and the reduction that is needed to DGME MA payments to fund the payments going to eligible hospitals. For FYs 2020 and 2021, the statutory formula for distributing nursing and allied health education payments will result in the capped payments of $60 million being distributed necessitating a reduction of 3.71 percent and 3.22 percent respectively to MA DGME payments.

CMS received one comment requesting clarification on how MA DGME payments are made relative to MA nursing and allied health payments when a hospital receives both types of payment. The final rule explains that these two policies are related but independent and each calculation is done separately according to its respective rules for calculating payment. Other comments raised concerns about various issues associated with these policies that CMS said was out-of-scope to anything they proposed. After considering the public comments, CMS is finalizing its proposal without change. Nursing and allied health education MA payments will remain capped at $60 million in each of these years and the reduction in MA DGME payments of 3.71 percent and 3.22 percent respectively for FYs 2020 and 2021 are unchanged from the proposed rule.

4. Medicare GME Affiliation Agreements and Rural Training Tracks

As noted above, hospitals are limited to the number of FTE residents they may count for DGME and IME payment to the number counted in 1996. There are provisions of regulations that allow the caps to be aggregated among hospitals that jointly train residents (known as affiliated groups).

Rural track programs (RTP) are designed to encourage the training of residents in rural areas. Historically, the Accreditation Council for Graduate Medical Education (ACGME) has separately accredited family medicine RTPs in the "1-2 format"—meaning the resident's first year is at a core family medicine program in an urban area and the second and third years are at another site in the rural area. There are provisions of law and regulations that allow urban and rural hospitals to receive adjustments to their caps for newly established RTPs. The adjustments for RTPs are determined in the same way as hospitals that are newly training residents in newly established training programs—based on the division of residents among the urban and rural hospitals during the 5th year of resident training.

[54] CMS released Change Request 2692 on May 23, 2003. This change request included a pool of $43.7 million for nursing and allied health education MA payments that required a 14.13 percent reduction to MA DMGE payments. The next Change Request was released on December 14, 2020 and provided the amounts for the nursing and allied health education MA pool for the years 2002 to 2018 that ranged from $8.7 million to $60 million and reductions to MA DMGE payments ranging from 4.58 to 9.88 percent.

When CMS first implemented the RTP regulations, it specified that the caps associated with rural tracks are separate and distinct from a hospital's general FTE caps. As a result, the rural track FTE limitations are not part of the regular FTE caps that hospitals may aggregate in Medicare GME affiliation agreements. This means that the flexibility afforded in affiliated group arrangements is not available when urban and rural hospitals jointly train residents in RTPs once caps are established at the end of the 5-year growth window. Stakeholders representing urban-rural training partnerships have requested that affiliated group arrangements be allowed for separately accredited 1-2 family medicine programs that have existed for a number of years, and either already have established their rural track FTE limitations, or have just recently reached or will reach the end of their 5-year cap building windows.

CMS agreed and proposed to allow urban and rural hospitals that participate in the same separately accredited 1-2 family medicine RTP to enter affiliation agreements for the RTP. CMS proposed the following requirements for RTP affiliated groups:

- Representatives of each urban and rural hospital must attest that the affiliated group is only for residents in the RTP and no other programs.
- Only separately accredited 1-2 family medicine programs that have rural track FTE limitations in place prior to October 1, 2022 are eligible.
- These affiliated group arrangements may become effective July 1, 2023—the beginning of the first residency training year after the October 1, 2022 effective date of this IPPS rule.

CMS proposed to preclude RTPs not separately accredited in the 1-2 format and that are not in family medicine from entering into affiliation agreements to distinguish accredited 1-2 family practice programs from other RTPs recognized under section 127 of the Consolidated Appropriations Act (CAA, 2021). The CAA, 2021 allows for cap adjustments for RTPs other than those that are separately ACGME accredited in family practice and allows for cap adjustments when new training sites are added to existing RTPs. As these provisions are effective October 1, 2022 and allow for new RTPs to be exempt from FTE caps for 5 years, CMS believes it is premature to allow these newer programs to participate in affiliated groups.

The rule specifies detailed requirements that must be fulfilled for an urban and rural hospital to participate in an affiliation agreement for a separately accredited 1-2 family practice program to aggregate FTE caps for an RTP. These rules are generally parallel to those that apply to other affiliated group arrangements.

Public comments strongly supported CMS's proposal to enable rural training flexibilities through Medicare GME affiliation agreements between urban and rural hospitals that have rural track programs. These commenters added that CMS should engage in future rulemaking that will allow any RTP, not just those separately accredited in family medicine that were established prior to October 1, 2022, to also engage in affiliation agreements following the conclusion of the cap-building period.

CMS agreed and reiterated its reason for distinguishing between accredited 1-2 family practice programs from other RTPs recognized under section 127 of the CAA, 2021 acknowledging that it may engage in further rulemaking once caps are established for RTPs that are not accredited in the 1-2 format accredited in family practice.

There was one comment opposed to CMS' proposal arguing that setting the cap based on the highest number of residents in any single program year across five years favors the urban hospital as they train residents in the first year of training. The commenter argued that CMS should use its authority to "adjust in an appropriate manner the limitation under subparagraph (F) [the DGME FTE cap] for such hospital and each such hospital located in a rural area that participates in such a training [rural training track]" to establish more equitable caps for rural hospitals. This commenter and another commenter recommended that the solution is to use the highest year, rather than using all five years when determining the ratio for cap apportionment.

CMS responded that the vast majority of commenters, including others with close ties to rural GME training, have submitted comments in support of its proposal, generally stating that this proposal will facilitate training in rural settings. With regard to the commenter's point that CMS's current cap methodology disadvantages the rural hospital in a RTP, CMS acknowledged that there might be other mathematical apportionment methods that, if tailor-made for RTPs, would result in higher caps for the rural hospital.

Nevertheless, CMS indicates that these rules are long-standing and that it is inadvisable to change the cap setting rules with the advent of CAA section 127 and the expectation that RTPs will develop not only in 3-year family medicine programs, but also in many other specialties of differing lengths. At this point, allowing Medicare GME affiliation agreements between the urban and rural hospitals participating in the same RTP may be the better solution, as it would allow the hospitals to customize their individual caps, rather than CMS instituting yet another national cap calculation methodology.

One commenter supported CMS' proposal but argued that hospital rules against comingled caps are misguided. Urban and rural hospitals participating in any RTP for the benefit of rural communities should be permitted flexibility to participate in affiliated group arrangements as it would promote the adoption of model partnerships. CMS reiterated how its rules work for separate affiliated group arrangements for the FTE caps in general and those for RTPs. However, it did not explain the underlying reason for why its rules prohibit comingling of RTP caps and other resident caps when participating in affiliated groups. CMS does not believe its rules limit the flexibility of rural hospitals seeking to create model partnerships as the commenter asserts.

After consideration of the public comments, CMS is finalizing its proposal without modification.

F. CAR-T and Immunotherapy Cases

In some cases, CAR-T cell or other immunotherapy patients may be part of a clinical trial where the high-cost therapy product is furnished to the hospital at no cost. Beginning with FY 2021, CMS adopted a differential payment for these cases to recognize hospitals' lower costs. CMS also excluded CAR-T cases billed with a clinical trial indicator (ICD-10-CM diagnosis code

Z00.6) and drug costs of less than $373,000—the average sales price of the two CAR-T cell products approved to treat relapsed/refractory diffuse large B-cell lymphoma in drug costs—from the relative weight calculation.

CMS proposed to adopt these same policies for FY 2023. For FY 2023, CMS estimated that the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases is 20 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases. Accordingly, CMS proposed to adjust the payment for MS-DRG 018 by applying an adjustor of 0.20 to the full payment amount in those situations where the hospital does not have a cost for the CAR-T or other immunotherapy product.

The proposed rule also indicated that this policy will not apply to clinical trial cases where the CAR-T or immunotherapy product was purchased through the normal mechanisms but the clinical trial was of another product. CMS did not find any occurrences in the data of this situation but developed modifier "ZC" that hospitals may use to exclude these cases from the policy when they occur.

CMS further notes that the policy will apply to expanded access use of immunotherapy—also known as "compassionate use," a potential pathway for a patient with an immediately life-threatening or serious disease to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. While CMS is unaware of any of these situations in the data, it believes a hospital would not have drug costs that are $373,000 or above because compassionate use drugs or biologicals are typically provided to the hospital at no cost.

There were no comments on the proposed payment policy that CMS is finalizing without change other than updating the adjustment based on final rule data to 0.21. One commenter requested that "compassionate use" situations be identified on a Medicare claim using condition code 90 to avoid manual processing by the MAC. CMS agreed. This issue is also addressed in section II. B. of this summary.

G. Hospital Readmissions Reduction Program (HRRP)

CMS finalizes as proposed to resume use of the *Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization* measure in the HRRP beginning with FY 2024 program year. Technical adjustments to the measure's specification also are affirmed, along with adding a risk adjustment for history of COVID-19 disease to the specifications of all of the program's measures starting with the FY 2024 program year.[55] Responses received to an RFI concerning the promotion of health equity by incorporating performance for socially at-risk populations into the HRRP in future years are also reviewed.

No changes are made to the Program's payment calculation methodology. Per policy, the FY 2023 applicable period—the 3-year period from which data are collected for HRRP calculations— will include discharges from July 1, 2018 through June 30, 2021. Also, per policy,

[55] Technical changes determined by CMS to be non-substantive are not subject to notice-and-comment rulemaking though may be announced during rulemaking as a method of informing interested parties.

CMS will use claims-paid data for the applicable period from the Medicare Provider Analysis and Review (MedPAR) file for aggregate payment calculations.[56] The usual review and correction period will be provided to hospitals that have questions about the calculation of their results.

CMS states that no reporting burden is associated with the HRRP as all of the program's measures are claims-based and require no data beyond those already submitted by hospitals for billing purposes. In the regulatory impact analysis section of the rule, CMS estimates that 2,273 hospitals, or 79.8 percent of those eligible (2273/2849), will be penalized under the Program in FY 2023. Aggregate penalties are estimated to represent 0.42 percent of total base operating DRG payments to those hospitals; as usual, estimated dollar amounts of penalties are not provided. An unnumbered table (see Appendix A section I.H.4. of the rule) shows the variation in these impacts when stratified by hospital characteristics (e.g., size, location).

1. HRRP Basics

Under the Program, hospitals with disproportionately high numbers of readmissions for 6 common conditions and procedures have their adjusted operating base DRG payments reduced by up to 3 percent: acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); elective total hip arthroplasty (THA)/total knee arthroplasty (TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass surgery (CABG). Excess Readmission Ratios (ERRs) are calculated for each hospital and condition combination, and each hospital's weighted average ERR is compared to the median ERR of its peer group. Peer group assignment is based on hospitals' proportions of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligible beneficiaries. From the ERR comparisons, each hospital is assigned an adjustment factor that ranges from 1.0 (no payment reduction) to 0.9700 (maximum 3 percent payment reduction).

In the rule, CMS provides sources for the legislative and regulatory histories of the HRRP and refers readers to the Program's requirements at §§412.152 through 412.154. Details of the program's scoring and payment methodology are available for download at https://qualitynet.cms.gov/inpatient/hrrp/resources. General information about the Program is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program and https://qualitynet.cms.gov/inpatient/hrrp.

2. Current HRRP Measures

No changes are made to the HRRP measure set for FY 2023 or subsequent years, shown below:

- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia (PN) Hospitalization (NQF #0506),
- Hospital 30-Day All-Cause Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization (NQF #0505),

[56] CMS uses the annual March MedPAR file update from each year of the applicable period and applies the exclusion rules from the HRRP measure set's methodology to select the claims to be used in HRRP calculations. Only Fee-for-Service Medicare claims are used.

- Hospital 30-Day, All-Cause, Unplanned, Risk-Standardized Readmission Rate (RSRR) Following Coronary Artery Bypass Graft (CABG) Surgery (NQF#2515),
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (NQF #1891),
- Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Heart Failure Hospitalization (NQF #0330), and
- Hospital-Level 30-Day, All-Cause Risk-Standardized Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #1551).

3. HRRP Policy Flexibility in Response to the COVID-19 PHE

a. Measure Suppression Policy, Measure Suppression Factors, and Extraordinary Circumstances Exception (ECE) Policy

CMS makes no changes to the program's measure suppression policy or the associated measure suppression factors for FY 2023, nor to the program's ECE policy.

During FY 2022 rulemaking, CMS adopted a cross-program measure suppression policy for the HRRP and its other value-based programs for the duration of the COVID-19 PHE.[57] The policy allows measure suppression and downstream adjustments to program calculations and payment reductions when the agency determines that circumstances caused by the COVID-19 pandemic have significantly affected the measures. Also adopted were Measure Suppression Factors for use in guiding decision-making about suppression (86 FR 45251). The ECE policy was updated during FY 2022 rulemaking to affirm its applicability to the COVID-19 PHE.

b. *Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia (PN) Hospitalization* measure (CMS 30-Day Pneumonia Readmissions Measure) (NQF #0506)

Resumption of Measure Use with Program Year FY 2024

CMS finalizes as proposed to resume the use of the CMS 30-Day Pneumonia Readmissions measure for scoring and payment adjustment purposes beginning with program year FY 2024 after the end of its previously finalized suppression for program year FY 2023.

Based on internal data analyses, CMS believes that changing patterns of COVID-19 disease along with ICD-10-CM diagnostic coding changes and measure specification updates will allow accurate identification of patients for whom pneumonia readmissions are not due to COVID-19. As a result, the population of patients for whom the measure is intended will be captured (i.e., readmissions that reflect quality of care delivered by the hospital rather than unpredictable and uncontrollable effects of a pandemic).

[57] CMS identifies the value-based programs as the HRRP, Hospital Value-Based Purchasing Program, Hospital Acquired Condition Reduction Program, Skilled Nursing Facility Value-Based Purchasing Program, and ESRD Quality Incentive Program.

Commenters mostly were supportive of measure resumption, though urged continued monitoring for impacts of the COVID-19 PHE as the patterns of disease and the range of available prevention and treatment strategies continue to evolve. CMS responds that monitoring will be ongoing. Some commenters recommended postponing measure resumption until the end of the PHE is declared and more experience has been gained with reporting new COVID-related diagnostic codes. CMS responds that its data simulations support sufficient reliability of the measure for resumption of its use in program year 2024. Some commenters asked that CMS make all of their HRRP data analyses publicly available. The agency responds that data have been included in discussions of the program during rulemaking. Other commenters opposed the agency's plan for uninterrupted public reporting of the measure's results even while the measure is suppressed. CMS disagrees, citing the value of performance transparency to the public, and believes that public reporting is appropriate when accompanied by caveats about COVID-19 impacts on the measure's results.

Technical Specification Changes to Exclude COVID-19 Patients

Also, for program year FY 2024 and subsequent years, CMS affirms its prior announcement that technical changes will be made to the pneumonia readmission measure's specifications to exclude patients with COVID-19 diagnoses present on admission (POA) from the measure's numerator and denominator. Diagnosis coding specific for pneumonia POA caused by COVID-19 has become available and will be added to the measure's exclusions. Also, a covariate adjustment will be added for patients with a history of COVID-19 disease occurring in the 12 months before their initial admissions for pneumonia.

CMS notes that the same covariate adjustment will be applied to all of the HRRP's other measures beginning with program year FY 2023. The covariate is being added earlier for those measures as they, unlike the pneumonia readmission measure, are not suppressed from the program for FY 2023. CMS shares comments it received about the changes though notes that technical changes are not subject to notice-and-comment rulemaking. The changes were announced in the preambles of the FY 2022 IPPS proposed and final rules as a means of reaching a wide audience of interested parties rather than publicized only via sub-regulatory guidance.

Many commenters were supportive of adding the covariate adjustment. Others were concerned that data about COVID coding accuracy are not mature enough to conclude that all patients will be identified. In particular, the random use of in-home testing was mentioned as a potential diagnostic confounder. Accounting for effects of "long COVID" was also raised as a concern. CMS mentions data from its analyses, though does not present them in detail, that suggest the covariate may not even be necessary. The agency has chosen to proceed with covariate addition to help ensure that COVID-related impacts on the HRRP measures are in fact sufficiently accounted for when making payment reductions under the program. CMS indicates that all HRRP measure specifications and results will be monitored and further adjusted as appropriate. CMS anticipates retaining the newly updated specifications for all of the HRRP measures permanently (i.e., beyond the end of the PHE) though will reconsider if future measure results suggest otherwise.

4. Request for Public Comment on Possible Future Inclusion of Health Equity Performance in the Hospital Readmissions Reduction Program

Through this request CMS sought comment on approaches to updating the HRRP by incorporating hospital performance for socially at-risk populations with a focus on using the CMS Disparities Methods (i.e., within-hospital and across-hospital comparisons). Feedback reports would initially be provided confidentially to hospitals. The agency's stated objective is to encourage providers to improve equity and reduce disparities without discouraging treatment of socially at-risk beneficiaries or penalizing hospitals that treat them in large numbers. Highlights from the agency's presentation of responses received are provided below, grouped by the questions posed in the request for comment. CMS does not respond to the comments and simply states that input received will be considered in future policy development. Readers are also referred to the broad-based RFI discussed in section IX.B. that focuses on key considerations for measuring healthcare quality disparities.

- Benefit and potential risks, unintended consequences, and costs of incorporating hospital performance for beneficiaries with social risk factors into the HRRP

Current disparity methods fail to provide actionable information for providers.
Benefits include improved care for all patients.
Hospitals will be held accountable for factors outside of their control, and publicly posting results will imply that hospitals alone are responsible for readmissions.
Before implementing any changes, CMS must assess financial effects on the HRRP.

- Preferred approach for linking payment reductions to performance in caring for socially at-risk populations: comparing outcomes for socially at-risk beneficiaries across hospitals or comparing outcomes within a hospital for one or more of its socially-at-risk subpopulations

Linkage could disproportionately penalize safety net providers.
Bonus points awarded to hospitals treating large numbers of at-risk beneficiaries could minimize unintended effects.
Peer grouping by dual eligibility patient proportions and stratified reporting to hospitals has a short track record, several years of which include the confounding performance measurement effects of the COVID-19 PHE. Time should be allowed for more data accrual and analysis before making further changes.
The performance period for HRRP measures already requires 3 years to yield reliable data; stratification will likely lead to sample sizes too small for reliability.
Improving quality for all beneficiaries through readmissions reduction is the purpose of the program; changing the purpose to advancing health equity could be considered inappropriate and outside of Congressional intent.
Support was greater for use of the CMS Disparities Methods in combination rather than either the within-hospital or across-hospital method alone.

- Measures or indices of social risk, in addition to traditional dual eligibility (full Medicare and Medicaid benefits), that should be used in the HRRP to measure hospital performance in achieving equity.

Adding measures is unnecessary because the program is currently designed to recognize hospitals treating large fractions of high-risk patients through peer grouping and risk adjustment using a factor known to reflect multiple demographic and social risk factors (i.e., dual eligibility).
Numerous potential social risk metrics were suggested (e.g., area-based indices) and support for continued use of dual eligibility was expressed.

H. Hospital Value-Based Purchasing Program (HVBP)

CMS finalizes suppression of multiple HVBP Program measures and adopts a special scoring rule for program year FY 2023. Funds withheld from hospitals per statute will be returned to hospitals as value-based incentive payments in amounts that match their withholds, yielding a net percentage payment adjustment of zero. Also finalized are updated baseline and performance periods for certain measures for program year FY 2025. Updated performance standards are provided for program years FY 2025 through FY 2027.

No changes are made to the Program's measure set as listed in section V.I.7 of this summary. Technical updates to the specifications for measures in the Clinical Outcomes domain beginning with program year FY 2023 as announced in the proposed rule are affirmed. No changes are proposed to established policies for retention and removal of HVBP measures, measure and case number minimums, domain weights, or the extraordinary circumstances exception process.[58]

CMS estimates that in the aggregate there would be no net financial impact to the HVBP Program for program year FY 2023. The estimated amount of base operating MS-DRG payment reductions would equal the estimated amount available for value-based incentive payments for FY 2023 discharges, approximately $1.7 billion. The Program also would be net neutral for hospitals. CMS also indicates that no burden changes occur as a result changes made in this rule.

1. HVBP Basics

Under the Program, CMS calculates the HVBP incentive payment percentage for a hospital based on its Total Performance Score (TPS) for a specified performance period. A hospital's incentive payment adjustment factor for a fiscal year combines a uniform 2 percent contribution to the Program's incentive payment funding pool (i.e., a reduction to each hospital's base operating DRG payments) with a performance-based, hospital-specific incentive payment percentage derived from the hospital's TPS. The adjustment factor may be positive, negative, or result in no change in the payment rate that would apply to the hospital absent the Program.

The TPS for each hospital is calculated by summing the greater of the hospital's achievement or improvement points for each measure then creating domain scores that themselves are summed as the TPS.[59] CMS converts the hospital TPS into a value-based incentive payment percentage

[58] Table V.I.-14 in the rule shows the current case minimums by domain.
[59] The four domain scores—Person and Community Engagement, Clinical Outcomes, Safety, and Efficiency and Cost Reduction—count equally toward the TPS, weighted at 25 percent each.

through a linear exchange function, under which the sum of all hospitals' payments will equal the total amount of dollars contributed to the VBP funding pool.

Additional information on the Program is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing and https://qualitynet.cms.gov/inpatient/hvbp.

2. HVBP Policy Flexibility in Response to the COVID-19 PHE

a. Measure Suppression Policy, Measure Suppression Factors, and Extraordinary Circumstances Exception (ECE) Policy

CMS makes no changes for program year FY 2023 to the program's measure suppression policy itself or the associated measure suppression factors, nor to the program's ECE policy. Proposals regarding suppression of specific measures are finalized and described further below.

During FY 2022 rulemaking, CMS adopted a cross-program measure suppression policy for the HVBP Program and its other value-based programs for the duration of the COVID-19 PHE. The policy allows measure suppression and downstream adjustments to program calculations and payment reductions when the agency determines that circumstances caused by the COVID-19 pandemic have significantly affected the measures. Also adopted were Measure Suppression Factors for use in guiding decision-making about suppression (86 FR 45267). Multiple measures were suppressed for program year FY 2022 and resulted in the adoption of a special scoring policy under which all funds withheld for purposes of the program for that year were returned to hospitals in full in accordance with the withholds (i.e., not based on performance).

b. Previously Finalized Actions for Program Year FY 2023

During FY 2022 rulemaking, CMS finalized actions for program year FY 2023 as listed below, which are unchanged by this FY 2023 IPPS/LTCH PPS final rule.

- Suppression of one of six measures in the Clinical Outcomes domain under measure suppression factor 2—*Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate following Pneumonia (PN) Hospitalization measure (NQF #0506) (MORT-30-PN).*
- Adoption of non-substantive technical specification updates for the five unsuppressed Clinical Outcomes domain measures—excluding admissions with either a principal or secondary diagnosis of COVID-19 from the numerators and denominators of the measures—with dissemination of the changes through sub-regulatory guidance.
    - Hospital 30-day mortality (MORT-30) rates following hospitalizations for acute myocardial infarction (AMI), chronic obstructive pulmonary disease (COPD), and heart failure (HF);
    - Hospital 30-day mortality (MORT-30) rate following coronary artery bypass graft surgery (CABG); and
    - Hospital-level complication rate (COMP-HIP-KNEE) following primary elective hip or knee joint replacement surgery (THA or TKA, respectively).

c. Newly Finalized Actions for Program Year FY 2023

(1) Person and Community Engagement Domain: Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Measure (NQF #0166)

CMS finalizes as proposed to suppress the HCAHPS measure for reasons including significant deviations in national performance and effects of significant national staffing shortages. Because HCAHPS data do not include individual patient diagnoses, the measure cannot be adjusted through technical specification changes that depend upon identifying COVID-19 patients. Further, since the HCAHPS measure is the only one in the Patient Safety domain of the HVBP Program measure set, CMS will be unable to calculate a domain score.

Most commenters were supportive of suppression. A few opposed suppression citing that the value of transparency should be prioritized. CMS responds that transparency will be served by public reporting of the data, accompanied by caveats concerning the limitations of the data.

(2) Safety Domain: Healthcare-Associated Infection (HAI) Safety Measures

CMS finalizes as proposed to suppress all 5 Safety Domain measures based on significant deviations in national performance, changes in safety guidelines, and effects of significant national staffing shortages. These measures are reported by hospitals through the National Health Safety Network (NHSN): catheter-associated urinary tract infection (CAUTI), central line-associated bloodstream infection (CLABSI), surgical site infections (SSI) after abdominal hysterectomy and colon operations, bacteremia caused by *Methicillin-resistant Staphylococcus aureus* (MRSA), and hospital-onset Clostridium difficile infections (CDI). CMS provides some data tables to support their decision for suppression.

CMS will not generate achievement or improvement points for these measures and will not calculate Safety Domain scores. HAI rates will be calculated and publicly posted with explanatory material about effects of the pandemic on the measure data. CMS notes that risk adjustment to account for COVID-19 effects is not feasible for these measures as the data are submitted to CDC as aggregate facility rather than individual patient level. CMS states a goal of resuming full use of these measures for scoring and payment adjustments for program year FY 2024.

Most commenters were supportive of suppression for purposes of scoring and payment adjustments. A few opposed suppression of any public reporting, voicing that the value of transparency should be prioritized. CMS responds that transparency will be served by public reporting of the data, accompanied by caveats concerning the limitations of the data. Individual commenters raised concerns including overemphasis by on statistical analysis compared to patient safety and whether CMS is exceeding its authority by suppressing these measures. CMS responds that a measure-by-measure approach to suppression based on available data was chosen because of the numerous effects of the COVID-19 PHE and because those effects were distributed quite unevenly in terms of timelines and geography. Another concern was voiced about potential worsening of disparities by suppression, but CMS believes that public posting of

data will allow data analysis for disparities. CMS also pledges to continue to monitor the results of these measures to detect unintended consequences of suppression.

d. Technical Specification Updates

CMS affirms technical specification updates beginning with program year FY 2023 that will add a covariate adjustment for patients with a history of COVID-19 diagnoses occurring in the 12 months before their initial admissions for pneumonia to 5 of the program's 6 Clinical Outcomes domain measures: 30-day All-Cause, Risk-Standardized Mortality Rates following hospitalizations for acute myocardial infarction (AMI), heart failure (HF), chronic obstructive pulmonary disease (COPD), coronary artery bypass graft surgery (CABG), and primary total hip or total knee arthroplasties (THA/TKA).

CMS announces adding the same covariate for history of COVID-19 diagnosis to the pneumonia mortality measure specifications for program year FY 2023 rather than waiting until FY 2024 when suppression of that measure will end. Also, for program year FY 2023, this measure's specifications will be revised to match the other mortality measures by excluding patients with diagnoses of COVID-19 POA. The fully updated specifications will be applicable when use of this measure in the HVBP Program resumes starting in program year FY 2024.

CMS shares comments it received about the technical specification updates although the updates are not subject to notice-and-comment rulemaking. The change announcements have been included during rulemaking for program years FY 2022 and FY 2023 as a means of reaching a wide audience of interested parties rather than publicized only via sub-regulatory guidance.

Many commenters were supportive of adding the covariate adjustment to the HVBP Program and noted the potential to account for the effects of "long COVID" with this adjustment. Others were concerned that data about COVID coding accuracy are not mature enough to conclude that all patients will be identified. In particular, the random use of in-home testing was mentioned as a potential diagnostic confounder. Some suggested that the 12-month lookback of the measure may be too short. CMS mentions data from its analyses that suggest the covariate may not even be necessary. The agency has chosen to proceed with covariate addition to help ensure that COVID-related impacts on the HVBP Program measures are in fact sufficiently accounted for when making payment adjustments under the program. CMS indicates that all HVBP Program measure specifications and results will be monitored and specifications further adjusted as appropriate.

Commenters were divided in their support of resuming use of the pneumonia mortality measure as part of the HVBP Program starting in program year FY 2023. CMS indicates that its data analyses support measure resumption. Hospitals will begin receiving confidential results reports for this updated measure in October 2022 and public reporting will begin in January 2023.

e. Special Scoring Rule for Program Year FY 2023

CMS finalizes as proposed to adopt a special scoring rule for program year FY 2023 for hospitals eligible for the HVBP Program. Three of 4 measure domains and almost half of the program's

total measure set will be affected by finalized measure suppression described earlier in the rule, and CMS believes that meaningful scoring and equitable payment adjustments are not possible. Key features of the special scoring policy as finalized are listed below and align with the special scoring policy implemented for program year FY 2022.

- Rates will be calculated for all HVBP Program measures.
- Achievement or improvement points will be calculated for the 6 unsuppressed measures.
- No hospital will be awarded a TPS.
- Each hospital's base-operating DRG payment amount will be reduced by 2 percent.
- CMS will assign to each hospital a value-based incentive payment amount that matches its 2 percent reduction (i.e., unrelated to any measure scoring results).
- Hospital-specific reports with measure rates for all measures regardless of suppression, achievement and improvement points for unsuppressed measures, and scores for the Clinical Outcomes and Efficiency and Cost Reduction domain scores will be provided confidentially to hospitals.
- After the review and correction period for hospital reports has ended, rates for both suppressed and unsuppressed measures will be displayed publicly with explanations about measure suppression and COVID-19 PHE effects on hospital performances.

Most commenters were supportive of the special scoring policy and associated payment methodology for program year FY 2023. A few commenters objected to the special scoring policy as unfairly ignoring the efforts of hospitals that have performed well thus far through the pandemic, but CMS reiterates that fair comparisons cannot be made on a national basis. Many recommended continued monitoring of performance on the program's measures to determine if continued suppression or special scoring is warranted for future years. CMS pledges to ongoing monitoring though believes that hospital performance beginning with program year 2024 will be sufficiently stable and reliable to resume use of all program measures and established scoring and payment methodology. Commenters disagreed as to whether program year FY 2023 results should be publicly reported; CMS affirms its decision to continue public reporting per established program policy.

3. Additional Suppression-Contingent Payment Details for FY 2023

In the regulatory impact analysis, CMS states that the impact for every hospital subject to the HVBP Program for program year FY 2023 will be a net percentage payment adjustment of 0. This impact is a result of measure suppression and the special scoring policy for program year 2023 as adopted in this final rule. In accordance with that policy, hospitals will be subject to the usual annual 2 percent withhold from their MS-DRG operating payments for the HVBP Program. However, the withheld funds will be returned to each hospital as payments equal to their respective withholds, unrelated to their performances on HVBP Program measures. CMS estimates that the withheld funds in aggregate will total $1.8 billion and therefore the monies returned to hospitals will total approximately $1.8 billion.

In the proposed rule, CMS used the program's established methodology to model program year FY 2023 payment adjustment factors using FY 2021 data as shown in Table 16 of that rule. These data were to be updated as Tables 16A and 16B once hospitals were awarded TPS scores

and payment adjustment percentages. Since no hospital will be awarded a TPS score due to measure suppression and the program year FY 2023 special scoring policy, Tables 16A and 16B will not be published. Absent measure suppression and special scoring, these tables would display final payment adjustments to hospitals and the final slope of the program's linear exchange function for the program year.

Finally, CMS acknowledges that the special scoring rule, under which no hospital is awarded a TPS, will affect some clinicians participating in the Merit-Based Incentive Payment System (MIPS) pathway of Medicare's Quality Payment Program (QPP). MIPS permits clinicians who meet the eligibility criteria for *facility-based measurement* to be scored for the MIPS Quality and Cost performance categories based on the HVBP Program's TPS results for their hospitals. Since TPS results will not be available for FY 2023, those clinicians will be expected to participate in the QPP through another MIPS option.

CMS received comments about the special scoring policy expressing concern for the effects of that policy on MIPS participants who are eligible for facility-based scoring. Options were suggested including assigning neutral MIPS payment adjustment percentages to the affected clinicians. CMS does not support any of the options suggested and states that changes to MIPS policies would have to be implemented through that program's policy-making processes.

4. Baseline and Performance Periods

CMS finalizes updates to the baseline periods for the CAHPS survey measure and the 5 HAI Safety Domain measures for program year FY 2025 as proposed. The changes are being made to account for the downstream effects of measure suppression due to the COVID-19 PHE.

Most commenters were supportive of the baseline period revisions. Opposition was rare and cited the lag times between the baseline period (finalized as 2019), the performance period (remains 2023) and the payment adjustment (program) year (FY 2025). CMS responds that no other, earlier 1-year baseline period without COVID-19 PHE impacts was available.

CMS provides updated tables for all measures and domains for HVBP Program years FY 2024 through FY 2028 as Tables V.I.-04 through V.I.-08 in the rule. The revised periods for the FY 2025 program year are reproduced below for the measures and domains being updated. The baseline and performance periods previously established for the program's remaining measures are unchanged and not shown.

Finalized Program Year FY 2025 Baseline and Performance Periods		
Measure	**Baseline Period**	**Performance Period**
Person and Community Engagement Domain		
HCAHPS	1/1/19 – 12/31/19	1/1/23 – 12/31/23
Safety Domain		
CAUTI	1/1/19 – 12/31/19	1/1/23 – 12/31/23
CLABSI	1/1/19 – 12/31/19	1/1/23 – 12/31/23
SSI	1/1/19 – 12/31/19	1/1/23 – 12/31/23
CDI	1/1/19 – 12/31/19	1/1/23 – 12/31/23

Finalized Program Year FY 2025 Baseline and Performance Periods		
Measure	**Baseline Period**	**Performance Period**
MRSA	1/1/19 – 12/31/19	1/1/23 – 12/31/23
Source: Tables V.I.-04 through V.I.-08 in the rule, excerpted by HPA		

5. Performance Standards

CMS provides finalized program year FY 2025 performance standards in Tables V.I.-9 and V.I.-10 of this final rule. The values listed reflect the updated baseline periods for the CAHPS survey and HAI measures that are newly finalized in this final rule (CY 2019). The values for program year FY 2025 for the Clinical Outcomes and Efficiency and Cost Reduction domains and measures also are provided in Table V.I.-09 and are unchanged by this final rule from when previously established.

CMS also provides as Tables V.I.-11 and V.I.-12, respectively, the previously established program year FY 2026 and program year FY 2027 performance standards for the Clinical Outcomes and Efficiency and Cost Reduction domains and measures. CMS notes that data from Q1 and Q2 of CY 2020 were excepted from program year FY 2027 calculations as a result of the quality data reporting waiver granted in CY 2020 as part of the agency's response to COVID-19 PHE impacts that were already identifiable at that time.

Finally, CMS provides Table V.I-13, which is titled as newly established standards for program year FY 2027. However, the accompanying narrative section of the preamble (section V.I.5.e.) describes this table as containing standards for program year FY 2028.

6. Requests for Information (RFIs)

CMS refers readers to section IX.E.9.a. of the rule wherein CMS describes comments received about possible future addition of two digital quality measures to the Hospital Inpatient Quality Reporting (IQR) Program measure set: the Healthcare-Associated Clostridioides difficile Infection Outcome Measure and the Hospital-Onset Bacteremia & Fungemia Outcome Measure. Measures from the IQR measure set are eligible for future adoption into the HVBP Program measure set after a period of use and public reporting through the IQR program, and the RFI also seeks feedback about the potential future inclusion of these two digital measures in the HVBP Program.

Readers also are referred to section IX.B. of the rule where CMS describes comments received in response to an RFI focused on overarching principles for use in measuring healthcare quality disparities in hospital quality and value-based purchasing programs, including the HVBP.

7. HVBP Measure Summary Table

Readers are referred to Table V.I.-03 of the rule that displays the HVBP measure set for HVBP program years FY 2023 through FY 2026. The table is reproduced below with minor formatting modifications and the addition of the HCAHPS component survey items.

HVBP Measures and Domains by Program (Payment) Year					
Measure	**NQF #**	**2022**	**2023**	**2024**	**2025/ 2026**
Clinical Outcomes Domain					
Acute Myocardial Infarction (AMI) 30-day mortality rate*	0230	X	X	X	X
Heart Failure (HF) 30-day mortality rate *	0229	X	X	X	X
Pneumonia (PN) 30-day mortality rate*	0468	X	X	X	X
Complication rate for elective primary total hip arthroplasty/total knee arthroplasty (COMP-HIP-KNEE)*	1550	X	X	X	X
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate*	1893	X	X	X	X
Coronary Artery Bypass Graft (CABG) 30-day mortality rate*	2558	X	X	X	X
Safety Domain					
CMS Patient Safety and Adverse Events Composite (CMS PSI 90)**	0531		Removed		
Central Line Associated Blood Stream Infection (CLABSI)*	0139	X	X	X	X
Catheter Associated Urinary Tract Infection (CAUTI)*	0138	X	X	X	X
Colon and Abdominal Hysterectomy Surgical Site Infections (SSI)*	0753	X	X	X	X
Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Bacteremia*	1716	X	X	X	X
Clostridium Difficile Infection (CDI)*	1717	X	X	X	X
Person and Community Engagement Domain					
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS)* *Communication with Nurses* *Communication with Doctors* *Responsiveness of Hospital Staff* *Communication About Medicines* *Cleanliness and Quietness of Hospital Environment* *Discharge Information* *Overall Rating of Hospital* *3-Item Care Transition measure (CTM)*	0166 0228	X	X	X	X
Efficiency and Cost Reduction Domain					
Medicare Spending per Beneficiary	2158	X	X	X	X
* Suppressed for payment purposes for program year FY 2023					
**The predecessor measure, the AHRQ PSI–90 patient safety composite, was removed beginning with FY 2019. Reporting of the successor measure was to start with FY 2023 but instead removal of the measure was finalized for FY 2023 in the FY 2022 IPPS/LTCH PPS final rule.					

I. Hospital-Acquired Condition (HAC) Reduction Program

For program year FY 2023, CMS finalizes proposals to suppress all six HAC RP measures and not to calculate measure scores or Total HAC Scores. Absent Total HAC Scores, no hospitals will be penalized under the HAC RP for the year. CMS also announces technical specifications updates to the CMS Patient Safety and Adverse Results Composite (CMS PSI 90) measure volume threshold, effective beginning with program year FY 2023. For program year FY 2024, CMS finalizes the suppression of FY 2021 data from all five Hospital-Associated Infections (HAI) measure calculations. CMS also announces risk adjustment technical specification updates for the CMS PSI 90 measure.

No changes are being made to established program policies for measure removal or retention, scoring review and corrections period, data validation, or granting extraordinary circumstances exceptions. Because hospitals will still be required to collect and submit HAC RP data despite measure suppression, CMS estimates that provider burden imposed by the HAC RP will not be changed from prior estimates for program years FY 2023 or FY 2024.

When the established HAC RP scoring and payment adjustment methodologies are followed, the penalties collected from poorly performing hospitals are transferred to the Medicare trust fund. Because no Total HAC Scores are being awarded for program year FY 2023, no penalties will be collected and no money transferred. CMS estimates the amount transferred to the trust fund would have been $350 million.

1. HAC RP Basics

Under the Program, a 1 percent reduction in IPPS payments is made to hospitals that are identified as being in the worst performing quartile nationally based on a set of six HAC-related measures. The Total HAC Score is calculated as the equally weighted average of the individual measure scores.[60] The distribution of Total HAC Scores for all hospitals is used to define the top quartile of hospitals (i.e., worst performers), members of which will be subject to the HAC program's penalty. Payment reductions are applied at the claim level. Performance data are reported confidentially to hospitals for review and correction, following which hospital-level results are publicly reported on the CMS Provider Data Catalog website https://data.cms.gov/provider-data/.

More information on the HAC Program is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program and https://qualitynet.cms.gov/inpatient/hac.

2. Current HAC Program Measure Set

No changes are proposed to the HAC RP measure set for program year FY 2023. The measure set contains a composite patient safety measure (CMS PSI 90) incorporating several patient safety indicators identified by the Agency for Healthcare Research and Quality (AHRQ). The set also includes five CDC NHSN Healthcare-Associated Infection (HAI) measures that address catheter-associated urinary tract infection (CAUTI), central line-associated bloodstream infection (CLABSI), surgical site infections (SSI) after abdominal hysterectomy and colon operations, bacteremia caused by Methicillin-resistant Staphylococcus aureus (MRSA), and hospital-onset Clostridium difficile infections (CDI). The measures for program year FY 2023 are listed in an unnumbered table in section V.J.3.a. of the rule. A table listing the measures by program year is provided in section V.J.8. of this summary.

[60] Winsorized z-scores are used by CMS when determining Total HAC scores as a means of mitigating outlier effects.

3. HAC Program Policy Flexibility in Response to the COVID-19 PHE

a. Measure Suppression Policy, Measure Suppression Factors, and Extraordinary Circumstances Exception (ECE) Policy

CMS makes no changes for program year FY 2023 to the program's measure suppression policy itself or the associated measure suppression factors, nor to the program's ECE policy. Proposals regarding suppression of specific measures were proposed and are finalized as described further below.

During FY 2022 rulemaking, CMS adopted a cross-program measure suppression policy for the HAC RP and its other value-based programs for the duration of the COVID-19 PHE. The policy allows measure suppression and downstream adjustments to program calculations and payment reductions when the agency determines that circumstances caused by the COVID-19 pandemic have significantly affected the measures. Also adopted were Measure Suppression Factors for use in guiding decision-making about suppression (86 FR 45302).

b. Prior Actions for Program Year FY 2023

For program year FY 2022, CMS did not suppress any measures or change the program's scoring methodology. Instead, CMS accounted for the impacts of the COVID-19 PHE by (1) excluding all CY 2020 data from performance calculations (measure and Total HAC scores) for program years FY 2022 and FY 2023, and (2) adjusting applicable performance periods for all measures for program years FY 2022, FY 2023, and FY 2024 to account for excluded data. (The adjusted appliable periods are shown in an unnumbered table in section V.J.2.b.(1) but are further modified later in the rule for future years as discussed below.) Having made those changes, CMS proceeded to calculate Total HAC scores and to apply payment penalties for program year FY 2022 using the previously established HAC RP methodology.

c. Final Actions for Program Year FY 2023

Measure Suppression and Results Reporting for NHSN HAI Measures

For program year FY 2023, CMS finalizes as proposed to suppress the CY 2021 HAI measure data based on its internal analyses showing continued COVID-19 PHE impacts on the measures. As a result, CMS also finalizes as proposed to suppress the 5 CDC NHSN HAI measures from the calculation of measure scores and the Total HAC score for the purposes of scoring and payment for program year FY 2023. Therefore, CMS further finalizes that no hospital will receive a Total HAC score for the year and no hospital will be penalized under the HAC RP for program year FY 2023. Per existing policy, the actual results (infection rates) for the 5 HAI measures still will be reported to hospitals and publicly. However, measure scores of "N/A", Total HAC Scores of zero, and payment reduction indicators of "no penalty" also will be reported publicly.[61]

[61] Measure scoring involves the awarding of achievement and improvement points based on the measure data which will not be possible due to suppression of CY 2021 data.

CMS received numerous public comments both in support of and in opposition to its HAI measure-related scoring and payment proposals. Supportive commenters agreed with CMS that hospitals should not be held accountable for extraordinary circumstances outside of their control and that the proposed changes would facilitate stability of hospitals during ongoing pandemic-related challenges. Commenters voicing opposition addressed concerns emphasizing loss of public accountability of hospitals for their outcomes. Commenters were also divided about public reporting of HAI measure results, citing the value of transparency and the potential for public confusion by skewed data. CMS rejects a suggestion to allow hospitals to opt in to reporting of their results.

Measure Suppression and Results Reporting for CMS PSI 90

CMS finalizes as proposed to suppress CY 2021 data from scoring of the CMS PSI 90 measure and data use for Total HAC score calculations and payment adjustments for program year FY 2023. CMS notes its findings of the impact on the measure's results of decreased case volumes for component safety indicators that are captured in the CMS PSI 90 composite measure. As noted above, the net effect of HAI and CMS PSI 90 suppression will be that no hospital will be penalized under the HAC RP for program year FY 2023.

Commenters were split between support and opposition, for reasons similar to those described above in response to HAI measure suppression and scoring changes, and CMS provides responses similar to those described above.

CMS also proposed for program year FY 2023 not to report CMS PSI 90 results to hospitals or publicly but does not finalize that proposal. The proposal was made primarily to address a mismatch in baseline and performance periods for this measure such that data falling within the COVID-19 PHE period would not be included in the baseline period but would be included in the performance period. As a result, measure results will be provided to hospitals and publicly displayed per existing policies. Caveats will be publicly provided describing the impacts of the COVID-19 PHE on the results.

CMS received many comments both in support of and in opposition to this proposal. Supporters cited ongoing pandemic effects leading to skewed data as well as baseline/performance period mismatch. Commenters opposing the proposal not to report measure results expressed transparency and public safety concerns.

CMS responds by acknowledging potential arguments raised on both sides of the reporting issue. However, CMS ends the discussion by stating that the agency has newly identified a method to adjust the CMS PSI 90 for effects of the pandemic by excluding COVID-19 patients. CMS does not provide further details about the methodology and states that it will become publicly available with release of the next version of the CMS PSI 90 measure's software. An associated announcement of a technical specification update is discussed later in the rule and below.

Alternatives Considered

CMS reprises three alternatives to the program year FY 2023 proposals for measure suppression and downstream consequences for Total HAC Scores and HAC RP payment reductions but does

not provide a separate discussion of comments received. Relevant comments appear to have been incorporated into discussions about specifics of the finalized proposals as described above.

- Suppressing some but not all measures;
  - Rejected by CMS for the associated decrease in Total HAC Score reliability.
- No measure suppression and following established pre-pandemic HAC RP methodology;
  - Rejected by CMS due to the geographic and temporal variations of COVID-19 effects and the associated skewed results.
- Reusing a previous fiscal year's applicable period as the applicable period for FY 2023;
  - Rejected by CMS as imposing a second penalty year on hospitals based on the prior year's data and not recognizing any quality improvements that occurred.

d. Final Actions for Program Year FY 2024

HAI Measure Suppression and Updated Applicable Periods

CMS finalizes as proposed to suppress CY 2021 CDC NHSN HAI data from the FY 2024 HAC Reduction Program due to significant deviation in national performance on the HAI measures and changes in care delivery and treatment guidelines. CMS notes that because HAI measure data are grouped to hospital internal locations (e.g., intensive care unit), they cannot be linked to individual-level COVID-19 diagnoses and thereby compensated for through risk adjustment, leaving suppression as the best option to adjust for the affected data.

Commenters were divided between support of and opposition to the proposal. Avoiding unfairly penalizing hospitals and ensuring transparency and public safety were the primary rationales offered for support and opposition, respectively. In response to commenters, CMS indicates that decisions about continued suppression of HAC RP measure scoring and related payment adjustments (e.g., use of Total HAC scores) will be forthcoming in future rulemaking based on monitoring by the agency of the results of the program's measures.

The decision to finalize suppression of all CY 2021 data from scoring calculations for HAI measures necessitates updates to previously finalized applicable periods for these measures that were shown previously in the rule in an unnumbered table in section V.J.2.b.(1). The CMS PSI 90 measure's applicable period is not changed. The updated applicable periods are shown as an unnumbered table in section V.J.2.b.(3) of the rule and below.

Finalized Applicable Periods for Program Years FY 2023 through FY 2025		
Fiscal Year	**Measure Set**	**Applicable Period**
FY 2023	CDC NHSN HAI	1/1/21 – 12/31/21
	CMS PSI 90	7/1/19 –12/31/19 and 1/1/21 – 6/30/21
FY 2024	CDC NHSN HAI*	1/1/22 – 12/31/22
	CMS PSI 90	1/1/21 – 6/30/22
FY 2025	CDC NHSN HAI	1/1/22 – 12/31/23
	CMS PSI 90	7/1/21– 6/30/23
* Changed from previously established period		

Technical Specification Update CMS PSI 90: Risk Adjustment for COVID-19 Diagnosis
CMS announces a technical specification update to the CMS PSI 90 measure to begin with program year FY 2024. The measure's software will be modified to include a diagnosis of COVID-19 in the measure's risk-adjustment model. CMS states that when the revised risk adjustment is incorporated, the previously observed higher rates of adverse safety events for patients with COVID-19 diagnoses versus those without are no longer seen.

CMS typically uses a sub-regulatory guidance process for making non-substantive changes to the technical specifications of HAC Program measures like the change described above for CMS PSI 90. Announcements made during rulemaking reach a large and diverse stakeholder audience and can be substituted for sub-regulatory guidance mechanisms for publicizing technical updates.

CMS did not solicit comments on the specification update but received some nevertheless. The update was supported by many commenters. Multiple commenters offered suggestions pertaining to COVID-19 PHE impacts on the measure along with suppression and public reporting of measure results including: continued monitoring of the measure's results to detect other impacts of the pandemic; continuation of CMS PSI 90 measure suppression through program year FY 2024 or the end of the PHE declaration; publicly releasing details of the pending software update; limiting reporting of the measure's results to confidential hospital-specific reports rather than public reporting; and accounting for potential confounding introduced by self-administered COVID-19 diagnostic testing and nonstandard or incomplete results reporting from such testing.

CMS reiterates planning to continue monitoring results of the CMS PSI 90 measure to detect any unintended consequences of the technical update and identify if additional risk adjustment or measure suppression is needed as the pandemic evolves. CMS also emphasizes the value of public reporting of patient safety measure results. CMS states that full software details will be publicly accessible when the next version is released. Finally, CMS notes that the CMS PSI 90 measure is being applied under the HAC RP in the hospital inpatient setting, where patients self-diagnosed with COVID-19 are typically routinely retested for COVID-19 at the time of hospital admission or emergency department evaluation.

4. Technical Specification Update: CMS PSI 90 Measure Case Volume

Unrelated to the COVID-19 PHE, CMS announces an update to the minimum volume threshold for the CMS PSI 90 measure. CMS notes that application of the currently specified threshold produces a small set of hospitals for whom the measure's reliability is close to zero. Updating the measure's technical specifications will resolve this problem by preventing those hospitals from receiving a CMS PSI 90 measure score. The update, effective with the next CMS PSI 90 measure software update, will require a hospital to meet two criteria to be scored. The hospital must have:

- One or more CMS PSI 90 component measures with at least 25 eligible discharges, and
- Seven or more CMS PSI 90 component measures with at least 3 eligible discharges.

CMS states that the updated specification will result in approximately 5 percent of hospitals no longer receiving a CMS PSI 90 score and 2.5 percent no longer receiving a Total HAC Score. Hospitals not receiving Total HAC scores are not included in the score distribution used to

determine the 75th performance percentile and penalize the worst-performing quartile, so that the total number of hospitals in the lowest performing HAC RP quartile will decrease slightly due to the case volume specification update. CMS believes that the majority of hospitals that will no longer receive Total HAC Scores will have fewer than 100 beds and as such are more likely to be rural than urban.

CMS did not solicit comments on this specification update but nevertheless some were received. Some supported the update while others offered suggestions for further refinement of CMS PSI 90 and its uses. Suggestions included using all-payer rather than Medicare-only data and examining the measure's intra-cluster correlation coefficient at minimum threshold rather than at the median.

5. No Mapped Locations Policy

For purposes of the HAC RP, hospitals have previously been able to receive a "no mapped locations (NML)" exemption. NHSN HAI measures are aggregated and reported using hospital internal locations ("mapped") rather than at the patient level. The NML exemption has been given to hospitals for two HAI measures (CAUTI and CLABSI) when a hospital (1) does not map an applicable internal location in the NHSN system (e.g., medical-surgical ward), (2) does not submit measure data, and (3) does not submit an IPPS Measure Exception Form.

CMS clarifies that for FY 2023 and subsequent years, the NML designation will no longer be available. Hospitals will be required to submit mapped data or, lacking a location applicable to CAUTI and/or CLABSI, submit an IPPS Measure Exception Form. If a hospital does not submit data and has not submitted an IPPS Measure Exception Form, the hospital would receive the maximum measure score (lower scores represent better HAC measure performance). CMS states that the NML policy change will affect only a small number of hospitals.

In the proposed rule, CMS did not solicit comments on this clarification. However, in this final rule the agency acknowledges having received one comment each in support and in opposition to the NML policy as clarified.

6. HAI Data Submission Requirements for Newly Opened Hospitals

CMS finalizes as proposed to update the definition of "newly opened" hospital applicable to the HAC RP beginning with program year FY 2023. A hospital will be considered to be newly opened for a program year if its Medicare-Accept Date falls within the final 12 months of the 24-month performance period for HAI measures for that program year.

For purposes of CDC NHSN HAI data submission requirements, "newly opened" hospital status had previously been determined by the date a hospital filed its Notice of Participation (NOP) for the Hospital IQR Program. At that time HAI measure results were routinely transferred from the Hospital IQR Program to the HAC RP. HAI measure results are now directly transferred from CDC to the HAC RP and are unrelated to the IQR Program NOP. CMS indicates that less than 0.25 percent of hospitals are impacted by the updated definition.

7. Requests for Information (RFIs)

CMS refers readers to sections later in the rule where CMS describes feedback received in response to two RFIs on topics that may potentially impact the HAC RP in future years. First, in section IX.E.9.a. CMS summarizes feedback about the adoption of two digital CDC NHSN quality measures into several CMS quality programs including the HAC RP. The measures are (1) Healthcare-associated Clostridioides difficile Infection Outcome Measure and (2) Hospital-Onset Bacteremia & Fungemia Outcome Measure. Second, in section IX.E.9.b. the agency summarizes input received about overarching principles for measuring disparities in healthcare quality that could be applied across the agency's quality programs, including the HAC RP.

8. Summary Table Measures and Performance Periods

The table below, created by HPA from information in this final rule and prior rules, summarizes the performance periods for the six HAC RP measures through the FY 2025 program year. Technical specifications for the program's measures are available for download at https://qualitynet.cms.gov/inpatient/measures/psi/resources (CMS PSI 90) and https://www.cdc.gov/nhsn/index.html (HAI measures).

HAC RP Measures and Applicable Performance Periods for FYs 2020-2025						
	NQF #	**FY 2021**	**FY 2022**	**FY 2023**	**FY 2024***	**FY 2025**
CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531	X	X	X	X	X
Applicable (Performance) Period		*7/1/17-6/30/19*	*7/1/18 - 12/31/19*	*7/1/19 - 12/31/19 plus 1/1/21 - 6/30/21*	*1/1/21 – 6/30/22*	*7/1/21 – 6/30/23*
CDC NHSN Measures						
Central Line-associated Blood Stream Infection (CLABSI)	0139	X	X	X	X	X
Catheter-associated Urinary Tract Infection (CAUTI)	0138	X	X	X	X	X
Colon and Abdominal Hysterectomy Surgical Site Infections	0753	X	X	X	X	X
Methicillin-resistant staphylococcus aureus (MRSA)	1716	X	X	X	X	X
Clostridium difficile (CDI)	1717	X	X	X	X	X
Applicable (Performance) Period CDC NHSN Measures		*1/1/18-12/31/19*	*1/1/19-12/31/19*	*1/1/21 - 12/31/21*	***1/1/22 – 12/31/22****	*1/1/22 -- 12/31/23*
*** Adjustments Made in this Final Rule to Applicable Periods due to COVID-19 Impacts**						

J. Rural Community Hospital Demonstration Program

1. Background

The Rural Community Hospital Demonstration program allows up to 30 rural community hospitals to receive reasonable cost payment for covered inpatient hospital services furnished to Medicare beneficiaries. The program has been in place since January 1, 2005 with a statutory expiration date that has been extended three times, most recently by section 128 of the Consolidated Appropriations Act, 2021 (CAA 2021). 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 be 5 years from when the program was last extended or the hospital first began participating.

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

2. Policies for Implementing CAA 2021 5-Year Extension

Section 128 of the CAA 2021 extended the demonstration for another five years and provided for the continued participation for all hospitals participating in the demonstration as of December 30, 2019. In FY 2022 IPPS final rule (86 FR 45314), CMS interpreted section 128 as providing for an additional 5-year period for hospitals participating as of that date.

Four hospitals ended the 5-year extension authorized by the CURES Act during FY 2020; CMS retained the policy used for previous extensions and applied the cost-based reimbursement methodology to the date following the last day of the previous period for each hospital that elects to continue participating in the demonstration. Similarly, each of the 22 hospitals with a scheduled end date during 2021, 2022, or 2023 is eligible for an additional 5-year participation period after its end date under the CURES Act extension. The period of participation for the last hospital under the CAA 2021 authority would extend until June 30, 2028.

3. FY 2023 Budget Neutrality Adjustment

CMS will continue to use its general budget neutrality methodology applied in previous years. It identifies 26 hospitals that will participate in the program in FY 2023. Using data from submitted cost reports with a cost report end date in 2020, CMS estimates that the demonstration program will cost $72,499,896 in FY 2023 which it will incorporate into the budget neutrality offset adjustment for FY 2023.

CMS has finalized cost reports for the 17 hospitals participating in FY 2017 which show the actual costs of the demonstration for this fiscal year to be $35,989,928. CMS did not provide a

demonstration cost estimate for FY 2017 because it anticipated that the demonstration would end in 2016. In the final rule, CMS includes the actual costs for the demonstration in FY 2017 in the budget neutrality offset for FY 2023.

The total budget neutrality adjustment is based on the sum of the two amounts and equals $108,439,824.

VI. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2023. For FY 2022, CMS established a national capital Federal rate of $472.59. CMS proposed a national capital Federal rate of $480.29 for FY 2023. The final national capital Federal rate will be $483.76 for FY 2023.

Update Factor:
For FY 2023, CMS will apply an update factor of 2.5 percent based on the capital input price index (CIPI) of 2.5 percent and other factors shown in Table 1 below.

Intensity is the change in total cost per discharge, adjusted for price level changes and changes in real case-mix. The capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology. For the 5-year period FY 2016 through FY 2020, CMS estimates that case mix intensity declined. As a result, CMS is not adopting any change to the capital update for intensity.

For FY 2023, CMS projects a 1.0 percent increase in total case-mix index. CMS estimates that the real case-mix increase will equal 1.0 percent for FY 2023. 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 (e.g., increases in case mix due to improved coding are removed from the capital update). As projected less real case mix nets to 0.0, CMS is not applying an adjustment for case mix change in FY 2023.

CMS uses the FY 2021 claims data to evaluate the effects of FY 2021 DRG reclassification and recalibration as part of the update for FY 2023. CMS assumes that the estimate of FY 2021 DRG reclassification and recalibration would result in no change in case-mix when compared with the case mix index that would have resulted if no changes were made to the DRGs. There will be no adjustment for reclassification and recalibration in the update framework for FY 2023.

CMS includes a forecast error correction if the difference between the projection of the CIPI in a prior year and the actual CIPI based on later information is more than 0.5 percentage points. Current historical data show that the forecasted FY 2021 CIPI (1.1 percent) was 0.1 percentage point higher than the later CIPI based on historical data (1.0 percent). As this difference is less than 0.5 percentage points, there will be no adjustment to the capital update for forecast error correction.

Table 1

CMS FY 2023 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE		
FY 2018-based CIPI		2.5
Intensity		0.0
Case-Mix Adjustment Factors:		
Projected Case Mix Change	1.0	
Real Across DRG Change	1.0	
Net Case-Mix Adjustment (Projected - Real)		0.0
Effect of FY 2021 Reclassification and Recalibration		0.0
Forecast Error Correction		0.0
Total Update		2.5

Other Adjustments:
For FY 2022, CMS estimated that outlier payments would be 5.29 percent of total capital IPPS payments. For FY 2023, CMS estimates that capital outlier payments will be 5.52 percent of total capital payments (including a 0.01 percentage point reduction for outlier reconciliation explained elsewhere in this summary). Therefore, the FY 2023 outlier adjustment factor is 0.9448 (-5.52 percent), compared to 0.9471 (-5.29 percent) in FY 2022. The net change is percent -0.24 percent (1 - 0.9448/0.9471). Thus, the outlier adjustment decreases the FY 2023 capital federal rate by 0.24 percentage points.

The geographic adjustment factor (GAF) is a function of the hospital wage index. As such, CMS has been reflecting changes to the wage data as well as its policy changes to the wage index (increasing the wage indexes that are below the 25th percentile and providing a 5 percent cap on reductions to wage indexes) in the budget neutrality adjustment.

To determine the GAF budget neutrality adjustment, CMS first removes the prior year's budget neutrality adjustment for policy adjustments to the wage index—the lowest quartile wage index policy and the 5 percent cap on reductions to the wage index. To remove the prior year budget neutrality adjustment for the increase in the lowest quartile wage index and the 5 percent cap on the wage index, CMS divides the capital Federal rate by 0.9974, which was the effect of these policy adjustments in FY 2022.

CMS then continues with its 2-step approach to determining GAF budget neutrality as follows:

- Isolate the impact of just the change to the wage data (e.g., without the increase to the lowest quartile wage indexes or the 5 percent cap on reductions to the wage index). CMS determined a budget neutrality adjustment of 1.0008 for FY 2023.
- Isolate the impact of the increase in the lowest quartile wage indexes and the 5 percent cap on reductions to the wage index (referred to by CMS as the Quartile/Cap adjustment factor). CMS determined a GAF budget neutrality factor of 0.9972 for FY 2023.

CMS also incorporates an adjustment for FY 2023 MS-DRG changes and recalibration of the relative weights. For FY 2023, CMS is adopting a 10 percent cap on reductions MS-DRG relative weights. Like it does with the wage index, CMS is calculating the MS-DRG recalibration

adjustment in two steps isolating the impact of changes in the relative weights without the 10 percent separately from the 10 percent cap itself.

- Isolate the impact of just the change to the MS-DRG relative weights (e.g., without the 10 percent cap on reductions to the relative weights). CMS determined a budget neutrality adjustment of 1.0006 for FY 2023.
- Isolate the impact of the 10 percent cap on reductions in the relative weights. CMS determined a budget neutrality adjustment of 0.9998 for FY 2023.

The total budget neutrality adjustment for the DRG relative weights is 1.0004 (1.0006 x 0.9998). This combined adjustment for GAFs due to changes in the wage index in step 1 above and changes for MS-DRGs and recalibration is 1.0012 (1.0008 x 1.0004 or 0.12 percent). The Quartile/Cap adjustment of 0.9972 (-0.028 percent) is then applied.

Final Rule Calculation:
The final rule includes the following chart to show how each of the factors and adjustments affects the computation of the FY 2023 national capital Federal rate compared to the FY 2022 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2022 and FY 2023 Capital Federal Rate

	FY 2022	FY 2023	Change	Percentage Change
Update Factor*	N/A	1.0250	1.0250	2.5
GAF/DRG Adjustment Factor*	N/A	1.0012	1.0012	0.12
Quartile/Cap Adjustment Factor**	0.9974	0.9972	0.9998	-0.02
Outlier Adjustment Factor**	0.9471	0.9448	0.9976	-0.24
Capital Federal Rate	$472.59	$483.76	1.0236	2.36

* 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 2022 to FY 2023 resulting from the application of the GAF/DRG budget neutrality adjustment factor for FY 2023 is a net change of 1.0012 (or 0.12 percent).
** The outlier adjustment factor and the lowest quartile adjustment factors are 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 2023 outlier adjustment factor is 0.9448/0.9471, or 0.9976 (-0.24 percent). The net change to the Quartile/Cap adjustment is 0.9972/0.9974 or 0.9998 (-0.02 percent).

Considering the update factor and the budget neutrality adjustments, CMS is adopting a national capital Federal rate for FY 2023 of $483.76, a 2.36 percent increase over the FY 2022 rate of $472.59.

VII. Changes for Hospitals Excluded from the IPPS

A. Rate-of-Increase

Most hospitals are paid under prospective payment systems. Some hospitals, however, 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 costs 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.

CMS proposed to update the TEFRA limits based on the hospital market basket of 3.1 percent using IGI's 4th quarter 2021 forecast for FY 2023 with historical data through the 3rd quarter of 2021. There were no public comments on CMS proposed update to the TEFRA limits. As finalized, the annual update to the TEFRA limit is based on IGI's 2021 2nd quarter 2022 forecast of the hospital market basket for FY 2023 with historical data through the 1st quarter of FY 2022 and is 4.1 percent.

B. Report on Adjustment Payments

TEFRA hospital cost limits may be adjusted for specific factors after the hospital submits its Medicare cost report. Section 4419(b) of Pub. L.105-33 requires the Secretary to publish annually in the *Federal Register* a report describing the total amount of adjustment payments made to excluded hospitals and hospital units. Total adjustment payments made to IPPS-excluded hospitals during FY 2021 were $25,950,962 as shown by hospital type in the below table.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	7	$48,831,338	$24,623,016
Children's Hospitals	2	$1,774,147	$1,015,213
RNHCIs*	4	$330,405	$312,463
Total	13	$51,935,890	$25,950,692

*Religious Non-Medical Health Care Institutions (previously known as Christian Science Sanatoria)

C. Critical Access Hospitals (CAHs)

The Frontier Community Health Integration Project (FCHIP) Demonstration[62] is designed to develop and test new models of care 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. Section 129 of the CAA, 2021 extended the FCHIP for another five years in the cost reporting year beginning January 1, 2022. Six CAHs in Montana and North Dakota elected to continue participation during the extension period.

The demonstration was 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 FY 2020. CMS found that the initial period of the demonstration was budget neutral and no reduction in payments to CAHs was necessary.

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

For the extension period, CMS proposed the same application of budget neutrality if the demonstration is found to increase costs—through an adjustment to payments for all CAHs nationwide. However, CMS proposed to make this adjustment in a single fiscal year rather than over three fiscal years as was its policy for the initial period (although the budget neutrality adjustment was unneeded for the initial period). CMS believes a one-year period is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data and/or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.

One commenter wrote in support of all of CMS' proposals for the FCHIP but requested that CMS open participation during the extension period to additional CAHs. CMS responded that section 129 of CAA 2021 limited the extension period to only those CAHs that participated in the initial demonstration period. CMS is finalizing all of its proposals without change.

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

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 are paid an IPPS comparable amount. The criteria for exclusion from the site neutral payment remain the same for FY 2023:

- 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.

The update for LTCHs uses a process that is generally consistent with prior regulatory policy and that cross-links to relevant IPPS provisions. For FY 2016 and FY 2017, the site neutral payment rate was a blend of the LTCH PPS standard federal rate and the IPPS comparable amount. Section 51005 of the BBA 2018 extended the transitional blended payment rate (50 percent LTCH standard federal payment and 50 percent IPPS comparable amount) for site neutral payment cases for an additional 2 years. The FY 2019 IPPS final rule made conforming changes to the regulations to implement the extended transitional blended payment.

With respect to data used for FY 2023 LTCH PPS rate setting, CMS uses the most recent data available including FY 2021 MedPAR claims and FY 2020 cost report data. See section I.F. of the summary above for a description of CMS' policy to modify the rate setting methodology to account for the ongoing COVID-19 PHE.

Summary of Changes to LTCH PPS Rates for FY 2023*	
Standard Federal Rate, FY 2022	$44,713.67
Update factors	
Update per Section 1886(m)(3)(C) of the Act (including productivity adjustment)	+3.8%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+3.8% (1.038)
Net update LTCHs not reporting quality data	+1.8% (1.018)
Adjustments	
Area wage index budget neutrality adjustment	1.0004304
Standard Federal Rate, FY 2023	
LTCHs reporting quality data ($44,713.67 x 1.038 x 1.0004304)	$46,432.77
LTCHs not reporting quality data ($44,713.67 x 1.018 x 1.0004304)	$45,538.11
Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$38,518
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$38,859
Impact of Policy Changes on LTCH Payments in FY 2023	
Total estimated impact	2.4% (≈ $71 million)
LTCH standard federal payment rate cases (72% of LTCH cases)	2.8% (≈ $61 million)
Site neutral payment rate cases (28% of LTCH cases)**	2.3% (≈ $9 million)
*More detail is available in Table IV: Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCHPPS Standard Federal Payment Rate Cases for FY 2023 (Estimated FY 2022 Payments Compared to Estimated FY 2023 Payments) on pages 2051-2052 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.	

A. MS-LTC-DRGs and Relative Weights

1. Background

Similar to FY 2022, the annual recalibration of the MS-LTC-DRG relative weights for FY 2023 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. The MS-LTC-DRG relative weights are not used to determine the site neutral payment rate and site neutral payment case data are not used to develop the relative weights.

2. Patient Classification into MS-LTC-DRGs

As proposed, CMS applies 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 incorporated into the MS-LTC-DRG system for FY 2023 since the two systems share an identical base. MS-DRG changes are described elsewhere in this summary and details can be found in section II.D. of the preamble of the final rule. Other changes to the MS-DRG that affect assignments under GROUPER Version 40 are discussed in section II.D, of the final rule, including changes to the

Medicare Code Editor (MCE) software and the ICD-10-CM/PCS coding system, apply to the LTCH PPS.

3. Changes for the FY 2023 MS-LTC-DRG Relative Weights Methodology

a. Averaging of Relative Weights for FY 2023

CMS finalizes modifications to its methodology for determining the FY 2023 MS-LTC-DRG Relative Weights. It determined that the COVID-19 cases grouped to a few MS-LTC-DRGs have, on average, meaningfully different costs than the non-COVID-19 cases grouped to those MS-LTC-DRGs. Thus, the relative weights calculated using all cases will be meaningfully different than the relative weights calculated excluding COVID-19 cases. CMS also believes there will be fewer COVID-19 hospitalizations in FY 2023 compared to FY 2021. Therefore, it finalizes its proposal to calculate the relative MS-LTG-DRG weights both including and excluding COVID-19 cases and then average the two sets of relative weights. Because this averaging approach reduces but does not eliminate the impact of COVID-19 cases on relative weight calculations, CMS believes the result is a reasonable estimation of the mix of cases for FY 2023 and a more accurate estimate of the relative resource use for FY 2023 cases.

b. Cap on Relative Weight Decreases

In past rulemaking, commenters have complained about the impact of significant fluctuations in relative weights for some MS-LTC-DRGs and have requested transition policies to mitigate those impacts. This is especially relevant in low-volume MS-LTC-DRGs.

CMS proposed, beginning in FY 2023, to establish a permanent 10-percent cap on the reduction to a MS-LTC-DRG's relative weight in a given year. The 10-percent cap would be applied to the relative weights for MS-LTC-DRGs with applicable LTCH cases but would not apply to no-volume MS-LTC-DRGs whose relative weight was determined by a cross-walk to another MS-LTC-DRG's relative weight.

CMS also proposed to implement the policy in a budget neutral manner. The budget neutrality adjustment would be applied to the MS-LTC-DRG relative weights, after application of the 10-percent cap, to ensure the cap would not change LTCH PPS standard Federal payment rates.

While commenters generally supported the 10-percent cap, some objected to the proposal to apply a budget neutrality adjustment. They worried that the budget neutrality adjustment may reduce the relative weights for high-volume MS-LTC-DRGs, including the five most commonly used MS-LTC-DRGs. MedPAC suggested the 10-percent cap also be applied to increases in relative weights.

CMS finalizes its proposals with a modification to better target the intended relief. Specifically, it will limit the application of the 10-percent cap to MS-LTC-DRGs with at least 25 cases. It did some additional analysis that showed limiting the cap to MS-LTC-DRGs with at least 25 cases resulted in a significant decrease to the number of MS-LTC-DRGs subject to the cap under its proposal (from 139 to 25). The agency believes this modification addresses commenters' concerns about the destabilizing impact of the budget neutrality adjustment because the budget

neutrality adjustment associated with this more limited cap policy (-0.13 percent reduction to the relative weights) is meaningfully less than the budget neutrality adjustment associated with our proposed cap policy (-0.34 percent reduction). CMS also believes 25 cases is the appropriate threshold. It declines to adopt MedPAC's suggestion to apply the cap to increases as well because it does not believe such a policy is needed to enable hospitals to more effectively budget and plan their operations.

CMS notes the 10-percent cap on reductions to a MS-LTC-DRG's relative weight applies only to a given MS-LTC-DRG with its current MS-LTC-DRG number; it does not apply when CMS creates new MS-LTC-DRGs or modifies the MS-LTC-DRGs as part of its annual reclassifications resulting in renumbering of one or more MS-LTC-DRGs.

c. Conforming Changes to Other Components of the FY 2023 MS-LTC-DRG Relative Weights Methodology

Generally, CMS continues to apply the other components of its current methodology to develop the MS-LTC-DRG relative weights for FY 2023 that are not impacted by the policies to average the relative weights and to impose a 10-cap on reductions to relative weights. Because the averaging policy requires the methodology to be applied on two sets of claims, one set with and the other set without COVID-19 cases, in determining the relative weights based on both sets of claims, 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) will continue to apply.

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

Historically, CMS uses three different categories of MS-LTC-DRGs based on volume of cases within specific MS-LTC-DRGs to determine relative weights:

- MS-LTC-DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight;
- MS-LTC-DRGs that contain between 1 and 24 applicable LTCH cases (i.e., low-volume MS-LTC-DRGs) that are grouped into quintiles and assigned the relative weight of the quintile; and
- No-volume MS-LTC-DRGs that are cross-walked to other MS-LTC-DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS-LTC-DRG

CMS will continue use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2023 MS-LTC-DRG relative weights.

a. Relative Weights Source Data

FY 2023 relative weights are derived from the March 2022 update of the FY 2021 MedPAR file. These data are filtered to identify LTCH cases meeting the established site neutral payment exclusion criteria. CMS notes that all LTCH PPS cases in FY 2021 were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria, but for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2023 (including MS-LTC-DRG relative weights), it used FY 2021 cases that met the statutory patient criteria

without consideration to how those cases were paid in FY 2021. 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 40 of the GROUPER to calculate the FY 2023 MS-LTC-DRG relative weights.

Consistent with current methodology, cases with a length of stay of 7 days or less were removed.

b. Volume-related Adjustments

CMS accounts for low-volume MS-LTC-DRG cases using its quintile methodology and uses it when calculating relative weights for both sets of claims (i.e., those that include and those that exclude COVID-19 cases). Generally, if an MS-LTC-DRG has 1-24 cases, it is assigned to one of five quintiles based on average charges. CMS assigns the low-volume MS-LTC-DRGs to specific low-volume quintiles by sorting the low-volume MS-LTC-DRGs in ascending order by average charge using its established methodology. It finds that there are 233 such MS-LTC-DRGs in the claims data that included COVID-19 cases and 232 such MS-LTC-DRGs that excluded COVID-19 cases. The quintiles for both sets of claims each contained 46 MS-LTC-DRGs with a remainder of 3 for cases including COVID-19 and a remainder of 2 for cases excluding COVID-19. Each remainder was assigned to the quintile that has an MS-LTC-DRG with an average charge closest to that reminder.

CMS then determined a relative weight and (geometric) average length of stay for each quintile; each quintile's weight and length of stay was then assigned to each MS-LTC-DRG within that quintile. The calculations were done separately for claims that included and claims that excluded COVID-19 cases. (See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these low-volume MS-LTC-DRGs.)

c. Remove Statistical Outliers

Consistent with its current methodology, CMS removed statistical outlier cases with a length of stay of at least 8 days. It continues to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS-LTC-DRG. After removing statistical outlier cases and cases with a length of stay of 7 days or less in each set of claims, CMS has applicable LTCH cases that have a length of stay greater than or equal to 8 days which it refers to as "trimmed applicable LTCH cases."

d. Adjust Charges for Short Stay Outliers

The effect of short stay outlier (SSO) cases (i.e., 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 case 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. CMS continues this policy and performs it on both set of claims (i.e., those with and those without COVID19 cases).

e. Hospital-Specific Relative-Value Methodology (HSRV)

CMS uses its HSRV methodology in FY 2023 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. It applies the HSRV methodology in calculating the relative weights for both set of claims (i.e., those with and those without COVID19 cases).

f. Adjustment for Nonmonotonically Increasing Relative Weights

Each MS-LTC-DRG contains one, two or three severity levels; resource utilization and relative weights typically increase with higher severity. CMS believes that using nonmonotonic relative weights to adjust payments would result in inappropriate payments; this is because payment for the cases in the higher severity level in a base MS-LTC-DRG (generally expected to have higher resource use and costs) would be lower than payment for cases in a lower severity level within the same base MS-LTC-DRG (which are generally expected to have lower resource use and costs). When relative weights decrease as severity increases in a DRG ("nonmonotonic"), CMS continues for FY 2023 to combine severity levels within the nonmonotonic MS-LTC-DRG for purposes of computing a relative weight to assure that monotonicity is maintained. Table 11 (listed in section VI. of the Addendum to the final rule) notes any adjustments made for nonmonotonicity for both sets of weights (i.e., those with and those without COVID19 cases).

g. Determination of Relative Weights for MS-LTC-DRGs with No Applicable LTCH Cases

As proposed, if an MS-LTC-DRG has zero cases after data trims are applied (CMS identifies 427 of these MS-LTC-DRGs), CMS will cross-walk it to another MS-LTC-DRG based on clinical similarities in resource use intensity and relative costliness to assign an appropriate relative weight. If the MS-LTC-DRG that is similar is a low-volume DRG that has been assigned to one of the five quintiles noted above, then the zero volume MS-LTC-DRG is assigned to that same quintile.

CMS removes from this total the 11 transplant, 2 "error" and 15 psychiatric or rehabilitation MS-LTC-DRGs. It also excludes MS-LTC-DRG 273 (Percutaneous and other intracardiac procedures with MCC) because there was one claim (a COVID-19 claim) grouped to it in the March 2022 update. In establishing relative weights based on claims that exclude COVID-19 cases, rather than assigning a cross-walked relative weight for MS-LTC-DRG 273, as proposed, CMS assign MS-LTC-DRG 273 the relative weight calculated using all applicable LTCH cases. Thus, there are 399 no-volume MS-LTC-DRGs (427 - 11 - 2 - 15 = 399) for which CMS assigns relative weights based on clinical similarity and relative costliness to 1 of the remaining 340 (767 - 427 = 340) MS-LTC-DRGs for which it calculated relative weights based on the trimmed applicable LTCH cases in the FY 2021 MedPAR file data. (See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these zero-volume MS-LTC-DRGs.)

CMS assigns a 0.0000 relative weight for each of the following:

- The 11 transplant MS-LTC-DRGs (since no LTCH has been certified by Medicare for transplantation coverage);

- The 2 “error” MS-LTC-DRGs (998 and 999) (which cannot be properly assigned to an MS-LTC-DRG group); and.
- The 15 psychiatric and rehabilitation proposed MS-LTC-DRGs (because these MS-LTC-DRGs would never include any LTCH cases meeting the site neutral payment rate exclusion criteria).

h. Normalize the Two Sets of relative Weights

CMS normalizes both sets of relative weights (those calculated using claims that include COVID-19 cases and that used claims that excluded COVID-19 cases). This is intended to ensure that the recalibration of the MS-LTC-DRG relative weights neither increases nor decreases the average case-mix index. CMS calculated a normalization factor of 1.33569 for all applicable LTCH cases that include COVID-19 cases and 1.33224 for all applicable LTCH cases that exclude COVID-19 cases. CMS then computed a simple average of the normalized relative weights and geometric mean length of stays from each set.

i. Budget Neutrality

Annual updates to the MS-LTC-DRG classifications and relative weights are done in a budget neutral manner. As proposed, the existing two-step methodology is used to achieve budget neutrality for the FY 2023 MS-LTC-DRG and relative weights update with modifications to account for the new policies to average both sets of relative weights and to apply a 10-percent cap on relative weight decreases. Essentially, CMS applies two budget neutrality factors to determine the MS-LTC-DRG relative weights for FY 2023; one before the application of the 10-percent cap (referred to as the “uncapped relative weights”) and the other after application of that cap. CMS uses the set of LTCH cases that include COVID-19 cases to model payments for determining budget neutrality factors.

(1) Budget neutrality for uncapped relative weights.

To determine budget neutrality adjustments for the update of the MS-LTC-DRG classifications and relative weights before applying the ten-percent cap (or the uncapped relative weights), CMS first applies its normalization factor to the recalibrated relative weights (see above). To do so, it uses the applicable LTCH cases from LTCH discharges from the FY 2021 MedPAR file, including the COVID-19 cases, and groups them using Version 40 of the GROUPER and the recalibrated FY 2023 MS-LTC-DRG uncapped relative weights to calculate the average case-mix index. Next, it groups the same applicable LTCH cases using the FY 2022 GROUPER (Version 39) and FY 2022 MS-LTC-DRG relative weights to calculate an average case-mix index. Finally, it computes the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2022 by the average case-mix index for FY 2023. As a result, in determining the MS-LTC-DRG relative weights for FY 2023, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by the normalization factor of 0.99884 in the first step of the budget neutrality methodology which produces “normalized relative weights.”

Next, CMS determined the first budget neutrality adjustment factor (for uncapped relative weights) by calculating the ratio of estimated total FY 2023 LTCH PPS standard Federal Payment rate payments for applicable LTCH cases (i) using GROUPER version 40 and (ii) using GROUPER

version 39 and the FY 2022 MS-LTC-DRG relative weights. CMS calculates a budget neutrality factor of 0. 9937739 which will be applied to each uncapped normalized relative weight.

(2) MS-LTC-DRG Cap Budget Neutrality Factor

When the relative weight for a MS-LTC-DRG would decrease by more than 10-percent in a given year, the reduction will be limited to 10-percent for that year. The 10-percent cap applies only to the relative weights for MS-LTC-DRGs with 25 or more applicable LTCH cases and does not apply to low-volume MS-LTC-DRGs identified in Step 3 or no-volume MS-LTC-DRGs identified in Step 8. Thus, for any MS-LTC-DRG where the FY 2023 relative weight would otherwise have been reduced by more than 10 percent, CMS caps the FY 2023 MS-LTC-DRG relative weight at 90 percent of that MS-LTC-DRG's FY 2022 relative weight.

CMS finalizes a 3-step methodology to determine the budget neutrality adjustment factor for its 10-percent cap on relative weight reductions. It:

- Simulates estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the capped relative weights for FY 2023 and GROUPER Version 40;
- Simulates estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped relative weights for FY 2023 (determined in Step 11) and GROUPER Version 40; and
- Calculates the ratio of the estimated total payments.

Each capped relative weight was multiplied by a budget neutrality factor of 0.998734. Extensive discussion of the entire 13-step process to determine MS-LTC-DRG relative weights is provided in the preamble to the final rule (pages 1058 through 1086 of the display copy).

B. Payment Rates and Other Changes

1. Overview LTCH PPS Standard Federal Payment Rates

As noted earlier, 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, and the LTCH market basket includes both operating and capital cost categories.

2. Annual Update for LTCH PPS Standard Federal Payment Rate for FY 2023

For FY 2021, CMS rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year. The 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs, which specifically reflects the cost structures of only LTCHs. Based on IGI's second quarter 2022 forecast with historical data through the first quarter of 2022, CMS finalizes an FY 2023 LTCH market basket update of 4.1 percent (reflecting forecasted compensation price growth of 4.8 percent) and a productivity adjustment of 0.3 percentage points (PP). For LTCHs failing to submit data to the LTCH Quality Reporting Program (QRP), the annual update would be further reduced by 2.0 percentage points. CMS notes that the "other

adjustment" under section 1886(m)(4)(F) of the Act does not apply for FY 2023. The LTCH update for FY 2023 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	4.1%	4.1%
Multifactor Productivity	-0.3 PP	-0.3 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	3.8%	1.8%

3. Area Wage Levels and Wage-Index

a. Labor Market Areas

CMS adopted the revised labor market area delineations announced in OMB Bulletin No. 20-01[63] (issued on March 6, 2020) effective for FY 2022 under the LTCH PPS. The agency determined that the changes in this OMB Bulletin do not affect the CBSA-based labor market area delineations used under the LTCH PPS. Thus, no changes to the specific wage index updates are necessary as a result of its adoption of the updates in OMB Bulletin 20-01. CMS did not propose and does not make any changes to the CBSA-based labor market area delineations for FY 2023.

CBSAs are made up of one or more constituent counties, and each CBSA and constituent county has its own unique identifying codes. The Census Bureau maintains a list of changes to counties or county equivalents and updates the Federal Information Processing Series (FIPS) codes. Effective October 1, 2022, CMS will implement the following update to the FIPS codes:

- Chugach Census Area, AK (FIPS State County Code 02–063) and Copper River Census Area, AK (FIPS State County Code 02–066) were created from former Valdez-Cordova Census Area (02–261) which was located in CBSA 02. The CBSA code for these two new county equivalents remains 02.

CMS notes that there are currently no LTCHs in these counties. Even if an LTCH opened in one of these counties, there would be no impact or change for purposes of the LTCH PPS wage indexes by reason of this update.

b. Labor-related Share

Based on IGI's second quarter 2022 forecast of the 2017-based LTCH market basket, CMS finalizes an FY 2023 labor-related share of 68.0 percent. This is based on the sum of the labor-related portion of operating costs (63.8 percent) and capital costs (4.2 percent). Operating costs include the following cost categories: wages and salaries; employee benefits; professional fees; labor-related;

[63] See https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf

administrative and facilities support services; installation, maintenance, and repair services; and all other labor-related services.

c. 5-percent Cap on Wage Index Decreases from the Prior Year

The agency notes that in previous rulemaking it implemented a temporary policy to apply 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index from the prior fiscal year by reason of large wage index decreases. In this rule, beginning with FY 2023, CMS finalizes its proposal to apply a permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. It believes the policy will provide increased predictability in LTCH wage indexes and payments and will mitigate significant payment reductions due to changes in wage index policy, such as the adoption of the revised CBSAs in FY 2021. CMS notes that the 5-percent wage index reduction cap policy for LTCHs is similar to the policy finalized in section III.N. for IPPS hospitals. To ensure budget neutrality, this policy is included in the determination of the area wage level budget neutrality factor.

Commenters supported the limit on reductions from year to year but objected to applying the policy in a budget neutral manner. MedPAC also suggested applying the 5-percent cap on increases as well as reductions. CMS adopts its policies as proposed.

An LTCH's wage index cap adjustment will be determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. New LTCHs that became operational during the prior Federal fiscal year will be subject to the LTCH PPS wage index cap whereas LTCHs that become operational on or after the first day of the fiscal year to which this final rule applies would not be subject to the cap (even when other LTCHs in the same geographic area are receiving a wage cap).

Permanent Cap on IPPS Comparable Wage Index Decreases. CMS calculates an "IPPS comparable amount" to determine payments for short-stay outliers and the site neutral payment rate. Additionally, an "IPPS equivalent amount" is calculated for LTCHs that do not meet the applicable discharge payment percentage. Calculation of these amounts includes adjustments to the IPPS operating and capital standardized amounts by the applicable IPPS wage index for non-reclassified hospitals in the same geographic area as the LTCH. CMS finalizes its proposal, beginning with FY 2023, to apply a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year.

Historically, CMS has not applied a budget neutral adjustment to changes to LTCH PPS payments that result from the annual update of the IPPS wage index for non-reclassified IPPS hospitals; thus, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner. An LTCH's applicable IPPS comparable wage index cap adjustment will be determined based on the wage index value assigned to the LTCH on the last day of the prior Federal fiscal year. New LTCHs that became operational during the prior Federal fiscal year are subject to the applicable IPPS comparable wage index cap whereas LTCHs that become operational on or after the first day of the fiscal year to which this final rule applies are not subject to the cap.

d. Budget Neutrality Adjustments

CMS computes the wage index in a manner that is consistent with prior years; this includes ensuring that any changes to the area wage index values or labor-related share are implemented in a budget neutral manner. As noted above, the 5-percent cap on wage index decreases will be applied in a budget neutral manner. CMS determines an FY 2023 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0004304.

4. Cost-of-Living (COLA) Adjustment

CMS continues updating the COLA factors for Alaska and Hawaii as it has done since FY 2014. To account for higher living costs in Alaska and Hawaii, a COLA is provided to LTCHs in those states that is applied to the nonlabor-related portion of the standard Federal payment rate. The COLA is determined by comparing Consumer Price Index (CPI) growth in Anchorage, Alaska and Honolulu, Hawaii to that of the average U.S. city published by BLS. The COLA is capped at 25 percent and updated every 4 years.

CMS uses data based on the 2009 OPM COLA factors updated through 2020. The table below shows the final COLAs for FY 2023 which are unchanged from the COLAs in effect for FY 2022.

Area	**FY 2023**
Alaska	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

5. Adjustment for High-Cost Outlier (HCO) Case Payments

CMS includes an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Section 1886(m)(7)(A) of the Act requires CMS to reduce the LTCH standard federal payment rate by 8 percent for high-cost outliers (HCOs). Section 1886(m)(7)(B) requires CMS to set an 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). Under the HCO policy, an LTCH receives 80 percent of the difference between the estimated cost of the case and the HCO threshold, which is the sum of the LTCH PPS payment for the case and the fixed-loss amount for that case.

a. Determining LTCH CCRs

CMS generally calculates the estimated cost of an LTCH case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. Generally, an LTCH's overall CCR

is computed based on the sum of LTCH operating and capital costs as compared to total Medicare charges, with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in some case, an alternative CCR is used, such as the statewide average CCR, a CCR that is specified by CMS, or one that the hospital requests. The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling (which is 3 standard deviations from the national geometric average CCR). If the LTCH's CCR exceeds the LTCH total CCR ceiling, it is assigned the applicable statewide CCR.

CMS uses its established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2022 update of the PSF. Thus, it finalizes an LTCH total CCR ceiling of 1.312 under the LTCH PPS for FY 2023 for HCO cases under either payment rate and for the site neutral payment rate.

CMS also uses its established methodology for determining the LTCH statewide average CCRs for urban and rural hospitals, based on the most recent complete IPPS total CCR data from the March 2022 update of the PSF. They are effective for discharges occurring on or after October 1, 2022 through September 30, 2023 (see Table 8C listed in section VI. of the Addendum to the final rule).

Payments for HCO cases are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge.

b. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

As noted above, CMS establishes a fixed-loss amount so that total estimated outlier payments under the LTCH PPS for federal standard payments are projected to equal 8 percent of total estimated payments under the LTCH PPS (i.e., 7.975 percent).

(1) Charge Inflation Factor

Due to a significant difference between estimated and actual charge inflation, CMS made a technical change to its methodology for determining the charge inflation factor in the FY 2022 IPPS/LTCH PPS final rule. The charge inflation factor is determined based on the historical growth in charges for the LTCH PPS standard federal payment rate cases. CMS calculates the inflation factor using historical MedPAR claims data instead of using estimates calculated from quarterly market basket update values determined by the CMS Actuary. CMS uses a three-step methodology:

- Identify standard Federal payment rate cases for the two most recently available fiscal years, removing any Medicare Advantage or all-inclusive rate provider claims.
- Remove statistical outliers, by (i) calculating a provider's average charge in both fiscal years; (ii) dividing the average charge for the more recent fiscal year by the average charge for the prior year; and (iii) trimming claims for providers whose calculated charge growth factor is outside 3 standard deviations from the mean provider charge growth factor.

- Using remaining claims, calculate a national charge inflation factor by dividing the national average charge for the more recent fiscal year by the average charge for the prior year.

However, for FY 2023, due to COVID-19 PHE data concerns, CMS did not propose to use the charge inflation factor derived from the most recently available data and based on the growth in charges that occurred between FY 2020 and FY 2021. CMS found that the one-year charge inflation factor of 1.113327 and two-year charge inflation factor of 1.239497 was abnormally high compared to recent levels before the COVID-19 PHE. Instead, it proposed to use the same charge inflation factor used in the FY 2022 IPPS/LTCH PPS final rule that was based on the growth in charges that occurred between FY 2018 and FY 2019. This results in a 1-year charge inflation factor of 1.060723, and a 2-year charge inflation factor of 1.125133. CMS finalizes its proposal to inflate the billed charges obtained from the FY 2021 MedPAR file by this 2-year charge inflation factor of 1.125133 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023.

(2) CCRs

Historically, CMS has used CCRs from the most recently available PSF file without any adjustment. CMS adjusts CCRs used to calculate the fixed-loss amount by a factor calculated based on historical changes in the average case weighted CCR for LTCHs. It uses a four-step methodology finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562-45566) described below with a modification for the data used.

- Identify providers with standard federal payment rate cases from the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims) and identify for each of these providers the CCR from the most recently available PSF.
- Trim providers with insufficient CCR data in the most recent PSF or the prior year PSF (i.e., providers whose CCR was missing; providers assigned the statewide average CCR for their state; and providers whose CCR was not updated between the most recent PSF and the prior year PSF).
- Remove statistical outliers. Calculate a provider's CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year PSF; and remove providers whose CCR growth factor is outside 3 standard deviations from the mean provider CCR factor.
- Using remaining providers, calculate a national CCR adjustment factor by determining the average case-weighted CCR from both the most recent PSF and the prior year PSF and dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

For FY 2023, due to COVID-19 PHE data concerns, CMS did not propose to use the CCR adjustment factor derived from the most recently available data; instead, it finalizes its proposal to use the CCR adjustment factor that was derived in the FY 2022 IPPS/LTCH PPS final rule, which is based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF. CMS notes that the CCR adjustment factor of 0.961554 determined in the FY 2022

IPPS/LTCH PPS final rule is close to the CCR adjustment factor of 0.957334 it calculated using the most recently available data from the December 2021 PSF and the December 2020 PSF.

(3) Fixed-loss Amount for LTCH PPS Standard Federal Payment Rate Cases

CMS did not propose any changes to its methodology to calculate the applicable fixed-loss amount for standard federal rate cases. It proposed a fixed-loss amount of $44,182 for FY 2023 which it estimated would result in 7.975 percent of LTCH standard federal payment rate cases being paid as HCOs. Commenters objected strongly to the significant increase in the fixed-loss amount as compared to the fixed loss amount of $33,015 for FY 2022; others expressed concern over the use of FY 2021 claims data in determining the outlier fixed-loss amount. Some commenters suggesting averaging the fixed-loss amounts calculated using FY 2019 and FY 2021 data; others suggested the agency use regulatory authority under the PHE (presumably under Section 1135 of the Act) to use the FY 2022 fixed loss amount of $33,015.

CMS finalizes a modified approach to calculating the fixed-loss amount for FY 2023. It establishes the FY 2023 outlier fixed-loss amount based on the average of the outlier-fixed loss thresholds calculated using FY 2021 data including and excluding COVID-19 claims. CMS also excludes claims from one LTCH (CCN 312024) from the FY 2021 claims data used in determining the FY 2023 outlier fixed-loss amount. Under this approach and based on the full set of LTCH claims data (including COVID-19 cases) from the March 2022 update of the FY 2021 MedPAR file adjusted for charge inflation and using adjusted CCRs from the March 2022 update of the PSF, CMS finalizes a fixed-loss amount of $38,518 for FY 2023.

(4) HCO Payments for Site Neutral Payment Rate Cases

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 2023, CMS proposed a fixed-loss amount for site neutral payment rate cases of $43,214; commenters made similar objections to those made in response to the proposed outlier fixed-loss amount. In the final rule, CMS establishes a fixed-loss amount for site neutral payment rate cases of $38,859; this is the same as the FY 2023 IPPS fixed loss amount. Thus, for FY 2023, CMS will calculate an HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount, which is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of site neutral payment rate payment and the fixed loss amount) for site neutral payment rate cases of $38,859.

CMS finalizes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2023. Consistent with the policy adopted in FY 2019, the HCO budget neutrality adjustment will not be applied to the HCO portion of the site neutral payment rate amount. CMS estimates that HCO payments for site neutral payment rate cases will be 5.1 percent of the site neutral payment rate payments.

6. IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS finalizes its proposal to include an applicable operating Medicare DSH and uncompensated care payment amount in the calculations of the “IPPS comparable amount” (under the SSO policy at §412.529) and the “IPPS equivalent amount” (under the site neutral payment rate at

§412.522). For FY 2023, the DSH/uncompensated care amount equals 74.28 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 the expansion of the insured population under the ACA.

C. Impacts

Though section 3711(b)(2) of the CARES Act waives the application of the site neutral payment rate for LTCH cases admitted during the COVID-19 PHE period (meaning that all LTCH PPS cases up to the date of publication of the final rule have been paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria), estimates of total LTCH PPS payments for site neutral payment rate cases in FYs 2022 and 2023 were calculated using the site neutral payment rate determined under §412.522(c) and the provisions of the CARES Act were not considered. Estimates were made based on the best available data for 339 LTCHs.

CMS projects that the overall impact of the final payment rates and factors, for all LTCHs from FY 2022 to FY 2023, will result in an increase of 2.4 percent or approximately $71 million in aggregate payments. This impact results from aggregate increases in payment of $9 million for site neutral cases (or 2.8 percent). It also results in aggregate increases in payment of $61 million for LTCH standard federal payment rate cases (or 2.3 percent); this is primarily due to the proposed 3.8 percent annual update and the projected 1.2 percent decrease in high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments. CMS estimates that aggregate FY 2022 LTCH PPS payments will be approximately $2.985 billion, as compared to estimated aggregate proposed FY 2023 LTCH PPS payments of approximately $3.056 billion.

CMS estimates that high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2022 to FY 2023. FY 2022 high-cost outlier payments are estimated to be about 9.15 percent of estimated total LTCH PPS standard Federal payment rate payments. As it does annually, CMS sets the high-cost outlier threshold for LTCH standard federal payment rate cases so that 8 percent of total payments are made as high-cost outliers. The difference between the 9.15 percent figure for FY 2022 and the estimate of 8.0 percent for FY 2023 accounts for the approximately 1.2 percent reduction in payment for high-cost outliers.

Table IV “Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments For LTCH PPS Standard Federal Payment Rate Cases for FY 2023” in the proposed rule shows the detailed impact by location, participation date, ownership type, region, and bed size for only LTCH PPS standard federal payment rate cases and does not include the detailed impact in payments for site neutral payment rate cases. CMS reports that regional differences in impacts are largely due to updates to the wage index.

Summary of Impact of Changes to LTCH PPS Standard Federal Payment Rate Cases for FY 2023		
	Number of LTCHs	**Estimated Percent Change in Payments per Discharge**
All LTCH providers	337	0.7%
By Location:		
Rural	17	0.7%
Urban	320	0.7%
By Ownership Type:		
Voluntary	53	-0.1%
Proprietary	273	0.8%
Government	11	0.0%
By Region		
New England	10	0.0%
Middle Atlantic	20	1.1%
South Atlantic	61	0.5%
East North Central	49	0.1%
East South Central	31	0.4%
West North Central	22	-1.2%
West South Central	94	1.2%
Mountain	27	1.2%
Pacific	23	1.1%
*More detail is available in "Table IV: Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCHPPS Standard Federal Payment Rate Cases for FY 2023 (Estimated FY 2022 Payments Compared to Estimated FY 2023 Payments)" on pages 2051-2052 of the display copy.		

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. RFI: Climate Change Impacts on Outcomes, Care, and Health Equity

In the proposed rule, CMS requested information about hospital responses to climate change from several perspectives: (1) how their patient populations are being affected, especially underserved groups; (2) how hospitals and the healthcare sector can effectively prepare for climate threats; (3) how CMS can support hospitals in crafting and implementing hospital responses; and (4) approaches hospitals are using to reduce their own greenhouse gas emissions. CMS posed an extensive list of discussion questions and topics for stakeholder feedback.

In this final rule, CMS described the comments as almost uniformly embracing the importance of setting goals for reduced emissions and increased climate resilience, but with repeated requests, including the following:

- Financing supports and incentives;
- Technical assistance tools to assist operational and clinical improvements in this area (with attention to frontline specialties whose work intersects with climate health);
- Standardized measures and measurement frameworks to help with progress tracking and reporting (with mixed views on whether such reporting should be mandatory or voluntary); and

- Updates to/simplification of emergency preparedness requirements, conditions of participation and other regulations to help all provider types be more responsive to climate-related challenges.

CMS said it will consider the feedback as it continues to understand how hospitals, nursing homes, hospices, home health agencies, and other providers can better prepare for the harmful impacts of climate change on their patients, how to support them in doing so, and pledged to continue to engage all interested parties via multiple avenues including future notice-and-comment rulemaking.

B. RFI: Measuring Healthcare Quality Disparities Across CMS Quality Programs

In the final rule, CMS restates background from the proposed rule—that health inequity is manifested by significant disparities in healthcare outcomes and persists in the United States, particularly for individuals belonging to underserved communities. CMS describes health equity as "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes."

CMS reiterates in the final rule that measuring healthcare disparities and reporting these results to healthcare providers is a cornerstone of its approach to advancing healthcare equity. Consistently measuring differences in care received by different groups of beneficiaries can be achieved by methods to stratify quality measures,[64] which has been identified by CMS' Office of Minority Health as a critical component of an organized response to health disparities.

The RFI sought input around 5 key considerations, listed below. Some highlights from the comments are included under each of the considerations. CMS' response to the comments was generally to note that the feedback would be taken into consideration in future policy development.[65]

1. Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs

CMS describes within- and between-provider disparity methods to present stratified quality measure results, which can drive system-wide advancement through incremental, provider-level improvement. In discussing methodological approaches to reporting disparities, CMS notes that the "within-provider" method compares a measure's results between subgroups of patients treated by a single provider with or without a given demographic or social risk factor. The "between-provider" method compares performance across providers on measures for subgroups who all have the factor of interest (e.g., compare a single provider with a national benchmark).

[64] Measure stratification is defined as calculating measure results for specific groups or subpopulations of patients.
[65] CMS noted it is considering using "drivers of health" terminology to more holistically capture other equity-related terms to describe upstream factors, such as "health related social needs," "social determinants of health," and "social risk factors."

CMS views the two methods as complementary when reporting data stratified by the presence or absence of a demographic or social risk factor.[66]

Commenters generally supported the overarching goals for measuring disparity and the goals of measure stratification, which can support hospital decision-making. Consistent with what CMS had described, commenters supported current use of dual-eligibility for Medicare and Medicaid as a financial stratification variable, accompanied by stratification by additional social risk factors. However, many commenters raised concerns about provider burden, the need for more resources, and the need for measures and data that are actionable, useful, consistent, valid, reliable, comparable and robust.

Commenters raised concerns about competition and gaming that may not result in improved care, and that a provider ranking system based on the results of nonmedical, social risk factors may not be an appropriate use of healthcare system resources.

2. Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

In the final rule, CMS reiterates which measures could be prioritized:

- Existing, validated and reliable clinical quality measures for which application of disparities methods and stratified reporting are feasible;
- Measures related to treatment or outcomes for which some evidence of disparities has been shown;
- Measures for which predetermined standards for statistical reliability and representativeness (e.g., sample size) have been met prior to results reporting; and
- Outcome measures as well as measures of access and appropriateness of care.

Several commenters emphasized the importance of avoiding measurement bias, particularly when stratifying with imputed data for demographic and social risk factors. Commenters noted that providers who care for large proportions of patients with social risk factors (such as safety-net hospitals) should not be unfairly penalized under these performance metrics. Commenters were generally supportive of using existing clinical quality measures and the other principles described by CMS. There was a range of suggestions, from technical strategies for reducing error and bias such as the Rasch Measurement Model to using data over longer period to address real-world concerns around ensuring statistical reliability for facilities with fluctuating demographics.

3. Principles for Social Risk Factor and Demographic Data Selection and Use

CMS describes considerations for prioritizing and expanding variables used for measure stratification, which may require the development of an approach specific to the quality programs based on care setting, patient population, and data availability:

[66] 2020 Disparity Methods Updates and Specifications Report, prepared for CMS by the Yale Center for Outcomes Research and Evaluation. Available at https://qualitynet.cms.gov/inpatient/measures/disparity-methods/resources#tab3.

- Patient-reported data are considered to be the gold standard, but national data sources of reliable, self-reported data are not yet available.
- CMS is considering criteria for appropriate use of three sources of social risk and demographic information—billing and administrative data, area-based indicators (e.g., Area Deprivation Index), and imputed variables when patient-reported data are unavailable.

CMS notes the numerous and diverse demographic and social risk factor variables to be considered during disparities analysis (e.g., gender identity, social isolation). CMS reports early positive experience using Medicare Bayesian Improved Surname Geocoding (MBISG) to impute missing values for race and ethnicity from administrative data, surname, and residence.[67]

Commenters offered a variety of views and suggested that CMS enhance the capture of standardized data sets and conduct research to identify factors that have disproportionate impact on health outcomes, to prioritize their collection. Several commenters believe that estimating an individual's race or ethnicity based on name and geography is inappropriate. One expressed several specific concerns regarding MBISG and pointed to an Urban Institute report.

Commenters suggested the use of additional social risk factors such as broadband internet access, social isolation, vision, mental health status, immigration status, and health literacy. A common theme throughout was recommending CMS explore existing data before imposing new reporting requirements. Although patient self-reported data are preferred, many clinicians already find it difficult to collect this information from their patients due to workflow issues, resource constraints, and the reluctance of some patients to self-report demographic and social risk data. Commenters offered suggestions regarding how to improve data self-reporting.

4. Identification of Meaningful Performance Differences

CMS notes that methods for detecting meaningful differences in performance of measures of disparity reporting could include the following:

- Statistical approaches for reliably grouping results (e.g., confidence intervals, clustering algorithm, cut points based on standard deviations);
- Application of ranked ordering and percentiles to providers based on their disparity measure performances, for beneficiary use in decision-making;
- Categorizing different levels of provider performance by applying defined thresholds and fixed intervals to disparity measure results; and
- National or state-level benchmarking (e.g., mean, median).

Commenters had significant feedback on ways to identify meaningful performance differences in stratified disparity results. The majority of commenters did not support rank orderings and percentiles. Feedback on the threshold approach was mixed. Several commenters suggested that

[67] Haas A., Elliott M.N., Dembosky J.W., et al. Imputation of race/ethnicity to enable measurement of HEDIS performance by race/ethnicity. *Health Serv Res*, 54(1):13-23. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6338295/pdf/HESR-54-13.pdf

across-hospital comparisons and comparisons of within-hospital results be done individually by hospital types or peer groups, to give more fair comparisons.

5. Guiding Principles for Reporting Disparity Measures

CMS mentions the possibility of using confidential reporting of stratified measure results to providers for a short period for new programs and/or new measures, while also acknowledging that public reporting is a statutory requirement in all its quality programs. CMS is exploring whether it would be prudent to first confidentially report all stratified measure results to give providers an opportunity to understand those results so they can begin to implement programs to reduce disparities before results are made public.

In general, commenters supported confidential reporting for at least a short period, although they provided mixed feedback on the appropriateness of public reporting. Numerous commenter suggestions and concerns are described in the rule.

C. RFI: FHIR in Hospital Quality Programs

In the proposed rule, CMS sought broad input on the transition to digital quality measurement. As in the proposed rule, CMS first provides an updated definition for digital quality measures (dQMs): quality measures, organized as self-contained measure specifications and code packages, that use one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. CMS sought feedback on the updated dQM definition, on challenges associated with non-EHR sources of patient data for dQMs, as well as the following, with further discussion of each found within section IX.C. of the rule:

- **Data Standardization to Leverage and Advance Standards for Digital Data**. CMS states that standardization is necessary across implementation guides and value sets to facilitate interoperability. CMS also continues to focus on FHIR-enabled application programming interfaces (APIs).
- **Approaches to Achieve FHIR eCQM Reporting.** CMS continues to test conversion of existing electronic clinical quality measures (eCQMs) for use with FHIR-based resources.

There was widespread support among commenters for CMS' efforts to transition to digital quality measurement and support for leveraging the FHIR standard and FHIR APIs. However, a few commenters noted the standard was not yet fully mature. Commenters differed in their input on the time to transition to dQMs.

Many commenters supported the refined dQM definition, but some noted the definition is still too broad and requested clarification. Several commenters noted the ambiguity around eCQMs compared to dQMs and requested further distinction. Commenters were divided on the use of non-EHR data sources for dQMs, with numerous suggestions and concerns offered. Again, many commenters raised concern with burden. Commenters requested clarity from CMS on the transition timelines, including timelines for the phase-out of or addition of eCQMs, the use of FHIR-based API, and when CMS would publish the required data elements and specifications

for required dQMs. CMS said it would continue to take all input into account as it develops future regulatory proposals for digital quality measurement transition efforts.

D. RFI: Advancing the Trusted Exchange Framework and Common Agreement

Version 1 of TEFCA was released by the Office of the National Coordinator (ONC) for Health Information Technology (HIT) on January 18, 2022. Goals for TEFCA include establishing a universal policy and technical floor for interoperability, simplifying connectivity for organizations to securely exchange HIT to improve patient care, and enabling individuals to gather their own healthcare information.

In the proposed rule's RFI, CMS asked the following questions:

- What are the most important use cases for different stakeholder groups that could be enabled through widespread information exchange under TEFCA? What key benefits would be associated with effectively implementing these use cases, such as improved care coordination, reduced burden, or greater efficiency in care delivery?
- What are key ways that the capabilities of TEFCA can help to advance the goals of CMS programs? Should CMS explore policy and program mechanisms to encourage exchange between different stakeholders, including those in rural areas, under TEFCA? In addition to the ideas discussed previously, are there other programs CMS should consider in order to advance exchange under TEFCA?
- How should CMS approach incentivizing or encouraging information exchange under TEFCA through CMS programs? Under what conditions would it be appropriate to require information exchange under TEFCA by stakeholders for specific use cases?
- What concerns do commenters have about enabling exchange under TEFCA? Could enabling exchange under TEFCA increase burden for some stakeholders? Are there other financial or technical barriers to enabling exchange under TEFCA? If so, what could CMS do to reduce these barriers?

CMS' brief summary of comments noted a wide range of comments, many of which did not recommend requiring TEFCA at this time and that there was confusion about TEFCA in the provider community. Many commenters raised concerns about the costs associated with participation, noting that the costs may be a barrier for many health care providers. CMS said it plans to share all the input with ONC and will take commenters' feedback into consideration in future policy development.

E. Hospital Inpatient Quality Reporting (IQR) Program

The Hospital IQR Program is a pay-for-reporting program. Hospitals that do not submit specified quality data or fail to meet all program requirements are subject to a one-fourth reduction in their annual payment update. CMS provides a list of references for readers interested in details of the legislative and regulatory history of the IQR Program. Additional information on the Program is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU and https://qualitynet.cms.gov/inpatient/iqr.

CMS finalizes as proposed 10 new measures for adoption into the IQR program, including three related to health equity and two focused on maternal health. Four are electronic clinical quality measures (eCQMs), one is a Patient-Reported Outcomes Performance Measure (PRO-PM), and two are claims-based. Also finalized as proposed are refinements for two other existing claims-based measures. The measure additions are spread out over the FY 2025 through FY 2028 payment determination years. CMS describes input received in responses to requests for comment about the potential future addition of two CDC NHSN HAI measures and future CMS maternal health-related quality activities.

CMS also finalizes policy changes related to reporting of eCQMs, PRO-PM and hybrid measures. Additionally, the agency finalizes establishing a publicly reported maternity care quality and safety designation for hospitals. No changes are proposed to policies regarding the retention, removal, addition, or updating of measures.[68] No changes are proposed to the program's extraordinary circumstances exceptions (ECE) policy or to the methodology for calculating Overall Hospital Quality Star Ratings.

CMS estimates that across 3,150 IPPS hospitals, the proposed changes for the Hospital IQR Program in this rule would result in a total information collection burden increase of 746,300 hours and a total cost increase of approximately $23,437,906 across a 4-year period from the CY 2023 reporting period/FY 2025 payment determination through the CY 2026 reporting period/FY 2028 payment determination. Burden estimates by measure and reporting/payment determination years are provided in four unnumbered tables in section XII.B.7.m. of the rule.

CMS further estimates that for FY 2023, 24 hospitals will not receive the full market basket rate update factor 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 (PIP). These hospitals would receive an update factor of 2.775 percent. Another 20 hospitals are estimated to receive an update of -0.3 percent because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program. (CMS also estimates that 158 hospitals will submit quality data but will fail to meet requirements for participation in the PIP and receive an update of 0.725%).

A summary table of Hospital IQR Program measures for payment years FY 2022 through FY 2026 is provided at the end of this summary section (see below IX.E.6.).

1. Hospital IQR Program Measure Set: New Measure Proposals

a. Hospital Commitment to Health Equity

CMS finalizes as proposed adding the structural measure *Hospital Commitment to Health Equity* to the Hospital IQR Program measure set, beginning with the CY 2023 reporting period/FY 2025 payment determination. CMS regards the measure as a building block for a future meaningful suite of measures to assess progress towards high-quality care regardless of patient social risk

[68] Relatedly, CMS notes that per statute a Hospital IQR Program measure must first be adopted into the program and be publicly reported on the Care Compare website for at least one year before that measure can be added to the Hospital Value-Based Purchasing Program.

factors or demographics. A complete list of domains and elements appears as Table IX.E-01 of the rule. Measure highlights are provided below. Full specifications are available for download at https://qualitynet.cms.gov/inpatient/iqr/resources. The measure has not been submitted for NQF endorsement and CMS does not state an intent to do so.

CMS provides a lengthy discussion of comments received and states that many commenters supported measure adoption as proposed. Some recommended expansion of the measure to address more domains and equity indicators. Others suggested changes to various elements and domains of the measure and to the "all-or-nothing" scoring. The agency further states that a few commenters opposed adoption, questioning whether the data would be meaningful and lead to change. Other concerns raised included the potential for misinterpretation of results by the public, reporting burden for hospitals—particularly those with limited EHR and IT capabilities (e.g., small, rural)—and lack of NQF endorsement. Suggested prior to measure implementation was an environmental scan and conducting listening sessions and focus groups to identify what hospitals are currently doing in this arena, avoiding duplication and associated burden.

CMS responds that the measure is actionable, meaningful, and is an important first step towards addressing the serious issue of health equity in CMS programs. The agency states that the measure will evolve over time to capture equity-related outcomes. CMS further states that variation in hospital performance on the measure is expected and that not every hospital will be able to attest initially to completing all domains. However, the agency notes that domain credit is awarded for completion of all elements and is not dependent on a hospital's results achieved by conducting the activities described by the elements. CMS regards the health equity gap as a substantive problem needing immediate attention so that an initial period of voluntary measure reporting and delay for NQF endorsement are unwarranted.

CMS clarifies that the measure will not be included in the IQR program's validation process at this time and that data submission is at the hospital CMS Certification Number (CCN) level. CMS further clarifies that it is not proposing a hospital designation related to health equity at this time. CMS notes that related resources for staff education and training will be available through the CMS Office of Minority Health (https://www.minorityhealth.hhs.gov/) and the QualityNet website (https://qualitynet.cms.gov/).

Numerator. Number of domains for which a hospital attests to completing all of the required elements.
Denominator. Five points (one for each domain available for attestation).
Calculation. A point is awarded for each domain to which a hospital attests affirmatively. No partial credit is awarded; all elements within a domain must be completed to affirmatively attest and receive a point for that domain.
Data Submission and Reporting. Web-based data submission using Hospital Quality Reporting (HQR) System and annual reporting per policy for Hospital IQR Program structural measures.
Pre-rulemaking. Measures Under Consideration (MUC) List December 2021. Despite concerns about actionability and how improved clinical equity outcomes will be measured, the Measure Applications Partnership (MAP) ultimately conditionally supported the measure for rulemaking.

b. Screening for Social Drivers of Health

CMS finalizes the addition of the structural measure *Screening for Social Drivers of Health* to the Hospital IQR Program measure set, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.[69] The measure is intended to promote adoption of screening by hospitals for health-related social needs (HRSNs) across five domains: food security, housing instability, transportation needs, utility difficulties, and interpersonal safety. The domains are described further in Table IX.E.-02 of the rule. The measure does not require use of a standardized screening tool.

Many commenters supported this measure—in combination with the *Screen Positive Rate for Social Drivers of Health* measure discussed in the next section of the rule and this summary—as enabling a data-driven approach to accounting for the impact of social drivers on patient health outcomes and access to care. Results of the measure combination could facilitate future collaborations between hospitals and community-based organizations to address HRSNs. Partnerships could be formed and investments leveraged based on community needs identified.

Some commenters encouraged CMS to expand the measure to include more domains, allow hospitals to select which domains to report, and permit optional reporting of additional domains beyond those required. CMS responds that the domains chosen were based on experience gained by the agency through the Accountable Health Communities (AHC) model and that domains may be added in future measure versions (https://innovation.cms.gov/innovation-models/ahcm). Others urged CMS to adopt the measure into other quality programs such as MIPS and the Hospital Outpatient Quality Reporting Program (OQR). CMS notes that a similar measure has been proposed for addition to MIPS for CY 2023 reporting. Harmonization with similar measures being considered through the Gravity Project and by the National Committee for Quality Assurance was recommended to CMS to achieve alignment, reduce provider burden, and facilitate interoperability. CMS agrees in principle but chooses to move ahead with its own measures for now.

Some commenters supported the measure but requested adoption be delayed or that the voluntary reporting period be extended to allow hospitals to adjust clinical workflows to streamline data collection and train staff to conduct screening in a culturally-sensitive manner. CMS declines, noting the urgency of addressing social drivers of health and having learned that over 90 percent of hospitals currently screen for at least one HRSN. The agency states that approaches used by AHC model participants for staff training may aid hospitals to implement this measure. CMS also declines to await NQF endorsement of this measure, stating no existing NQF-endorsed measures are suitable. CMS indicates its intention to seek NQF endorsement in the future.

Other concerns were voiced by some measure supporters. Emphasis on protecting patient rights and transparency was recommended. CMS responds that patients are free to opt out of screening and expects hospitals to make patients aware of that option. CMS defers to hospitals about how

[69] CMS variably refers to this measure as a *structural* or *process* measure in the preamble, but more often as a structural measure.

they will disclose to patients how and why the information collected will be used. Commenters were concerned that hospitals often lack resources to address needs identified by screening. CMS acknowledges the issue but notes that this measure is an early step on the journey towards health equity and the data collected will establish the baseline necessary for determining next steps. CMS was encouraged to consider that identified HRSNs are likely to have spillover effects on caregivers, with which CMS agrees.

Several objections to measure adoption were voiced. Failure to require use of a standardized screening tool that supports interoperable exchange of the data gathered limits the reliability and value of the measure. CMS disagrees and states that a self-selected screening tool allows flexibility so that each hospital can tailor screening to match its IT resources and the patients and community it serves. The agency indicates that future measure versions will address standardization and interoperability. CMS notes that hospitals may already be using EHR software that permits specific capture of many HRSNs in an interoperable fashion. Some commenters were critical of the evidence base linking HRSN screening to better health outcomes for the inpatient setting. CMS disagrees and states that a robust evidence base exists to directly link the HRSNs of this measure with patient outcomes from interventions directed by screening results. Ambiguity introduced by unclear and overlapping terminology (e.g., social risk factors, social determinants of health, HRSN, social drivers of health) reduces measure reliability and utility. CMS acknowledges the potential for confusion and says it will preferentially use the term social drivers of health for describing upstream non-clinical circumstances that can impair clinical outcomes. Finally, CMS reiterates the successful screening of over 1 million Medicare and Medicaid beneficiaries during the testing period of the AHC model.

CMS clarifies that the measure requires hospitals to screen for all five of the measure's included HRSN domains, and states that prior references to screening for "one or all" of the domains in the FY 2023 IPPS/LTCH PPS proposed rule were inadvertent technical errors. CMS further clarifies that screening should occur during the inpatient admission, but allows for recent medical record documentation of screening done in the outpatient clinic setting to be counted. CMS also confirms that data submission will occur online through the CMS HQR System. Lastly, CMS emphasizes repeatedly that the measure is intended to provide hospitals with individualized, actionable data and not to support comparisons across hospitals. Any other use of the data, such as risk adjustment of existing measures, would not be implemented without first being proposed through notice-and-comment rulemaking.

> Numerator. Number of patients admitted to an inpatient hospital stay who are screened for all of the five HRSN domains.
> Denominator. Number of patients admitted to an inpatient hospital stay.
> Exclusion. Patients younger than 18 years of at the time of admission are excluded from the numerator and denominator. Also excluded from the denominator are patients who opt out of screening and patients who are unable to complete the screening themselves and lack a guardian or caregiver available do so on the patient's behalf.
> Calculation. The numerator of patients admitted and screened for all five HRSNs divided by the number of admissions.
> Data Submission and Reporting. Not explicitly stated in the rule but possibly would be done electronically through the HQR System.

Pre-rulemaking. MUC List December 2021. Despite lack of a standardized screening tool requirement and an unclear link between the measure and better patient health outcomes, the MAP ultimately awarded the measure conditional support for rulemaking pending NQF endorsement. CMS states that the measure has been submitted for NQF review.

c. Screen Positive Rate for Social Drivers of Health

CMS finalizes as proposed adding the *Screen Positive Rate for Social Drivers of Health* structural measure to the Hospital IQR Program measure set, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years.

CMS regards this measure as a companion measure to the newly finalized *Screening for Social Drivers of Health* measure. Together they are intended to enhance standardized data collection for use in identifying high-risk individuals who could benefit from being connected by the hospital to community-based services relevant to their HRSNs. CMS believes that results from the screen-positive measure should be valuable during discharge planning for patients and could support reliable impact estimates for the effects of the included HRSNs on hospital utilization.

Many commenters supported adoption of this measure as a means of advancing health equity by providing data that will facilitate understanding of the links between social drivers of health and health outcomes, care disparities, clinician quality performance, and healthcare costs. Other potential benefits named included increasing healthcare delivery system transparency and promoting data-driven investments in community-based resources. CMS agrees, describes this measure as the next logical step after HRSN screening, and states that the measure will encourage hospitals to assume accountability for identifying the unmet HRSNs of their patients.

Some commenters supported the measure but requested adoption be delayed to allow hospitals sufficient time to prepare to collect the data and familiarize themselves with the data submission requirements. CMS declines, noting the urgency of addressing social drivers of health and having learned that over 90 percent of hospitals already are screening for at least one HRSN. Others raised concerns about public reporting of screening rate results, including ease of interpretation and the risk that consumers will interpret high screen-positive rates as indicators of poor-quality performance by a hospital. CMS responds that public reporting provides information that patients will find useful in healthcare decision making and that should encourage hospitals to focus attention and organizational resources on health equity initiatives.

Some commenters were critical of the measure. The measure's design to generate five distinct rates may produce small sample sizes and unreliable results for some rates for some hospitals depending upon their patient populations. Others questioned whether the measure's specifications were fully developed and adequately tested. CMS believes that the measure is well-designed and fully-specified, cites the extensive testing of HRSN screening during the AHC model's 5-year test period, and notes support for rulemaking was awarded by the MAP.

Other commenters believed the measure to be a case-mix assessment tool possibly suited for use as a risk adjuster but not as a standalone quality measure. They also cited lack of results

comparability across hospitals because the prevalence of the measure's HRSNs will vary based on each hospital's community and patients served. CMS disagrees, stating that the measure fits its definition of a structural quality measure. CMS notes the measure is not intended for use in cross-hospital comparisons or as a risk adjuster for other measures. It is designed to provide hospital-specific feedback about the prevalence and distribution of the five measured HRSNs in an individual hospital's catchment.

CMS states that the measure is part of its longer-term strategy to improve patient outcomes and eliminate equity gaps in the inpatient setting. The agency emphasizes that any adaptation of the measure for use in comparing hospitals would require notice-and-comment rulemaking. At this time, CMS does not expect hospitals to address the root causes identified by screening but they are expected to facilitate linking patients to community resources.

CMS addresses a concern that this measure's numerator and denominator are mismatched or incongruent. This concern arose because of a misunderstanding about the numerator of the companion screening measure, as that numerator is meant to serve as the denominator for the screen-positive measure. As noted above, the screening measure's numerator is the number of patients each screened for all five HRSNs included in that measure, not for "one or more" HRSNs as was incorrectly stated in some prior agency documents. The correct definition of the screening measure numerator will lead to a single, uniform denominator for use in calculating all five of the HRSN rates as is required by the screen-positive measure's specifications.

> Numerator. For each HRSN, the number of patients who screen positive on the date of admission.
> Denominator. For each HRSN, the number of patients screened.
> Exclusion. Patients younger than 18 years at the time of admission are excluded from the numerator and denominator. Also excluded from the denominator are patients who opt out of screening and patients who are unable to complete the screening themselves and lack a guardian or caregiver available do so on the patient's behalf.
> Calculation. A separate rate is calculated for each screening domain, so that five rates are calculated by each hospital for screen-positive patients divided by screened patients.
> Data Submission and Reporting. Web-based data collection using Hospital Quality Reporting (HQR) System and annual reporting per policy for Hospital IQR Program structural measures.
> Pre-rulemaking. MUC List December 2021. MAP review ultimately ended with a recommendation of conditional support for rulemaking pending NQF endorsement. Concerns expressed during MAP review included lack of screening tool standardization and methods for assuring patients that self-reported screening will not affect their care. CMS states an intent to submit the measure for NQF endorsement in the future.

d. Cesarean Birth eCQM

CMS finalizes as proposed adding an eCQM Cesarean Birth to the Hospital IQR Program measure set, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. The measure is intended to facilitate safer maternal care by assessing the rate

of low-risk, Nulliparous Term Singleton Vertex (NTSV) pregnancies delivered by Cesarean section (C-sections) as a step towards reducing the rate of non-medically indicated C-sections and their associated excess morbidity, mortality, and costs.

Many commenters were supportive, believing that the data are necessary to address the current maternal health crisis and could lead to improved clinical practices. Some commenters supported the measure but asked for delayed implementation or extension of the voluntary reporting period. CMS states that the timeline as proposed is sufficient for hospitals and health IT vendors to prepare for eCQM reporting. CMS also states that delay for further reliability and validity testing is unnecessary as additional testing was completed in 2021. The measure has been submitted to NQF and is under review.

Many commenters did not support adoption of this measure. Some believed that the measure design does not capture the factors that contribute to negative maternal outcomes after C-sections and others assert that there is no consensus about ideal C-section rates. Lack of NQF endorsement was also cited as an objection to measure adoption. CMS responds that the measure is a key first step in promoting improvement of maternal care quality and will aid hospitals in assessing their own low-risk pregnancy C-section rates for compliance with clinical guidelines. CMS notes that the chart-abstracted version of this measure has held continuous NQF endorsement since 2008 and that both the chart-abstracted and electronic measure versions are in use by The Joint Commission. Some commenters suggested broader exclusion criteria but CMS disagrees. CMS also disagrees that additional risk adjustment is needed as the measure is specified to target a low-risk population.

CMS clarifies that hospitals that do not perform deliveries may report using zero denominator declarations or case threshold exemptions as discussed later in the rule and this summary.

> Numerator. The subset of patients in the denominator having C-section deliveries.
> Denominator. Nulliparous women with a singleton vertex fetus at ≥ 37 weeks of gestation who deliver a liveborn infant.
> Inclusion. This is an all-payer measure.
> Exclusion. Patients with abnormal fetal presentations (e.g., breech) or placenta previa. Patients with confirmed diagnoses of COVID-19 diagnoses with related respiratory conditions or having related respiratory procedures.
> Calculation. Patients having NTSV deliveries by C-section divided by all NTSV deliveries.
> Risk Adjustment. None. The NTSV descriptor identifies a relatively low-risk pregnancy and the exclusion criteria further reduce the risk of the eligible population.
> Data Sources. Patient-level data are collected through hospital EHRs with measure calculation performed by the CEHRT for submission to CMS.[70]
> Data Submission and Reporting. This measure will follow established policies for eCQM submission. The measure can be voluntarily self-selected by a hospital for reporting during reporting period CY 2023 but would become mandatory for reporting beginning with the CY 2024 reporting period.

[70] EHR = electronic health record. CEHRT = certified electronic health record technology, meaning certified to the standards set by the Office of the National Coordinator for Health Information Technology as required by the CMS Promoting Interoperability Program for acute care hospitals and critical access hospitals.

Pre-rulemaking. MUC List December 2018. The final outcome of MAP review was conditional support for rulemaking pending NQF endorsement. The MAP suggested further feasibility testing and stakeholder consultation which have been completed. The measure has been submitted for NQF endorsement in the Spring 2022 cycle.

e. Severe Obstetric Complications eCQM

CMS finalizes as proposed adding the eCQM *Severe Obstetric Complications* to the Hospital IQR Program measure set, beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. The measure assesses the proportion of patients with severe obstetric complications that occur during inpatient hospitalizations for deliveries. Rates are calculated separately for patients with or without transfusion as their only qualifying numerator event.

Many commenters supported addition of the measure, believing the measure aligns with currently identified clinical best practices. CMS agrees, stating that the measure is intended to facilitate safer care by increasing awareness of major obstetric complications and their associated morbidity and mortality and through encouraging adherence to clinical guidelines. Hospitals not performing deliveries are exempt from reporting the measure. CMS declines requests to delay measure implementation or extend the voluntary reporting period citing the urgency of the maternal health crisis. CMS also declines to delay implementation to await NQF endorsement but notes that the measure has been submitted to NQF and is under review.

Numerous commenters objected to the measure's adoption. Some believed the measure is unlikely to drive meaningful improvement. Others questioned the feasibility of measure reporting and the complexity of the documentation required. Several stated that the measure does not focus on preventable events. CMS disagrees with these commenters and states that the feasibility and reliability of the measure have been proven during field testing in a variety of settings (e.g., rural). Commenters recommended that separate measure results related to transfusions administered not be reported publicly to avoid creating an impression that transfusions always imply poor care quality and to avoid discouraging medically necessary transfusions. CMS disagrees but will monitor measure performance for unintended consequences.

CMS clarifies that patients with COVID-19 diagnoses are excluded from the measure. CMS also clarifies that measure's housing instability risk adjuster is defined by a series of ICD-10-CM Z-code diagnoses as listed in an unnumbered table in section E.5.d. of the rule. Finally, CMS emphasizes that the measure is designed for data collection through a hospital EHR with measure calculation to be performed by the hospital's associated CEHRT.

Numerator. Inpatient hospitalizations for severe obstetric complications that are not present on admission and occur during the delivery hospitalization (see Table IX.E-03 in the rule for the qualifying diagnoses for inclusion in the numerator—e.g., sepsis—and section IX.E.5.d.(4). for the qualifying procedures—e.g., hysterectomy).

Denominator. Inpatient hospitalizations for patients at least 8 years of age and less than 65 years of age admitted for acute care who undergo a delivery procedure for a stillbirth or livebirth greater than or equal to 20 weeks' gestation.
Calculation. Proportion of eligible patients with severe obstetric complications occurring during delivery hospitalizations, reported as a rate per 100,000 deliveries. Rates are calculated separately for patients with or without transfusion as their only qualifying numerator event.
Risk adjustment. This measure is extensively risk adjusted, and separate risk adjustment models are used for cases in which blood transfusion is the only qualifying numerator event. Variables used for adjustment include demographics (e.g., age), certain preexisting conditions (e.g., hypertension), laboratory values, vital signs on admission, and certain social risk factors (e.g., housing instability).
Data Sources. Patient-level data are collected through hospital EHRs with measure calculation performed by the hospital's CEHRT.
Data Submission and Reporting. This measure will follow established policies for eCQM submission. As proposed, the measure can be voluntarily self-selected by a hospital for reporting during reporting period CY 2023 but will become mandatory for reporting by all hospitals beginning with the CY 2024 reporting period/FY 2026 payment determination.
Pre-rulemaking. MUC List December 2021. MAP review ended with a recommendation of conditional support for rulemaking pending NQF endorsement, after having expressed concerns related to discouraging necessary blood transfusions, sample size and minimum case volumes, and the risk-adjustment methodology.

f. Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e)

CMS finalizes as proposed adding an outcome eCQM *Hospital Harm—Opioid-Related Adverse Events* to the Hospital IQR Program measure set beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. The measure uses naloxone (opioid-antagonist) administration as a marker for adverse opioid-related events triggered by opioid administration to inpatients, most of which are avoidable. The measure is intended to provide information to hospitals to improve their monitoring of and response to inpatients given opioids who experience drug-related adverse events (e.g., respiratory depression).

The measure definition includes time parameters to exclude pre-hospital opioid administration and to ensure that opioid administration in the hospital preceded naloxone treatment. The measure has a lengthy development history with multiple refinements, and its addition to the Hospital IQR Program data set was first proposed but not finalized during FY 2020 rulemaking.

Many commenters were supportive and believed that measure adoption will lead to fewer opioid-related adverse inpatient events. CMS agrees and states that the measure captures critically important hospital safety information. Some supporters requested delayed measure implementation to allow hospitals and EHR vendors to be fully prepared. CMS declines and notes the agency's goal of transitioning to digital measurement across its quality enterprise.

Some opposed measure adoption since it focuses on relatively rare events and might contribute to undertreatment of postoperative pain. CMS plans to monitor for unintended consequences.

Some suggested additional exclusions for addition to the measure's specifications. CMS declines to do so at this time and states the measure has been rigorously tested and shown to be reliable as currently specified. Commenters recommended that several years of data accrual and analysis precede any consideration of adopting this measure into P4P programs. CMS responds that adoption into a P4P program would require notice-and-comment rulemaking.

CMS clarifies that all opioids that are formulated for inpatient use are included in the measure's specifications. CMS also clarifies that there is no "target rate" for this measure as it will be used in a pay-for-reporting program (hospital IQR program). CMS indicates that the number of events is not expected to fall to zero but that inter-hospital variation is expected to decline.

Numerator. Proportion of inpatient encounters where patients have been administered an opioid followed by administration of naloxone within 12 hours.
Denominator. Patients receiving at least one opioid dose during their hospitalizations.
Exclusions. Patients under 18 years of age are excluded. Patients receiving naloxone in the hospital's operating room are excluded. Use of naloxone during procedures performed outside of the operating room are included. If naloxone is administered more than once, only the first treatment episode is included.
Calculation. Inpatient encounters where patients have been administered an opioid followed by administration of naloxone within 12 hours divided by hospitalizations that include at least one opioid administration.
Risk adjustment. This measure is not risk adjusted as opioid-related adverse events should be avoidable regardless of patient risk factors. This decision was supported by the NQF Scientific Method Panel based on testing results from the measure developer.
Data Sources. Patient-level data are collected through hospital EHRs with measure calculation performed by the hospital's CEHRT.
Data Submission and Reporting. This measure will follow established policies for eCQM submission and be eligible for self-selection by hospitals for reporting beginning with the CY 2024 reporting period/FY 2026 payment determination. (Mandatory reporting is not being proposed.)
Pre-rulemaking. MUC List December 2021. MAP review of the refined and retested measure resulted in support for rulemaking. The measure received NQF endorsement December 7, 2021.

g. Global Malnutrition Composite Score eCQM (NQF #3592e)

CMS finalizes as proposed the addition of the eCQM *Global Malnutrition Composite Score* to the Hospital IQR Program measure set beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. The four measure components correspond to the four elements of recommended optimal nutritional care: screening, complete assessment of patients screening positive, documentation of degree of malnutrition, and nutritional care plan development. All four components are significantly associated with improved outcomes for 30-day hospital readmissions. Tables IX.E.-04 through IX.E.-06 in the rule provide details of the component measures.

Many commenters were supportive of measure adoption to help close the gap between identification and intervention for malnutrition, especially for an aging population or those with food insecurity as a HRSN. Some were concerned that the measure could be overly subjective and that reporting could be complex, especially for smaller facilities. CMS disagrees, stating that the measure is designed for data collection through the hospital EHR and results processed through the associated CEHRT. CMS notes that the measure aligns with its goal of digital quality measurement across its programs. Both support and opposition were voiced about future mandatory reporting; CMS finalizes the measure as voluntary, as proposed, and available for self-selection by hospitals.

Some requested delay because implementation of this multi-component measure will require change to multiple clinical workflows but CMS declines. Finally, CMS clarifies that a higher measure score signifies better performance but emphasizes that the measure is not scored since the IQR program is a pay-for-reporting not pay-for-performance program.

Numerator. Four component scores.
Denominator. 100 percent for each component score.
Exclusions. Patients with lengths of stay < 24 hours are excluded from the denominator of each component.
Calculation. The component measures are first scored separately from 0-100 percent. The component scores are summed and an unweighted average is determined and reported as the composite score.
Data Sources. Patient-level data are collected through hospital EHRs for each component measure, and composite measure calculation is performed by the hospital's CEHRT.
Data Submission and Reporting. This measure would follow established policies for eCQM submission and be eligible for self-selection by hospitals for reporting beginning with the CY 2024 reporting period/FY 2026 payment determination.
Pre-rulemaking. MUC List December 2020. MAP review ended in conditional support for rulemaking pending NQF endorsement. Concerns raised were resolved through submission of additional performance data and by linking structured EHR data fields to standardized nutrition assessment tools. The measure received NQF endorsement in June 2021 (NQF #3592e*).*

h. Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (NQF #3559)

CMS finalizes as proposed phased adoption of the *Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)* measure to the Hospital IQR Program measure set. Finalized are two voluntary reporting periods (portions of CY 2025 and CY 2026), followed by mandatory reporting for the period running from July 1, 2025 through June 30, 2026 that impacts the FY 2028 payment determination. The mandatory reporting period sequence continues for subsequent year payment determinations.

This PRO-PM is based on a measure developed for and used in the Comprehensive Care for Joint Replacement (CJR) model beginning in 2015 and that is still being collected.[71] It uses standardized, validated survey instruments completed within 3 months pre- and at about 1-year postoperatively to assess patient-perceived pain and function, the two main reasons for which THA and TKA operations are performed. Risk adjustment includes numerous variables. Specifications are available in the Hip and Knee Arthroplasty zip file available for download at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.

CMS reports receiving many supportive comments about this measure in response to the proposed rule and to its RFI about this measure's adoption issued during FY 2022 IPPS/LTCH PPS rulemaking. Respondents emphasized the importance of the data to joint replacement clinical care teams and to patients. Some viewed the measure as incentivizing collaboration between hospitals and providers both pre- and postoperatively. Some asked for delayed implementation or extension of the voluntary reporting period to allow hospitals and providers to fully prepare to report this complicated measure. CMS declines, stating the necessity to promptly begin capturing patient-reported outcomes (PRO) data for these commonly performed procedures and noting that two voluntary periods have been finalized before reporting becomes mandatory. CMS also states that many hospitals have already incorporated PRO data collection into their workflows (this may refer to CJR participant hospitals but that is not stated).

Despite support, some concerns were voiced. Commenters note the shift of THA/TKA procedures to the outpatient setting since this measure was developed and question whether the utility and accuracy of this measure have been impaired. CMS acknowledges the concern but disagrees. The agency commits to monitoring the effects on the measure of the shift in settings and notes that the robust risk adjustment built into the measure should capture the differences in patient populations related to site of service (e.g., more frail inpatients versus healthier and more mobile outpatients). CMS notes having issued RFIs concerning transitions of this and similar measures to the outpatient hospital and ambulatory surgery center quality programs. Another concern was response bias that affects reporting frequency and results reported when data are gathered from disadvantaged populations, potentially skewing results. CMS responds that risk adjustment of this measure explicitly addresses response bias. Some voiced concern about survey fatigue for patients but CMS states that few patients will receive both HCAHPS and IQR PRO-PM surveys.

Numerous commenters did not support measure adoption. They opposed adoption of this complicated and burdensome measure concurrently with many other new IQR program measures and increased eCQM reporting requirements. Others stated that patient-driven factors outside of providers' control (e.g., compliance with postoperative physical therapy) affect measure results. CMS reiterates the need to proceed promptly with adding PRO measures to the program. Commenters requested full reporting by CMS of the results and implementation issues surrounding use of this measure in the CJR model. CMS responds that lessons learned from the model have been incorporated into the IQR measure design and otherwise reports only that the early years of measure reporting showed hospital-level variations. CMS describes the lower reporting threshold of the IQR measure (50 percent) compared to the CJR measure (80 percent)

[71] CJR model participation is mandatory for a selected group of hospitals nationwide.

as a lesson learned without providing additional details. Commenters urged CMS to publicly report experience from the CJR measure before the IQR measure transitions to mandatory reporting and CMS agrees to consider this request.

Many commenters cited excess burden associated with the IQR THA/TKA PRO-PM measure, mentioning the lack of a central data repository and the prolonged measurement period since patient tracking may extend as long as 425 days postoperatively. They concomitantly argued for a shorter postoperative reporting window, stating that most functional improvement has occurred within 90 days postoperatively. CMS acknowledges that the measure imposes financial, labor, and resource burdens but asserts that the benefits of the measure outweigh the burden. CMS states that the reporting window was chosen after extensive input from clinical experts and patient representatives. CMS believes that the flexibility in data submission methods offered for the measure will mitigate reporting burden. CMS states that measure burden will be monitored though does not explicitly agree to a targeted burden review before the transition to mandatory reporting. Finally, many commenters recommended that CMS create payment incentives to report this measure, noting that quality score bonus points were offered in the CJR model to incent reporting. CMS says that incentive payments cannot be offered as the IQR program design is pay-for-reporting.

Numerator. Risk-standardized proportion of patients meeting pre-defined thresholds for substantial clinical improvement.
Denominator. Medicare beneficiaries 65 years of age or older undergoing elective primary THA or TKA as inpatients.
Exclusions. Patients with hip/knee fractures, who die before discharge, leave against medical advice, or have staged procedures.
Calculation. All patient-level results for a hospital are aggregated ("hospital-level") to produce a case-mix adjusted risk-standardized improvement rate (RSIR). PRO tool response rates utilize completed matched pre- and postoperative assessments.
Risk Adjustment. Preoperative mental health is accounted for using 2 validated PRO tools, and health literacy based on a standardized questionnaire. Other variables are included to adjust for non-response bias (e.g., patient demographics, race, dual eligible status).
Data Sources. Completed patient self-assessments, Medicare claims and beneficiary databases, and Census Bureau survey data.
Data Submission and Reporting. Multiple submission mode options are available. Hospitals submit multiple data elements, drawn from prespecified reporting periods, during preset submission windows. There will be two voluntary reporting periods (one each in 2025 and 2026) followed by mandatory reporting starting in 2027 for payment determination (program) year FY 2028. Data from the voluntary periods will not be publicly reported but indicators will identify hospitals choosing to voluntarily report. Public release of results and response rates will start with the first mandatory reporting cycle. The submission and reporting cycles for the voluntary and first mandatory periods are shown in Tables IX.E.-07 and IX.E.-08 in the rule and in the table below.
Pre-rulemaking. Appeared on the December 2020 MUC List. Supported by the MAP for rulemaking. NQF endorsed in November 2020 (NQF #3559).

Preoperative and Postoperative Reporting Periods for THA/TKA PRO-PM					
Reporting Period	**Performance Period**	**Preoperative Data Collection Window**	**Preoperative Data Submission Deadline**	**Postoperative Data Collection Window**	**Postoperative Data Submission Deadline**
VOLUNTARY REPORTING					
Voluntary 1 (2025)	1/1/2023 through 6/30/3023	10/3/2022 through 6/30/2023	10/2/2023	10/28/2023 to 8/28/2024	9/30/2024
Voluntary 2 (2026)	7/1/2023 through 6/30/2024	4/2/2023 through 6/30/2024	9/30/2024	4/26/2024 to 8/29/2025	9/30/2025
MANDATORY REPORTING*					
Mandatory 1 (2027)	7/1/2024 through 6/30/2025	4/2/2024 through 6/30/2025	9/30/2025	4/27/2025 to 8/29/2026	9/30/2026
Source: Tables IX.E.-07 and IX.E.-08 in the rule, consolidated by HPA.					
* Data reported during this timeline will affect FY 2028 payment determinations.					

i. Substantive Measure Refinement and Reintroduction: Medicare Spending Per Beneficiary (MSPB) Hospital (NQF #2158)

CMS finalizes as proposed to add a refined version of the MSPB-Hospital claims-based measure to the Hospital IQR Program measure set beginning with the FY 2024 payment determination. The prior, original version was removed from the program beginning with the FY 2020 payment determination after routine triennial measure maintenance review, at which point the measure's associated costs were believed to outweigh benefits of its continued use. When removed from the IQR program, the original version was not simultaneously removed from the HVBP program's measure set, where it had been adopted previously into the Efficiency and Cost Reduction domain. The original version currently remains actively used in the HVBP Program.

CMS states that the benefits of the refined measure, unlike its predecessor measure, now outweigh its costs. The agency lays out a plan to propose replacement of the original measure in the HVBP program's measure set with the refined measure in the future, once the statutory requirement for use and public reporting of the refined measure as part of the Hospital IQR Program are met. CMS notes the improved alignment of the refined MSPB-Hospital measure with cost measures used by CMS in other settings (i.e., physician and PAC quality programs).

Several commenters supported adoption of the refined measure into the IQR program and strongly supported allowing readmission to trigger a new episode. They asked for projected impacts of the refined measure on hospitals in the IQR program as compared to results using the original measure and for projections of the effects of using the refined measure in the HVBP Program. CMS refers commenters to statistics submitted during the NQF process, available for download under Measures Under Review 2158 on the NQF website at https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear= CMS adds that projections concerning the HVBP Program impacts cannot be made in isolation without incorporating results of other measures in that program since Total Performance Scores are used to make payment adjustments.

Several concerns were raised and opposition to measure adoption expressed by some commenters. The coexistence of two similarly named measures with different specifications (and

yielding different results) in two separate CMS hospital quality programs was noted by numerous commenters. CMS says this scenario is unavoidable as statute requires that the HVBP program's measure set contain a measure in the Efficiency and Cost Domain at all times and the original MSPB-Hospital measure is the sole measure in that domain. CMS states that explanatory materials will be provided with results reports to minimize confusion. Further, CMS notes that the original measure results are posted to the Provider Data Catalog whereas the refined measure results will appear on Care Compare.

Some commenters stated that allowing readmissions to trigger new episodes could lead to double counting of costs within the IQR program and jeopardy for double penalties through the IQR program and the HRRP. CMS responds that the first scenario is addressed through risk adjustment for inpatient admission within the prior 30 days and that the second scenario does not represent double jeopardy since the two programs assess readmissions for distinct purposes. In response to comments about measure reliability, validity, and social risk factor adjustment, CMS reprises results presented to the NQF and judged to be suitable by that entity for measure endorsement. Some commenters stated that a pure cost measure without embedded quality criteria could lead to care stinting. CMS responds that the IQR program has a broad mix of cost and quality measures. Finally, CMS rejects a request to delay adoption until the end of the COVID-19 PHE, citing data that show a small impact of the pandemic on measure performance in CY 2021.

Refined specifications. The refined MSPB-Hospital measure differs from the original version by (1) new service inclusion and exclusion rules that reduce the capture of services outside of the control of providers, (2) allowing readmissions to trigger new episodes, and (3) modifying the measure calculation from sum of observed costs divided by sum of expected costs to mean of observed costs divided by expected costs. Revised MSPB Amount = [(Sum Observed Costs/Expected Costs)/# Attributed Episodes) x Average Observed Cost Nationally]. The changes are believed to more accurately measure costs for which hospitals should be held accountable while reducing the effects of outliers on final measure scores. Consideration was given to adjusting the measure for beneficiary social risk factors, but no adjustments were made after extensive analyses showed the impacts of social risk factors on the measure to be inconsistent and limited. The refined methodology is available at https://qualitynet.cms.gov/inpatient/measures/mspb/methodology.
Pre-rulemaking. Given the extent of measure changes, the refined measure was placed on the December 2021 MUC List. MAP review concluded with support for rulemaking. The refined measure also received NQF endorsement in June 2021. The NQF Consensus Standards Approval Committee concurred with not making adjustments for social risk factors.

j. Substantive Measure Refinement and Reintroduction: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550) (THA/TKA Complication Measure)

CMS finalizes as proposed to add a refined version of the claims-based THA/TKA Complication Measure to the Hospital IQR Program measure set beginning with the FY 2024 payment determination. The prior, original version was removed from the Program beginning during FY 2018 IPPS rulemaking after routine triennial measure maintenance review as part of a CMS

initiative to reduce provider burden. The refined measure newly captures 26 additional ICD-10-CM diagnosis codes describing complications of these procedures (e.g., M7.02XS Periprosthetic fracture around internal prosthetic left hip joint, sequela). CMS analyses show that adding these diagnoses increases the complication rate by about 0.5 percent. Admissions with principal or secondary COVID-19 diagnoses are excluded from the numerator when assessing non-surgical complications (e.g., pneumonia within 7 days postoperatively). A covariate adjustment for a history of COVID-19 also is part of the refined measure (and has been separately finalized for the current HVBP program's measure version). Public reporting of the refined measure will begin in 2023 on Care Compare.

When removed from the Hospital IQR Program, the original measure version was retained for use in the HVBP program's measure set, where it had been adopted previously into the Clinical Outcomes domain and remains in active use. The agency lays out a plan to propose replacement of the original measure with the refined measure in the future, once the statutory requirement for use and public reporting of the refined measure before HVBP Program adoption are met.

Many commenters supported adopting the refined measure into the IQR program to more accurately identify THA/TKA complications. Some commenters opposed adoption because THA/TKA cases are rapidly shifting to outpatient sites of service. CMS acknowledges the concern but disagrees and believes the measure's risk adjustment will account for impacts of the shift. The agency commits to monitoring the effects on the measure of the shifts. Some commenters believed the expanded diagnosis list will create reporting burden for providers, but CMS responds that this claims-based measure does not require data submission by hospitals so imposes no burden. CMS responds to a concern about social risk factor inclusion by noting the agency's data analysis suggested little impact of social risk factor adjustment and that the analysis was reviewed by the NQF. CMS intends to monitor whether social risk factor adjustment should be added in future years.

Other commenters objected to the coexistence of two similarly named measures with different specifications (and yielding different results) in two separate CMS hospital quality programs. CMS says this scenario is unavoidable as statute requires that a measure must be added to the IQR program and results reported publicly for at least a year before the start of the measure's performance period once it is added to the HVBP Program. CMS states that explanatory materials will be provided with results reports to minimize confusion. Further, CMS notes that the original measure results are posted to the Provider Data Catalog whereas the refined measure results will appear on Care Compare. CMS also clarifies that the refined measure version will replace the original version for use in Overall Hospital Quality Star Ratings beginning with public reporting in 2023.

Refined specifications. The refined THA/TKA Complication measure differs from the original version by the addition of 26 ICD-10 diagnostic codes for mechanical complications in the outcome (numerator) specifications. The data source for the codes are Part A claims. The refined measure otherwise aligns with the original, HVBP measure version, and includes any complication occurring during the index admission to 90 days afterward. (Once one complication occurs, subsequent complications are not separately counted.) The list of added complication diagnoses is found in section IX.E.5.i.(4). of the rule and expanded information is available in

the Hip and Knee Arthroplasty Complications (ZIP) folder at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.
Pre-rulemaking. The refined measure appeared on the December 2021 MUC list. MAP review concluded with support for rulemaking pending NQF review and re-endorsement. CMS intends to submit the measure to the NQF in the Fall 2024 cycle. The original measure was re-endorsed in July 2021.

2. Hospital IQR Program Measure Set: Current Measure Refinements

a. Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective THA and/or TKA (NQF #3474) (THA/TKA Payment Measure)

CMS proposes to refine the current THA/TKA Payment Measure by adding 26 ICD-10 diagnostic codes for complications of THA or TKA to the outcomes currently captured in the numerator of this measure. The 26 codes are listed in section IX.E.6.a.(4) of the rule and are the same as those proposed for addition to the THA/TKA Complication Measure as described previously in the rule and this summary. These diagnoses were identified during routine measure maintenance review. CMS proposes to add these diagnoses beginning with the FY 2024 payment determination.

CMS states that the proposed refinement does not substantively change the data sources, cohort, inclusion/exclusion criteria, or risk adjustment of the original measure. The payment window for the measure will continue to include all payments during the first 30 days after admission and a pre-defined set of postoperative settings and services for days 31-90 after the index admission. The settings and services are taken from those specified for the THA/TKA Complications Measure. The refined measure was included on the December 2021 MUC List. MAP review concluded with conditional support of the measure for rulemaking pending NQF review and endorsement. CMS states its intent to submit the refined measure for the Fall 2022 NQF cycle.

CMS anticipates that the expanded numerator will lead to an increased rate of complications (rising from 2.42 percent to 2.93 percent) and thereby an increase in payments for episodes of care in which complications occur. An estimate of increased payments is not provided. Measure specifications are available in the Hip and Knee Arthroplasty Payment (ZIP) folder at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.

Some commenters were supportive, viewing the measure as more fully capturing complications and their associated costs. Concern was raised about overlap between the refined THA/TKA measure and the refined MSPB Hospital measure described above. CMS responds that both measures use the same claim standardization process but that the MSPB Hospital measure cohort is much larger and more broadly based than that of the THA/TKA payment measure. CMS also notes that the refined THA/TKA payment measure is meant to be used for quality improvement and analytic purposes in tandem with the THA/TKA complications measure described earlier.

b. Excess Days in Acute Care (EDAC) After Hospitalization for Acute Myocardial Infarction (AMI) (NQF #2881) (AMI EDAC)

This measure captures adverse care outcomes during care transitions after hospitalizations for AMI within 30 days after discharge (e.g., ED visits). CMS finalizes as proposed to refine the current AMI EDAC measure by increasing the minimum case count from 25 to 50 cases to address reliability concerns identified during routine measure maintenance review. Hospitals not meeting the minimum case threshold will receive confidential feedback but their results will not be publicly posted. Public reporting on Care Compare will occur for hospitals meeting or exceeding the threshold, after confidential reporting and a review and corrections period. The refinement will be effective beginning with the FY 2024 payment determination. Measure specifications are available for download (AMI EDAC ZIP file) https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.

Some commenters were supportive of the refined measure. Others suggested that the measure, with or without refinement, adds little to the IQR program's value or utility. CMS disagrees and says that the measure provides information in which patients are interested separate from available data about readmissions after AMI hospitalizations. CMS also rejects a commenter's assertion that the measure actually was designed to address substitution by hospitals of observation stays for readmissions and improve performance on readmissions measures. In response to a commenter, CMS details the adjustments made to the AMI EDAC measure as technical updates for COVID-19 impacts (e.g., risk adjustment for a prior diagnosis of COVID-19). A suggestion was made to increase the cohort and thereby measure reliability by changing the measure to include all-payer rather than Medicare-only data. CMS will consider this change for future years. Concern was raised about similar reliability issues for the Pneumonia EDAC and Heart Failure EDAC measures and why their case minimums were not being refined. CMS responds that measure reliability for the latter two measures has continued to be acceptable including during NQF review in early 2021.

3. Quality and Safety of Maternal Care

a. Establishing the Maternal Care Designation

CMS finalizes establishing a designation to reflect the quality and safety of maternal care delivered by a hospital that would be publicly reported on a public-facing CMS website beginning in Fall 2023. The designation will be awarded to hospitals that report "Yes" to both questions embedded in the Maternal Morbidity Structural Measure of the Hospital IQR Program. Data collection for that measure began with Q4 CY 2021 data.

A "Yes" response requires an affirmative answer to both parts of the measure's question.
Part 1. Does your hospital or health system participate in a Statewide and/or National Perinatal Quality Improvement Collaborative Program aimed at improving maternal outcomes during inpatient labor, delivery and post-partum care?

Part 2. Has your hospital implemented patient safety practices or bundles related to maternal morbidity to address complications, including, but not limited to, hemorrhage, severe hypertension/preeclampsia or sepsis?

Many commenters were supportive of establishing a public designation for delivery of high-quality maternal health care. The initially low burden associated with incorporating existing attestation measures was appreciated. However, many also urged CMS to quickly move past structural/attestation measures to more measures that are clear, consistent, evidence-based, and patient-centered. Commenters encouraged CMS to consider risk adjustment and stratified data reporting of program results as well as effects of the COVID-19 PHE. Others urged CMS to monitor whether lack of designation leads to reduced access to delivery services and closure of obstetric units. Commenters expressed frustration that stakeholders were not engaged by CMS in developing the designation initiative.

Many commenters opposed the proposed designation as attestation is insufficient to establish actual delivery of high-quality care. Concern was raised that the measure will mislead consumers into believing the designation clearly indicates that a hospital is delivering an exceptional level of maternal care. Several noted that many smaller or rural hospitals are unlikely to have sufficient resources to participate in the perinatal collaboratives required to attest to the Maternal Morbidity Structural Measure. Many objected to basing the designation on a measure that is not NQF-endorsed. Some stated that the absence of a neonatal health component on the designation criteria is unacceptable for initiatives to address maternal health. Other commenters noted that patients' choices of delivery sites are often constrained by factors such as insurance coverage and clinician admitting privileges. Concerns were raised that a designation based on criteria that are constantly in a state of flux will not be meaningful to the public. Harm to the reputation of non-hospital birthing facilities by lack of designation was raised as a concern.

To most comments, CMS responds that the designation is merely a first step in addressing the nation's ongoing maternal health crisis, meant to inform the public in a meaningful and consumer-friendly manner about maternal care quality. CMS indicates that the special needs of smaller or rural hospitals will be considered as the designation criteria evolve. CMS notes discretion granted in statute for adoption of measures that are not NQF-endorsed (section 1886(b)(3)(B)(viii)(IX)(bb) of the Act). CMS acknowledges that patient choice may be constrained by multiple factors. The agency also notes that many measures and programs undergo periodic revisions without loss of credibility. CMS states that incentive payments to hospitals with limited resources are not possible within the design of the IQR program but that the agency will explore offering technical assistance to those facilities. Finally, CMS clarifies that the designation is not available outside of subsection (d) hospitals, specifically IPPS-exempt, self-governing children's hospitals.

b. Solicitation of Comments

CMS solicited input about additional sources of data other than the Maternal Morbidity Structural Measure for use in structuring the designation, particularly about relevant patient experience-of-care measures.

Commenters urge CMS to incorporate evidence-based outcome measures and existing categorizations of maternal care such as the Levels of Maternal Care described by the American College of Obstetricians and Gynecologists. Some recommended CMS consider other payment models analogous to trauma activation or develop a maternal and fetal health disproportionate share reimbursement model. A suggestion was made that an accreditation agency might be better suited than CMS to managing the designation process.

CMS notes the payment structure limitations imposed by the IQR program's statutory requirements. The agency commits itself to continued refinement of the designation and its current and future criteria and measures.

Support for addition of the two newly finalized IQR program maternal health eCQMs for adoption into the hospital designation imitative was divided. The provider burden imposed by eCQMs was noted. Other possibilities mentioned were PRO-PMs, measures of access to culturally competent care and alternative maternity care providers (e.g., doulas and lactation consultants), minimum facility staffing rates, and completion rates for initial scheduled postpartum visits. NQF endorsement of measures included in the designation was recommended.

CMS indicates it will continue to evaluate the newly finalized IQR program eCQMs and other options for additional criteria to use in awarding the birthing hospital designation. CMS states that the urgency of the maternal health crisis may not permit time to await NQF endorsement of measures.

CMS also asked for suggestions for naming the maternity care hospital designation. Many were offered such as *Quality Birthing Hospital* or *Birth Star Hospital*. CMS does not finalize a name.

c. RFI: Additional Activities to Advance Maternal Health Equity

In addition to recognizing hospitals for quality and safety of maternal care, in the proposed rule CMS requested information on other potential policy approaches to advancing maternal health equity. These approaches could involve but would not be limited to Medicare's Conditions of Participation (CoPs) and quality reporting programs (e.g., Hospital IQR Program). CMS posed a long and detailed list of questions and topics for comment to which readers are referred (section IX.E.8.e of the rule).

CMS received many suggestions and recommendations, some of which are highlighted below.

- Dissemination of best practices in maternity care,
- Potential applicability of certain CoPs to maternal health outcomes,
- Staff training on implicit bias and antiracism in maternity care,
- Risk adjustment and results stratification methods,
- Maternal health safety monitoring program frameworks,
- Building referral relationships between hospitals and community-based providers,
- Staffing cross-functional and holistic maternity care teams, and
- Design of tools for evaluating customer experience.

4. Hospital IQR Program Measure Set: Potential Future Measures

a. Clostridioides difficile CDC NHSN Healthcare-Associated Infection (HA-CDI) Outcome Measure

In the proposed rule, CMS invited input on the potential addition of a new measure tracking new *Clostridioides difficile* infections (CDI) among hospital inpatients, using algorithmic determinations based on EHR data. Measure data would be submitted through the CDC NHSN reporting system. A less strictly specified measure of new CDIs (NQF #1717) was removed from the IQR program during FY 2019 rulemaking but retained in the HVBP Program and the HAC RP and remains in active use in those two programs. Key features of the new digital quality measure (dQM) are listed below.

> Numerator. Patients with (1) a qualifying *C. difficile*-positive assay on an inpatient encounter on day 4 or later of an inpatient admission and with no previously positive event in ≤ 14 days before the inpatient encounter; and (2) qualifying antimicrobial therapy newly started within the appropriate window (i.e., based on timing of stool specimen collection).
> Denominator. Expected number of hospital CDIs based on predictors including facility size and patient location within the hospital.
> Exclusions. Patients in ED and other outpatient locations. Patients from well-baby nurseries and neonatal intensive care units.
> Risk adjustment. Done for facility characteristics and volume of exposure/facility size.
> Data Sources. Microbiology, medication administration, patient location (e.g., type of nursing unit), patient encounter, and patient demographic data are extracted from the facility's EHR.
> Data Submission and Reporting. CDC plans to enable and promote reporting of this measure using FHIR®-based resources but also plans to enable reporting using other more widely available formats.
> Pre-rulemaking. The HA-CDI measure was included on the December 2021 Measures Under Consideration (MUC) list. CDC is the measure's steward. The measure was suggested for potential use in multiple CMS quality reporting programs for post-acute care providers as well as the Hospital IQR Program. The HA-CDI measure was reviewed by the MAP, who conditionally supported the measure for rulemaking, contingent on NQF endorsement once the revised measure is fully tested. CMS reports that CDC intends to submit the measure in the future for NQF endorsement.

Many commenters supported future adoption of this measure as an improvement over predecessor measures. Some advocated a phased adoption timeline to allow hospitals to gain familiarity with dQM reporting. Others opposed adoption of the measure into the IQR, HVBP and HAC Reduction programs until it is fully specified and results from comprehensive testing of the measure are available and until the measure can be reported through a FHIR-based API. Delay for NQF endorsement was also advocated. CMS notes that CDC is still refining the measure's specifications and identifying measure submission mechanisms other than via FHIR since an API for the measure is not yet available.

Others were concerned that since the measure counts patients receiving antibiotic treatment for CDI, clinicians may feel pressured to withhold treatment. Some recommended exclusion of immunocompromised patients in whom empiric antibiotic administration may be justified without laboratory confirmation of CDI. Commenters also questioned whether the measure is appropriate for use in PPS-exempt cancer hospitals. CMS believes the measure may ultimately be applicable to many of the agency's quality programs and would advance the agency's transition to a fully digital quality platform. CMS further notes that future adoption of this measure into any of its programs would be done through notice-and-comment rulemaking.

b. CDC NHSN Hospital-Onset Bacteremia and Fungemia Outcome Measure

In the proposed rule, CMS invited input on the potential addition of a new dQM measure tracking hospital-onset bacteremia and fungemia events among hospital inpatients to multiple programs including the IQR, HVBP, HAC Reduction, and PPS-exempt cancer hospital quality programs. The measure tracks bloodstream infections without limitation by species, unlike current measures that track specific organisms such as methicillin-resistant Staphylococcus aureus (MRSA), and would incorporate algorithmic determinations based on EHR data. Measure data would be submitted through the CDC NHSN reporting system. A CDC NHSN measure tracking MRSA is currently used in the HVBP and HAC Reduction programs. Key features of the new digital quality measure (dQM) are listed below.

Numerator. Number of observed hospital-onset bacteremia events.
Denominator. Number of expected hospital-onset bacteremia events derived from predictive models using facility-level and patient-level predictive factors.
Exclusions. Patients with bacteremia or fungemia present on admission are excluded from the numerator. Patients not assigned to an inpatient bed in an applicable location are excluded from the denominator.
Calculation. Ratio of observed events to events expected from the predictive model.
Data Sources. Microbiology, medication administration, patient location (e.g., type of nursing unit), patient encounter, and patient demographic data are extracted from the facility's EHR.
Data Submission and Reporting. Options are still under development by CDC, ranging from conventional clinical document architecture to FHIR-based applications.
Pre-rulemaking. The measure has been through a number of refinements and MAP reviews. It appeared on the July 2021 MUC List and during MAP review received conditional support for rulemaking pending NQF review once the measure is fully tested. CDC intends to submit the measure to the NQF after completing measure testing.

Many commenters supported future adoption of this measure as an improvement over predecessor measures and some were optimistic that the dQM format would reduce reporting burden. Others recommended initial adoption into the IQR program and extension to other programs only after hospitals and CMS gain experience with the measure, while some supported early adoption into the HVBP and HAC Reduction programs.

Others opposed adoption of the measure into the IQR, HVBP and HAC Reduction programs until it is fully specified and results from comprehensive testing of the measure are available and

until the measure can be reported through a FHIR-based API. Delay for NQF endorsement was also advocated. CMS notes that CDC is still refining the measure's specifications and identifying measure submission mechanisms other than via FHIR since an API for the measure is not yet available. Many believed that dQM reporting will consume inordinate hospital resources. Others were concerned about untended clinical consequences such as reduced ordering of blood cultures to manipulate measure performance. Some advocated risk adjustment for immunocompromised patients. Others supported peer grouping during measure scoring.

CMS believes the measure may ultimately be applicable to many of the agency's quality programs and would advance the agency's transition to a fully digital quality platform. CMS further notes that future adoption of this measure into any of its programs would be done through notice-and-comment rulemaking.

5. Hospital IQR Program Measures: Form, Manner, and Timing of Data Submission

CMS reviews procedural and data submission requirements for the Hospital IQR Program; no changes are proposed to these policies except as described below.

a. Reporting and Submission Requirements for eCQMs

CMS finalizes as proposed to increase the eCQM reporting and submission requirements by increasing measure reporting from four eCQMs (one mandatory and three self-selected) to six eCQMs (three mandatory and three self-selected) beginning with the CY 2024 reporting period/FY 2026 payment determination. Four calendar quarters of data reporting will be required for each eCQM and all must be reported using technology certified to the 2015 Edition Cures Update.

The finalized increase of numbers of measures to be reported reflects the addition of two new maternal health eCQMs for mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination: *Cesarean Birth* and *Severe Obstetric Complications*. CMS states the increase also advances its policy goal to incrementally expand eCQM reporting requirements in preparation for transitioning to a digital quality reporting platform. The finalized eCQM reporting parameters are shown in the table below.

Some commenters supported the increase in numbers of eCQMs for mandatory reporting. Most commenters, however, opposed the increase for reasons including the following:

- The continuously increasing demands in terms of amount of data to be reported,
- The time required with each new eCQM added to adjust clinical workflows and train staff on the new measures,
- Delayed delivery by EHR vendors of updated software and delivery of products that often have not been adequately tested and are not truly production ready, and
- Accelerating strain on hospital financial and IT personnel resources by increased IQR demands imposed concurrently with increasing demands of other CMS programs and other federal EHR requirements.

CMS clarifies that hospitals that do not perform deliveries should utilize zero denominator declarations or case threshold exemptions in order to meet requirements for reporting the Cesarean Birth and Severe Obstetrics Complications eCQMs.

CMS declines requests to reconsider or to delay the increased mandatory eCQM reporting requirements. CMS cites the agency's strategic plan for continued movement from chart-abstracted measures to eCQMs and ultimately dQMs and the compelling need to promptly address the nation's maternal health crisis. CMS believes that ample time is being provided for hospitals to ramp up their eCQM reporting efforts. The agency encourages hospitals to work with their EHR vendors to obtain updated software timelier and encourages vendors to deliver fully-tested products that can be fully implemented without delay. CMS will continue to seek opportunities to streamline reporting requirements and processes. The agency also discusses its work to ensure the reliability and validity of eCQM data along with the improvements recently achieved by implementing the HQR System for eCQM submission by hospitals. CMS concludes by emphasizing that the benefits of moving inexorably forward with increased eCQM and dQM reporting will far outweigh the imposed provider burden and lead to improved quality measurement processes, better and more useful quality data, and ultimately to improved health outcomes for patients.

Current and Proposed eCQM Reporting and Submission Requirements by Year			
Reporting Period/ Payment Determination	**eCQM Data Publicly Reported**	**Total # eCQMs Reported**	**eCQMs Required to be Reported**
CY 2021/FY 2023	Two self-selected quarters of data	Four	Four self-selected
CY 2022/FY 2024	Three self-selected quarters of data	Four	Three self-selected and Safe Use of Opioids-Concurrent Prescribing
CY 2023/FY 2025	Four quarters of data	Four	Three self-selected and Safe Use of Opioids-Concurrent Prescribing
CY 2024/FY 2026 and subsequent years	Four quarters of data	Six	Three self-selected and Safe Use of Opioids-Concurrent Prescribing and Cesarean Birth* and Severe Obstetric Complications*
* Measures finalized in this rule Source: Consolidation by HPA of Tables IX.E.-14 and IX.E.-15 in the rule			

b. Reporting and Submission Requirements for Hybrid Measures

CMS finalizes as proposed to remove the zero denominator declarations and case threshold exemptions policies for hybrid measures beginning with the FY 2026 payment determination. These hybrid measure policies were adapted from eCQM policies to avoid penalizing hospitals who had no patients meeting the denominator criteria of hybrid measures. These hospitals identified themselves proactively through making zero denominator declarations or claiming case threshold exemptions. CMS has subsequently determined that whether or not a hospital has met the denominator minimum for a hybrid measure is automatically detected during the

agency's data processing and measure calculation processes, eliminating the need for use of zero denominator declarations and case threshold exemptions by hospitals.

The sole commenter was supportive of the changes as proposed.

c. Reporting and Submission Requirements for Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

CMS finalizes as proposed submission and reporting requirements for PRO-PM measures since this is a new measure type for the Hospital IQR Program. CMS first proposes that hospitals would have the choice of selecting from multiple data submission approaches for these measures unless the agency stipulates otherwise. Choices would include but not be limited to sending data directly to CMS for measure calculation and utilizing an external entity such as a vendor or registry to submit to CMS on the hospital's behalf.

Secondly, CMS finalizes submission and reporting requirements specific to the newly finalized THA/TKA PRO-PM, the IQR program's first PRO-PM, as shown below. The timelines apply whether the hospital or a third party submits the data to CMS and data submission is through the agency's HQR System. The finalized measure will affect payments beginning with the FY 2028 payment determination year. CMS anticipates issuing confidential hospital-specific reports in 2027 followed by public reporting on Care Compare after a review and correction period.

Some commenters supported that multiple submission mechanisms should generally be allowed for PRO-PMs. Several commenters were supportive of the proposed THA/TKA PRO-PM and its associated reporting requirements, believing the measure allows patient voices to be heard during all phases of their care. Some expressed support for having the choice of multiple data submission mechanisms and a few supported the proposed reporting timelines. Some asked for delayed implementation or extension of the voluntary reporting period to allow hospitals and providers to fully prepare to report this complicated measure. CMS declines, stating the necessity to promptly begin capturing patient-reported outcomes (PRO) data for these commonly performed procedures and noting that two voluntary periods will have preceded mandatory reporting.

Many commenters objected to this measure's adoption and to the associated reporting timelines due to the excessive financial, labor, and other resource costs involved to successfully report this PRO-PM. CMS acknowledges the concerns raised. Some commenters urged CMS to transparently and comprehensively review and publicly report experience from the CJR measure before the IQR measure transitions to mandatory reporting. CMS responds that lessons learned from the model have been incorporated into the IQR measure design and notes that the measure's initial 50 percent reporting threshold is based on CJR model average response rates for pre- and postoperative patient outcome surveys. To a commenter voicing concern about patients experiencing survey fatigue, CMS responds that few patients are likely to receive both HCAHPS and PRO-PM surveys. Some suggested that CMS should incentivize measure reporting through incentive payments, but CMS states that the IQR program is designed to be pay-for-reporting and that incentive payments are precluded by statute.

THA/TKA PRO-PM REPORTING TIMELINE					
VOLUNTARY REPORTING					
Voluntary 1 (2025)	1/1/2023 through 6/30/3023	10/3/2022 through 6/30/2023	10/2/2023	10/28/2023 to 8/28/2024	9/30/2024
Voluntary 2 (2026)	7/1/2023 through 6/30/2024	4/2/2023 through 6/30/2024	9/30/2024	4/26/2024 to 8/29/2025	9/30/2025
MANDATORY REPORTING					
Mandatory 1 (2027)	7/1/2024 through 6/30/2025	4/2/2024 through 6/30/2025	9/30/2025	4/27/2025 to 8/29/2026	9/30/2026
Source: Tables IX.E.-07 and IX.E.-08 in the rule, consolidated by HPA.					

d. Reporting and Submission Requirements for the eCQM Validation Process

CMS finalizes as proposed to modify the previously finalized eCQM validation process by increasing the requirement that hospitals submit timely and complete data from 75 percent of requested charts to 100 percent. The new submission threshold requirement will be effective beginning with CY 2022 eCQM data affecting the FY 2025 payment determination and subsequent years. A hospital failing to submit timely and complete records would not meet the validation requirement and thereby be subject to a reduced annual payment update for failing to meet all Hospital IQR Program requirements. The new threshold is presented in tabular form as Table IX.E-18 of the rule. CMS also finalizes regulation text changes to reflect the increased submission threshold.

Commenters were divided between support and opposition. Supporters noted that most hospitals were already exceeding the 75 percent threshold. Some requested delay due to lingering COVID-19 PHE impacts on hospital resources. Some commenters described vendor-related issues including timeliness of interactions with the agency's validation vendor and requested that hospitals not be penalized for vendor-related delays. CMS responds that the validation timelines are sufficiently generous and declines to defer adoption of the 100 percent submission threshold. CMS notes that validation requirements for chart-abstracted measures are not affected by eCQM validation requirements. No comments were received about the regulation text changes.

6. Previously Finalized and Proposed Hospital IQR Program Measures

CMS provides tables showing the Hospital IQR Program measure set for each of the FY 2024 through FY 2028 payment determinations and subsequent years. Selected information from those tables is consolidated into the table below.

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
Chart-Abstracted Process of Care Measures						
Severe sepsis and septic shock: management bundle (NQF #500)	X	X	X	X	X	X
PC-01 Elective delivery < 39 weeks gestation (NQF #0469)	X	X	X	X	X	X
ED-1 Time from ED arrival to departure for admitted patients (NQF#0495)	Removed					

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
ED-2 Time from admit decision to departure for admitted patients (NQF #0495)	X	Removed				
IMM-2 Immunization for influenza (NQF #1659)	Removed					
VTE-6 Incidence of potentially preventable VTE	Removed					
Electronic Clinical Quality Measures						
AMI-8a Primary PCI w/in 90 minutes arrival CAC-3 Home Mgmt Plan Document to Caregiver 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 Time from ED arrival to departure for admitted patients (NQF#0495) ED-2 Time from admit decision to ED departure for admitted patients (NQF #0497) EDHI-1a Hearing Screening Pre-Hospital Discharge PC-01 Elective delivery < 39 completed weeks gestation (NQF #0469) PC-05 Exclusive breast milk feeding (NQF #0480) Safe Use of Opioids – Concurrent Prescribing (NQF #3316c) Hospital Harm-Severe Hypoglycemia (NQF #3503e) Hospital Harm-Severe Hyperglycemia (NQF #3533e) *Hospital Harm Opioid Related Adverse Events HH-ORAE *ePC-02 Cesarean Birth *ePC-07/SMM Severe Obstetric Complications *Global Malnutrition Composite Score GMCS (NQF #3592e)	Report 4 of the following 15 eCQMs: AMI-8a CAC-3 ED-1 ED-2 EHDI-1a PC-01 PC-05 STK-02 STK-03 STK-05 STK-06 STK-08 STK-10 VTE-1 VTE-2	Report 4 of the following 8 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2	Report 4 of the following 9 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2 Safe Use of Opioids	Report Safe Use of Opioids AND 3 of the following 8 eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2	Report Safe Use of Opioids 3 of the following 12* eCQMs: ED-2 PC-05 STK-02 STK-03 STK-05 STK-06 VTE-1 VTE-2 HH-01 HH-02 ePC-02* ePC-07*	Report Safe Use of Opioids AND Cesarean Birth (ePC-02)* AND Severe Obstetric Complications (ePC-07)* AND 3 of the following 9* eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-01 HH-02 HH-ORAE* GMCS*
Healthcare-Associated Infection (HAI) Measures						
Central Line Associated Bloodstream Infection (CLABSI)	X	Removed				
Surgical Site Infection: Colon Surgery; Abdominal Hysterectomy	X	Removed				
Catheter-Associated Urinary Tract Infection (CAUTI)	X	Removed				
MRSA Bacteremia	X	Removed				
Clostridium Difficile Infection (CDI)	X	Removed				
Healthcare Personnel Influenza Vaccination (NQF #0431)	X	X	X	X	X	X
Healthcare Personnel COVID-19 Vaccination			X	X	X	X
Claims-Based Measures						
Mortality						

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
Pneumonia 30-day mortality rate	Removed					
Stroke 30-day mortality rate	X	X	X	X	X	X
COPD 30-day mortality rate	Removed					
CABG 30-day mortality rate	X	Removed				
Readmission/Coordination of Care						
Hospital-wide all-cause unplanned readmission (NQF #1789)	X	X	X	X	X	Removed
Excess days in acute care after hospitalization for AMI (NQF #2881)	X	X	X	Refine*	Refine*	Refine*
Excess days in acute care after hospitalization for HF (NQF #2880)	X	X	X	X	X	X
Excess days in acute care after hospitalization for PN (NQF #2882)	X	X	X	X	X	X
Claims and Electronic Data Measures (Hybrid)						
Hybrid HWR (all-cause readmission) (NQF #2879)				V		X
Hybrid HWM (all-cause mortality)					V	X
Patient Safety						
PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351)	X	X	X	X	X	X
THA/TKA complications	X	X	Removed	Refine*	Refine*	Refine*
Efficiency/Payment						
AMI payment per 30-day episode of care (NQF #2431)	X	X	X	X	X	X
Heart Failure payment per 30-day episode of care (NQF #2436)	X	X	X	X	X	X
Pneumonia payment per 30-day episode of care (NQF #2579)	X	X	X	X	X	X
THA/TKA payment per 30-day episode of care	X	X	X	Refine*	Refine*	Refine*
MSPB-Hospital				Refine*	Refine*	Refine*
Patient Experience of Care						
HCAHPS survey (NQF #0166)	X	X	X	X	X	X
Patient-Reported Outcome-Based Performance Measure (PRO-PM)						
Hospital-Level THA/TKA PRO-PM*						V*
Structural Measures						
Maternal Morbidity			X	X	X	X
Hospital Commitment to Health Equity HCHE *					X*	X*
SDOH-1 Screening for social Drivers of Health*					V*	X*
SDOH-2 Screen Positive Rate for Social Drivers of Health*					V*	X*
*Finalized Change FY 2023 IPPS Proposed Rule V = voluntary reporting X = mandatory reporting						

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

The PCHQR Program applies to hospitals meeting the description of *PPS-exempt cancer hospital* (PCH) as defined at section 1886(d)(1)(B)(v) of the Act. The Program has 11 participants that focus on the care of oncology patients and are paid on a cost basis, subject to a per discharge limit (target amount), rather than through a prospective payment system (PPS).

The Program requires quality reporting by PCHs and measure data are publicly available but the results have no associated payment consequences.

In this rule, CMS finalizes as proposed to revise the Program's measure removal policy, timelines for public display of two measures, and summarizes feedback about two potential, future measure additions. No changes are proposed to the Program's measure set, nor to policies for measure retention, technical specifications maintenance, or extraordinary circumstances exceptions. No updates are proposed to established data submission requirements and deadlines.

1. Measure Removal Policy Revision

CMS finalizes as proposed to create a patient safety exception to the PCHQR Program's measure removal policy. The exception would apply if CMS were to determine that continuing to require data submission on a measure raises specific patient safety concerns. Having made such a determination, the agency could choose to remove the measure immediately from the Program without rulemaking. CMS is required to promptly notify PCHs and the public about the patient safety concerns and immediate measure removal, including through publication of a notice in the Federal Register.

Comments received were supportive and the finalized exception is added as a new paragraph at §412.24(d)(3)(iii).

2. Public Reporting of Measure Results

Timelines for public reporting of PCHQR Program measure data are proposed through rulemaking and generally follow a period of confidential reporting to hospitals. Data are posted to the Provider Data Catalog website (https://data.cms.gov/provider-data/).

End-of-Life Measures
CMS finalizes with modification to begin public display of data from four end-of-life (EOL) measures. Display will begin with FY 2025 program year data (data collection period July 1, 2022 through June 30, 2023) rather than FY 2024 program year data as proposed. These measures were added to the Program's measure set beginning with program year FY 2020 and are included in Table IX.F-02 of the rule (reproduced below) with the remaining PCHQR program measures.

Some commenters were supportive but others requested a delay to allow hospitals to review their FY 2022 confidential feedback reports. Release of these reports was delayed by one year due to the COVID-19 PHE. CMS agrees that delay is warranted and finalizes that reporting of the four EOL measures will begin with FY 2025 program year data.

Unplanned Readmission Measures
CMS finalizes as proposed to begin public display of data from the 30-Day Unplanned Readmission for Cancer Patients measure with program year FY 2024 data. This measure was added to the Program's measure set beginning with program year FY 2021. Display will begin with the July 2023 refresh or as soon as feasible thereafter.

Commenters were generally supportive. CMS notes that confidential hospital-specific reports for this measure were provided to the PCHs in July 2021 for the FY 2022 program year.

3. Request for Information (RFI): Potential Future HAI Measure Adoption

CMS refers readers to section IX.E.9.a of the rule where CMS summarizes input received concerning adoption of two digital quality measures that would track certain hospital-acquired infection rates for future adoption into several CMS quality programs including the PCHRP: *Healthcare-associated Clostridioides difficile Infection Outcome* and *Hospital-Onset Bacteremia & Fungemia Outcome*. Measures would be reported through the CDC NHSN. CMS notes that cancer patients are often immunosuppressed and therefore at increased risk for healthcare-associated infections.

4. PCHQR Program Measures for the FY 2024 Program Year and Subsequent Years

CMS summarizes the PCHQR program's measure set in tables IX.F.-01 and IX.F.-02 of the rule, shown as a consolidated table below.

PCHQR Program Measures for FY 2024 and Subsequent Years	
Measure	**Public Display Start Date**
Safety and Healthcare Associated Infection	
Colon/Abdominal Hysterectomy SSI (NQF #0753)	2019
NHSN CDI (NQF #1717)	2019
NHSN MRSA bacteremia (NQF #1716)	2019
NHSN Influenza vaccination coverage among health care personnel (NQF #0431)	2019
NHSN COVID-19 vaccination coverage among health care personnel	October 2022
NHSN CLABSI (NQF #0139)	Deferred until October 2022
NHSN CAUTI (NQF #0138)	Deferred until October 2022
Clinical Process/Oncology Care	
Oncology: Plan of Care for Pain (NQF #0383)	2016; Finalized for program removal FY 2024
The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOL-Chemo) (NQF #0210)	Finalized for 2024
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215)	Finalized for 2024
Intermediate Clinical Outcomes	
The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216)	Finalized for 2024
The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL-ICU) (NQF #0213)	Finalized for 2024
Patient Experience of Care	
HCAHPS (NQF #0166)	2016
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	April 2020; Finalized for program removal FY 2022
30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188)	October 2023

PCHQR Program Measures for FY 2024 and Subsequent Years	
Measure	**Public Display Start Date**
Surgical Treatment Complications for Localized Prostate Cancer	Not Displayed
Source: Tables IX.F.-01 and IX.F.-02 of the rule, modified and consolidated by HPA	

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

The LTCH QRP is a pay-for-reporting quality program implemented in FY 2014. LTCHs submit data to CMS on the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS) patient assessment instrument using the Internet Quality Improvement Evaluation System Assessment Submission and Processing (iQIES ASAP) system. The LCDS requires reporting of multiple standardized patient assessment data elements (SPADEs) that are interoperable and are common to post-acute care (PAC) providers.[72] An LTCH that fails to meet the program's quality data reporting requirements is subject to a 2.0 percentage point reduction in the annual update factor. Information about many aspects of the program is available through the LTCH QRP website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting.

In this rule, CMS proposes no measure additions, revisions, replacement or removal for program year FY 2023, and no policy changes are proposed for the LTCH QRP. No new reporting burden is imposed on LTCH providers as a result of this rule. The rule presents three requests for information (RFIs) related to (1) concepts for future measures, (2) addition of a digital quality measure (dQM), and (3) principles for measuring equity and healthcare quality disparities across the CMS quality enterprise.

The program year FY 2023 LTCH QRP measure set is provided as Table IX.G.-01 in the rule. A summary table of Program measures by year is provided in section IX.G.4. below.

1. RFI: LTCH QRP Quality Measure Concepts under Consideration

CMS provides excerpts of comments received in response to an RFI concerning three concept areas under consideration in which one or more measures would be developed for future use in the LTCH QRP. Comments are grouped below for each concept area. CMS does not respond directly to any comments and will take all input under advisement.

1) Cross-setting Function – CMS is considering a functional measure for use across all PAC settings that would incorporate both of the domains of self-care and mobility.

Commenters were generally supportive, though one expressed a preference for separate rather than composite measures. Heterogeneity of patients across facilities was noted for which commenters suggested risk adjustment may be needed to address.

[72] Post-acute care providers required to report SPADEs are long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.

2) Health Equity Measures – CMS expresses interest in structural measures that assess an organization's leadership in advancing health equity goals or assess progress towards achieving equity priorities.

Support for adding a health equity structural measure to the LTCH QRP was divided. Some were strongly supportive of addition. Others raised concerns about the effect of small sample sizes on measure accuracy and about the ability of LTCHs to meaningfully improve on such a measure.

3) COVID-19 Vaccination Coverage among PAC Patients – CMS invites comment on the value of a measure assessing whether LTCH patients are current on their vaccinations.

Commenters advised CMS to defer consideration of adding this measure until the evolving definition of "fully vaccinated" stabilizes.

4) Other Concepts

Additional concepts suggested for consideration as the basis for future measure development included malnutrition screening, patient experience and satisfaction, patient-reported outcome measures, and caregiver engagement.

2. RFI: LTCH QRP Digital Quality Measures and *Clostridioides difficile* Infection Outcome Measure

CMS requested input into requiring electronic submission of quality data from LTCHs via their electronic health records (EHRs) as part of the LTCH QRP. Specifically, CMS posed questions related to the future inclusion of the *NHSN Healthcare-Associated Clostridioides difficile Infection Outcome Measure (HA-CDI)*[73] as the LTCH QRP's first digital quality measure (dQM). CMS does not respond directly to any comments and will take all input under advisement.

The LTCH-QRP currently requires reporting of NQF #1717 *NHSN Facility-wide Inpatient Hospital-Onset Clostridium difficile Infection Outcome Measure* (*CDI*). The CDI measure does not utilize EHR-derived data; instead, each LTCH collects data and submits it on a monthly basis to CDC using the NHSN's online module for multidrug resistant organisms and C. difficile infections.[74] The HA-CDI dQM's associated software would include an embedded Measure Calculation Tool (MCT) that interfaces with a facility's EHR to extract data, calculate the measure, and submit the results. CMS reports, however, that the CDC is developing multiple submission options so that facilities with less advanced health IT systems (e.g., unable to support an MCT) could still transmit their HA-CDI data to CDC.

Commenter support for using EHRs to collect and submit data for LTCH QRP measures was divided. The potential for digital measures to ultimately reduce provider reporting burden was appreciated but practical barriers for reaching that potential were cited. These included:

[73] The name of the bacterium that causes the illness being tracked by the CDI and HA-CDI measures was updated in 2016 from *Clostridium difficile* to *Clostridioides difficile* based on bacterial genome sequencing results.
[74] CDC processes the data then transmits the output to CMS.

- Slow uptake and incomplete dissemination of EHRs in the LTCH community as PAC providers were not eligible for prior federal incentive to adopt EHRs; incentive payments were recommended.
- Substantial variability exists in the capabilities for the EHRs that are in use as well as in the health IT resources and personnel available across LTCHs.
- A transition period to digital reporting would be essential and a period of at least 2 years was suggested.
- Timelines must reflect adequate time for on-site testing by LTCHs after vendors deliver software modules.
- LTCHs and their representatives should be invited to join CMS in strategic planning and to participate in pilot programs or other trials.

Specific to the NHSN CDI digital measure, commenters expressed concerns about the definition of "treatment" and noted a potential for gaming.

3. RFI: Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs

CMS describes health equity as "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes." The agency is committed to addressing persistent inequities through improving data collection to better measure and analyze disparities across its quality programs, policies, and measures.

In this RFI, CMS described and invited input about key principles and approaches the agency could consider when addressing disparities through quality measure development and stratification, particularly as applicable to the LTCH QRP. Topics for comment were grouped by CMS around 5 key considerations and 2 potential measures. Comment highlights are provided below under each topic. CMS does not respond directly to any comments and will take all input under advisement.

- **Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs**

  Commenters were largely supportive of using one or both of the disparities' methods, tailoring the choice to the measure, risk factor, and goal of the analysis. Peer grouping was also supported for between-provider comparisons. Some indicated that patient experience measures may be inappropriate for subgroup comparisons. Support for and against decomposition approaches were voiced.

- **Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting**

  Prioritization was deemed to be essential and most commenters favored beginning with existing measures for which some evidence of disparities already exists. Many supported outcomes over process measures and measures for which patient-level data are already being collected. Minimizing provider burden was given high priority along with choosing

measures with maximum potential impact (e.g., potentially avoidable events). Measures with adequate sample size and measures addressing patient access to care also were supported by many commenters. Prompt provider feedback and alignment across CMS and other federal programs were supported as desirable characteristics of measures.

- **Principles for Social Risk Factor and Demographic Data Selection and Use**

  Most commenters supported using race/ethnicity and dual eligibility status. Disability status also received considerable support. Other suggestions spanned a wide range of other factors.

- **Identification of Meaningful Performance Differences**

  Support was received for and against a variety of approaches including benchmarking, rank ordering, percentile ranking, and defined thresholds. The risk for unintended consequences was mentioned for each approach. Some suggested tailoring the approach to the quality program and patient population being analyzed. Others strongly recommended that CMS define a statistically acceptable meaningful threshold for determining the existence of a disparity and adopt a high reliability standard when setting measure minimums.

- **Potential Health Equity Measures for the LTCH QRP**
  Health Equity Summary Score (HESS)[75]

  The HESS was developed by the CMS Office of Minority Health to assess care provided by MA plans to beneficiaries with social risk factors or high-risk demographics. It is a composite measure that includes multiple measures—clinical and experience-of-care survey items[76]—and multiple at-risk groups. CMS notes that a version of the HESS adapted for acute care hospitals is under development for the Hospital IQR Program.

  Conceptual support for a HESS-type measure for the LTCH QRP was voiced. Several technical concerns were raised, such as methodological ambiguities.

  Hospital Commitment to Health Equity Structural Measure

  CMS described a potential structural measure, *Hospital Commitment to Health Equity,* that combines attestations from 5 distinct domains of commitment: strategic plan for disparities reduction; demographic and social risk factor data collection; disparities analysis; quality improvement activities; and leadership involvement in reducing disparities. CMS has finalized this measure for adoption into the Hospital IQR Program begin with payment determination year FY 2025 and sought input about adaptation for use in the LTCH QRP.

---

[75] Agniel D., Martino S.C., Burkhart Q, et al. Incentivizing excellent care to at-risk groups with a health equity summary score. *J Gen Intern Med*, 2021; 36(7):1847-1857. https://link.springer.com/content/pdf/10.1007/s11606-019-05473-x.pdf.

[76] Clinical measures are from HEDIS (maintained by the National Committee for Quality Assurance); survey items are from the Consumer Assessment of Healthcare Providers and Systems (CAHPS, maintained by the Agency for Healthcare Research and Quality).

The low burden level of most structural measures was seen as attractive by commenters although some viewed structural measures as box-checking exercises.

4. LTCH QRP Measure Set Summary Table

The program year FY 2023 LTCH QRP measure set is provided as Table IX.G.-01 in the rule. A summary table of Program measures by year is provided below.

LTCH QRP Measure Set, by Rate (Program) Year				
Measure Title	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
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)	Replaced			
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	X	X	X	X
Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short-Stay) (NQF #0680)	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	Removed		
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717)	X	X	X	X
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (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	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	X
Mechanical Ventilation Process Measure: Compliance with Spontaneous Breathing Test by Day 2 of the LTCH Stay	X	X	X	X
Mechanical Ventilation Outcome Measure: Ventilator Liberation Rate	X	X	X	X
Transfer of Health Information to the Provider – PAC Measure			X	X
Transfer of Health Information to the Patient – PAC Measure			X	X
COVID-19 Vaccination Coverage among Healthcare Personnel				X

H. Medicare Promoting Interoperability Program

A hospital that is not identified as a meaningful user of certified electronic health record technology (CEHRT) under the Medicare Promoting Interoperability Program (PIP) is subject to an update factor reduction equal to three quarters of the market basket. In this section, the term hospital includes a critical access hospital unless otherwise noted.

1. EHR Reporting Periods in 2023 and 2024

CMS defines the term "EHR reporting period for a payment adjustment year" at 42 CFR 495.4, to mean, for eligible hospitals and CAHs that are new or returning participants in the Medicare Promoting Interoperability Program, the following:

- The EHR reporting period in CY 2023 is a minimum of any continuous 90-day period within CY 2023; and
- The EHR reporting period in CY 2024 is a minimum of any continuous 180-day period within CY 2024.
-

Both the PIP and the QPP require the use of CERHT that meets the 2015 Edition Base EHR definition (45 CFR 170.102) and that has been certified to certain other 2015 Edition health IT certification criteria. Because of the COVID-19 PHE, ONC extended until December 31, 2022 (and for electronic health information (EHI) export until December 31, 2023) the date by which health IT developers must make technology available that is certified to the updated or new certification criteria. After that date, providers must use only certified technology updated to the 2015 Edition Cures Update for an EHR reporting period or performance period in CY 2023. CMS does not propose any changes to this policy. CMS reminds stakeholders that participants are only required to use technology meeting the CEHRT definitions during a self-selected EHR reporting period or performance period of a minimum of any consecutive 90 days in CY 2023 which would include the final 90 days of 2023.

2. Electronic Prescribing Objective: Changes to the Query of Prescription Drug Monitoring Program Measure and Technical Update to the E-Prescribing Measure

a. Query of Prescription Drug Monitoring Program (PDMP) Measure

CMS discusses the history of the PDMP measure. In past rulemaking, it was added as an optional measure for EHR reporting periods in 2019, 2020, 2021, and 2022 and eligible for 5 bonus points in 2019, 2020 and 2021 and 10 bonus points in 2022. Hospitals electing to report this measure 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.

In the FY 2022 IPPS/LTCH PPS rulemaking cycle, commenters continued to express concern to CMS that making this measure mandatory for reporting in 2022 was premature. They stated that

PDMPs themselves are still maturing, and they are not yet consistently integrated into EHR workflow. EHR developers complained that effectively incorporating the ability to count the number of PDMP queries in the EHR would require more robust measurement specifications which will add to costs borne by health care providers.

CMS reports on the current status of PDMP adoption, noting that all 50 states and several localities host PDMPs. It found an increase in the number of PDMPs that are integrated with HIEs, EHRs, and/or Pharmacy Dispensing Systems. Additionally, the SUPPORT Act of 2018 (P.L 115-271) included new federal funding and requirements for PDMPs, and mandated use of PDMPs by certain Medicaid providers to help reduce opioid misuse and overprescribing and promote the effective prevention and treatment of opioid use disorder. CMS proposed a number of changes to this measure, all of which are finalized in this rule.

CMS finalizes the following changes to the Query of PDMP measure for CY 2023:

- To require the reporting of the Query of PDMP measure for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program with two exclusions:
    - Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include drugs from Schedules II, III, and IV, and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and
    - Any eligible hospital or CAH that cannot report on this measure in accordance with applicable law.
- To remove the phrase "except where prohibited and in accordance with applicable law" from the measure description because that exception is provided as an exclusion under the changes finalized above.
- To expand the Query of PDMP measure to include Schedule III and IV drugs.

The revised measure description reads as follows: "For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history." CMS believes it is feasible to require providers to report the current Query of PDMP measure requiring a "yes/no" response and notes that it would minimize burden on providers. CMS maintains the associated points at 10 points, and the maximum total points for this objective remains at 20 points for 2023.

Some commenters noted inconsistencies across state lines with regard to interoperability standards, varying degrees of implementation, and complexities resulting from inconsistent state laws and licensing requirements. Others did not support requiring the Query of PDMP measure due to a lack of standardized privacy and security protocols. CMS acknowledges the challenges raised by commenters and pledges to support improvements to the technical approaches that support data exchange between systems. It will work with ONC to consider whether these approaches should be incorporated into the ONC Health IT Certification Program and the Medicare Promoting Interoperability Program.

The agency also notes that all states collect data on schedules II, III, and IV drugs. It finalizes its proposal to expand the measure to include additional Scheduled drugs; it believes this expansion will facilitate more informed prescribing practices and improve patient outcomes. The query of the PDMP for prescription drug history must occur before the electronic transmission of an electronic prescription for a Schedule II opioid or Schedule III or Schedule IV drug. CMS notes that all permissible prescriptions and dispensing of Schedule II, III, or IV drugs will be included no matter how small the amount prescribed during an encounter and that only one query must be performed for multiple prescriptions for Schedule II opioids or Schedule III and IV drugs prescribed on the same date by the same eligible hospital or CAH. In response to a comment, CMS clarifies that the Query of PDMP measure does not include or apply to Schedule II drugs that are not opioids (for example, central nervous system stimulants).

CMS only proposed two exclusions, which it finalizes. It did not propose an additional exclusion for providers in states where integration with a statewide PDMP is not yet feasible or not yet widely available. This is because it believed the flexibility of the Query of PDMP measure and the implementation of PDMPs in all 50 states increases the number of PDMPs offering some degree of integration with EHRs. However, in response to comment, it finalizes the following additional temporary exclusion, which is available for use only in CY 2023: Any eligible hospital or CAH for which querying a PDMP would impose an excessive workflow or cost burden prior to the start of the EHR reporting period they select in CY 2023. The temporary exclusion is intended to address the concern that accessing state PDMPs can be time-consuming and disruptive to clinical workflow if technology requires exiting the hospital medical record, connecting with the state PDMP, and then compiling supporting documentation for attestation using multiple systems. CMS also notes for eligible hospitals and CAHs located in a state that does not have an operational statewide PDMP, they would need to check a limited county-level PDMP to meet the requirements of the Query of PDMP measure, which could interrupt workflows for providers.

CMS hopes to further modify the Query of PDMP measure in future rulemaking to be numerator/denominator-based, and to require use of standardized functionality within CEHRT to support the actions associated with the measure while reporting on a numerator and denominator.

b. Technical Update to the E- Prescribing Measure

In the 2021 PFS final rule, CMS finalized that the “drug-formulary and preferred drug list checks” criterion will no longer be associated with measures under the Electronic Prescribing Objective; thus, they are currently not required to meet the CEHRT definition for the Medicare PIP and the MIPS Promoting Interoperability performance category, beginning with 2021 EHR reporting and performance periods.

CMS neglected to revise the description of the objectives and measures for the PIP in 2022. Thus, to reflect the removal of the certification criterion relating to drug-formulary and preferred drug list checks, it makes the following technical revisions in the final rule:

- The measure description is revised to read "For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT"; and
- The numerator is revised to read "[t]he number of prescriptions in the denominator generated and transmitted electronically".

3. Health Information Exchange (HIE) Objective: Addition of an Alternative Measure for Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA)

a. Background

CMS provides background on the HIE Objective and its associated measures as well as on TEFCA. In the FY 2022 IPPS/LTCH PPS final rule, the HIE Bi-Directional Exchange measure was finalized under the HIE Objective. The measure is worth 40 points (the total amounts of points available under the HIE Objective) and is an alternative to reporting on the two existing HIE Objective measures (i.e., the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure). Eligible hospitals and CAHs must attest to 3 statements.

The 21st Century Cures Act required HHS to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally." ONC's three goals for TEFCA are as follows:

1. Establish a universal policy and technical floor for nationwide interoperability.
2. Simplify connectivity for organizations to securely exchange information to improve patient care, enhance the welfare of populations, and generate health care value.
3. Enable individuals to gather their health care information.

CMS noted in finalizing the HIE Bi-Directional Exchange measure that TEFCA was likely an important way for eligible hospitals and CAHs to enable bi-directional health information exchange in the future and that it would explore ways to provide further guidance or update this measure to align with the use of health information networks that participate in TEFCA in the future. CMS highlights what it calls important additional developments for TEFCA which are described in detail in the preamble.

CMS discusses Qualified Health Information Networks (QUINs). These entities sign a legal contract (i.e., the Common Agreement) with an ONC Recognized Coordinating Entity (RCE); the RCE ensures compliance with the terms of the Common Agreement. QHINs connect directly to each other to facilitate nationwide interoperability, and each QHIN can connect Participants, which can connect Subparticipants. The QTF[77], which was developed and released by the RCE, describes the functional and technical requirements that a HIN must fulfill to serve as a QHIN under the Common Agreement, including QHIN-to-QUIN exchange and other duties.

[77] Qualified Health Information Network (QHIN) Technical Framework (QTF) Version 1.0 (Jan. 2022), https://rce.sequoiaproject.org/wp-content/uploads/2022/01/QTF_0122.pdf

b. New Enabling Exchange Under TEFCA Measure

CMS notes that prospective QHINs will likely begin signing the Common Agreement and apply for designation. HHS expects that stakeholders across the care continuum will have increasing opportunities in 2023 to enable exchange under TEFCA. This means stakeholders would: (1) be signatories to either the Common Agreement or an agreement that meets the flow-down requirements of the Common Agreement (called a Framework Agreement under the Common Agreement), (2) be in good standing (that is not suspended) under that agreement, and (3) be enabling secure, bi-directional exchange of information to occur, in production.

CMS previously requested comment on whether participation in TEFCA should be considered a health IT activity that could count for credit within the HIE Objective instead of reporting on measures for this objective. Given the alignment between enabling exchange under TEFCA and the existing HIE Bi-Directional Exchange measure, CMS finalizes its proposal to add an additional measure in 2023 through which an eligible hospital or CAH could earn credit for the HIE Objective by connecting to an entity that connects to a QHIN or connecting directly to a QHIN. The new measure is called the "Enabling Exchange Under TEFCA measure."

For 2023, CMS there will be three reporting options under the HIE objective:

- Report on both the Support Electronic Referral Loops by Sending Health Information measure and the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure;
- Report on the HIE Bi-Directional Exchange measure; or
- Report on the Enabling Exchange Under TEFCA measure.

CMS finalizes its proposal to reduce the total amount of points for the HIE Objective to 30. Thus, the Enabling Exchange Under TEFCA measure will be worth 30 points.

The Enabling Exchange Under TEFCA measure will be reported by attestation, and the measure requires a "yes/no" response. CMS does not finalize its proposal that the measure be calculated by reviewing only the actions for patients whose records are maintained using CEHRT because no calculation is required for the measure. Eligible hospitals and CAHs must attest to the following:

- Participating as a signatory to a Framework Agreement (in good standing that is not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy.
- Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under the Framework Agreement.

Eligible hospitals or CAHs must use the capabilities of CEHRT to support bi-directional exchange under a Framework Agreement, which includes capabilities that support exchanging

the clinical data within the Common Clinical Data Set (CCDS) or the United States Core Data for Interoperability (USCDI).

4. Public Health and Clinical Data Exchange Objective

a. Background

CMS previously established a policy for this objective that eligible hospitals and CAHs must report on four of six measures.[78] CMS believes those four measures will put public health agencies on better footing for future health threats and a long-term COVID-19 pandemic recovery by strengthening three important public health functions: early warning surveillance, case surveillance, and vaccine uptake.

b. Modifications to the Reporting Requirements for the Public Health and Clinical Data Exchange Objective

CMS is concerned by rising antimicrobial-resistant infections caused by pathogens that no longer respond to the drugs designed to kill them and directly threaten patient and population health. It is also worried that misuse and overuse of antimicrobials both facilitates the emergence of drug-resistant pathogens and exposes patients to needless risk for adverse effects. Slowing the emergence of new resistant threats and preventing the spread of existing resistant infections requires robust systems for collecting, analyzing, and using AUR data to direct action. Antimicrobial use (AU) data delivered to antimicrobial stewardship programs (ASPs) enable stewards to develop, select, and assess interventions aimed at optimizing antimicrobial prescribing. Currently, approximately 2,000 acute care hospitals and 1,000 CAHs voluntarily report to CDC's National Healthcare Safety Network's (NHSN) AUR Module. CMS believes that requiring an AUR measure under the Medicare PIP would enable the development of a true national picture of the threat posed by antimicrobial overuse and resistance.

CMS proposed to require reporting on a fifth measure under the Public Health and Clinical Data Exchange Objective (AUR Surveillance) beginning with the EHR reporting period in CY 2023. While CMS finalizes its proposal to require reporting of this measure, in response to comments, it delays adoption of the measure until the EHR reporting period in CY 2024. The measure description is as follows:

- AUR Surveillance measure: The eligible hospital or CAH is in active engagement with CDC's National Healthcare Safety Network (NHSN) to submit antimicrobial use and resistance (AUR) data for the EHR reporting period and receives a report from NHSN indicating their successful submission of AUR data for the EHR reporting period.

To receive credit, eligible hospitals and CAHs must report a "yes" response or an exclusion for which they are eligible. A "no" response or the failure to report a response will result in no credit for the measure and thus failure to meet the Objective. There are no additional points for reporting this measure.

[78] The four measures are Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting.

To report this measure, eligible hospitals and CAHs must use technology certified to the criterion at 45 CFR 170.315(f)(6), "Transmission to public health agencies – antimicrobial use and resistance reporting."

There are three exclusions for an eligible hospital or CAH for the measure as follows:

- Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period;
- Does not have electronic medication administration records (eMAR)/barcoded medication administration (BCMA) records or an electronic admission discharge transfer (ADT) system during the EHR reporting period; or
- Does not have an electronic laboratory information system (LIS) or electronic ADT system during the EHR reporting period.

CMS anticipates reviewing the second and third exclusions for future EHR reporting periods.

c. Revisions to Active Engagement

In the EHR Incentive Program Stage 3 final rule (80 FR 62862 through 62864), beginning with the EHR reporting period in 2016, CMS defined active engagement under the Public Health and Clinical Data Registry Reporting Objective as follows:

> Active engagement is defined as when an eligible hospital or CAH is in the process of moving towards sending "production data" to a public health agency or clinical data registry, or is sending production data to a public health agency or clinical data registry.

CMS clarified that "production data" refers to data generated through clinical processes involving patient care; it is used to distinguish between this data and "test data" which may be submitted for the purposes of enrolling in and testing electronic data transfers.

(1) Revision to Options for Active Engagement.

CMS established three options to demonstrate active engagement, in the hope that eligible hospitals would get to option three: (1) Complete registration to submit data. (2) Test and validate electronic submission of data. (3) Complete testing and validation of the electronic submission and electronically submit production data to the PHA or CDR.

CMS proposed to consolidate current options 1 and 2 into one option beginning with the EHR reporting period in CY 2023. It did not propose any substantive changes to the individual options or requirements for selecting individual options. CMS finalizes the proposal. The two options are as follows:

- Option 1. Pre-production and Validation (a combination of current option 1, completed registration to submit data, and current option 2, testing and validation);
- Option 2. Validated Data Production (current option 3, production).

CMS made the following clarifications in response to comments: (1) Option 1: Pre-Production and Validation includes both the completion of registration to submit data with the PHA or CDR, as applicable, and being in the process of testing and validation of the electronic submission of data. Upon receiving an invitation from the PHA or CDR to begin testing and validation, the eligible hospital or CAH should begin testing and validation. If, at any point in the process, an eligible hospital or CAH encounters a lack of readiness on the part of the PHA or CDR, the eligible hospital or CAH could consider whether it could report an exclusion for one or more of the measures associated with the Public Health and Clinical Data Exchange Objective. (2) To move from Option 1: Pre-production and Validation, to Option 2: Validated Data Production, the eligible hospital or CAH must finish validation. Only the PHA or CDR can confirm validation has been completed and a production state has been reached.

(2) Reporting Requirement for Level of Engagement

Currently, there is no requirement for eligible hospitals and CAHs to report their level of active engagement for any of the measures associated with the Public Health and Clinical Data Exchange Objective. Thus, beginning with the EHR reporting period in CY 2023, in addition to submitting responses for the required measures and any optional measures a hospital chooses to report, CMS finalizes its proposal to require eligible hospitals and CAHs to submit their level of active engagement using the options for active engagement (i.e., either Pre-production and Validation or Validated Data Production) for each measure they report.

Commenters raised several objections to this proposal. Some suggested delaying the requirement until the technology can facilitate the reporting. Others were concerned that PHAs may not be able to offer documentation of level of active engagement in a reasonable amount of time to support compliance with a 90-day reporting period. A few commenters requested that CMS provide further guidance illustrating expectations for completion of active engagement options and how eligible hospitals and CAHs can prove their active engagement status. Another commenter asked that CMS allow eligible hospitals and CAHs at least one year of stable reporting of public health measures without implementing this active engagement reporting requirement. Many commenters supported an exclusion for situations in which the state or public health department has not declared readiness or lacks resources for timely onboarding.

CMS notes that exclusions exist for each measure in this Objective. Further, it believes most eligible hospitals and CAHs are successfully reporting these measures. It provides the following examples of demonstrating levels of engagement:

- A dated report or screenshot from CEHRT that documents successful submission to the registry or PHA. The report should include evidence to support that it was generated for that eligible hospital's or CAH's system (for example, identified by CCN and eligible hospital or CAH) name or;
- A dated report or screenshot of successful registration or electronic transmission (for example, screenshot from another system, etc.). The report should include evidence to support that it was generated for that eligible hospital or CAH (for example, identified by CCN and eligible hospital or CAH name) or;

- A letter or email from a registry or PHA confirming registration.

(3) Changes to the Duration of Active Engagement Options

As noted above, eligible hospitals and CAHs currently are not required to report their level of active engagement, or advance from one option to the next option within a certain period of time. CMS proposed, beginning with the EHR reporting period in CY 2023, that eligible hospitals and CAHs may spend only one EHR reporting period at the Pre-production and Validation level of active engagement per measure, and that they must progress to the Validated Data Production level for the next EHR reporting period for which they report a particular measure.

The options for active engagement assume the same PHA or CDR is used by the hospital. In the event an eligible hospital or CAH chooses to switch between one or more CDRs or PHAs, CMS proposed to permit them to spend an additional EHR reporting period at the Pre-production and Validation phase to assist with onboarding to the new CDR or PHA.

Objections were raised to the proposal, stating that the progression out of the Pre-production and Validation level of active engagement is often not under hospital control and depends on the resources available from a given PHA and their technical capabilities and timeliness in communications. It was suggested that the proposal could lead to rushed validation and poor data quality, particularly with a move to a 180-day EHR reporting period and that EHR vendors may not be ready for testing in 2023 or 2024. Some commenters recommended adding an exclusion to allow for when public health agencies have limited resources to validate and onboard. One comment suggested allowing at least one year of stable reporting of public health measures before instituting limits on the length of time eligible hospitals and CAHs can spend in the preproduction and validation level of active engagement.

CMS finalizes the proposal to limit the amount of time an eligible hospital or CAH may spend at the pre-production and validation level of active engagement to one EHR reporting period with the modification that this limitation will apply beginning with the EHR reporting period in CY 2024.

(4) Public Health Reporting and Information Blocking

ONC recently released an information blocking frequently asked questions (FAQ) (IB. FAQ43.1.2022FEB) that highlights important points about public health reporting and information blocking.[79] One of those points is if an actor is required to comply with another law that relates to the access, exchange, or use of EHI, failure to comply with that law may implicate the information blocking regulations. An example of this is where a law requires actors to submit EHI to public health authorities, an actor's failure to submit EHI to public health authorities could be considered an interference under the information blocking regulations. The actor's practices would be evaluated to determine whether the unique facts and circumstances constitute information blocking, consistent with additional ONC frequently asked questions.[80]

[79] See https://www.healthit.gov/curesrule/faq/would-not-complying-another-law-implicate-information-blockingregulations.
[80] See https://www.healthit.gov/curesrule/faq/how-would-any-claim-or-report-information-blocking-be-evaluated.

5. Changes to the Scoring Methodology for the EHR Reporting Period in 2023

The performance-based scoring methodology under the Medicare PIP for EHR reporting periods in 2022 is shown in the following table:

Performance-Based Scoring Methodology for EHR Reporting Periods in 2022

Objective	Measures	Maximum Points
e-Prescribing	e-Prescribing	10 points
	Bonus: Query of (PDMP)	10 points (*bonus*)*
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	20 points
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	20 points
	-OR-	
	Health Information Exchange Bi-Directional Exchange*	40 points*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	40 points
Public Health and Clinical Data Exchange	Report the following 4 measures: * Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Electronic Reportable Laboratory Result Reporting	10 points
	Report one of the following 2 measures: * Public Health Registry Reporting Clinical Data Registry Reporting	5 points (*bonus*)*

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.

* Signifies a final policy adopted in the FY 2022 IPPS/LTCH PPS final rule.

In proposing to make the Query of PDMP measure required, CMS proposed to retain the 10 points associated with it, which are currently allocated as bonus points in 2022 and also proposed to reduce the points associated with the HIE Objective measures from the current 40 points to 30 points beginning with the CY 2023 EHR reporting period.

The Public Health and Clinical Data Exchange Objective and its four required Measures is worth 10 points. For a number of reasons, including incentivizing more electronic reporting of public health information, CMS proposed to increase the points for this Objective to 25. CMS proposed to balance this increase by reducing the points for the Provide Patients Electronic Access to Their Health Information measure from the current 40 points to 25. Table IX.H.-04 of the proposed rule (reproduced below) showed the proposed performance-based scoring methodology for EHR reporting periods in 2023.

TABLE IX.H.-04: PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN CY 2023

Objective	Measures	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of (PDMP)*	10 points*	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points*	Required (eligible hospital or CAH's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points*	
	-OR-		
	Health Information Exchange Bi-Directional Exchange*	30 points*	
	-OR-		
	Enabling Exchange under TEFCA*	30 points*	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points*	Required
Public Health and Clinical Data Exchange	Report the following 5 measures: * Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Electronic Reportable Laboratory Result Reporting AUR Surveillance Reporting*	25 points*	Required
	Report one of the following 2 measures: * Public Health Registry Reporting Clinical Data Registry Reporting	5 points (*bonus*)*	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored.
*Signifies a proposal made in this FY 2023 IPPS/LTCH PPS proposed rule.

If an exclusion is claimed, Table IX.H.-05 in the final rule shows how points will be redistributed. The table indicates that—

- if an exclusion for the e-Prescribing measure is claimed, the 10 points are redistributed to the HIE objective;
- if an exclusion for the Query of PDMP measure is claimed, the 10 points are redistributed to ePrescribing measure; and
- if an exclusion for all five Public Health and Clinical Data Exchange measures is claimed, the 25 points are redistributed to the Provide Patients Electronic Access to Their Health Information.

CMS finalizes its proposed changes to the scoring methodology for the EHR reporting period in CY 2023 without modification.

6. Public Reporting of Medicare PIP Data

Of the various types of data that CMS makes publicly available on its website with respect to the Medicare PIP, it does not currently report total performance scores of eligible hospitals and CAHs. Explaining that it seeks to increase transparency and encourage interoperability, beginning with the EHR reporting period in CY 2023 the agency proposed to publish on a CMS website available to the public the total score of up to 105 points for each eligible hospital and CAH under the Medicare PIP program, and the CMS EHR certification ID that represents the

CEHRT used by the eligible hospital or CAH, beginning with the total scores and CMS EHR certification IDs for the EHR reporting period in CY 2023.

CMS proposed to provide eligible hospitals and CAHs a 30-day preview period to review their data before publication, using the current policy and operational process for the Hospital IQR Program and use the Hospital Quality Reporting (HQR) system.

While the agency did not propose to publish individual measure scores at this time on this website, it will continue to evaluate that possibility for future rulemaking. CMS indicates that the total score and CMS EHR certification ID data could be made available to the public as early as the Fall of CY 2024 or as soon as operationally feasible. CMS will use the Compare tool hosted by Health and Human Services (currently available at: https://www.medicare.gov/care-compare) to post the Medicare PIP data.

In the final rule, CMS clarifies that although it caps the total score at 100 points, the actual score includes the addition of any bonus points earned by the eligible hospital or CAH that could total up to 105 possible points.

7. Additional Policies: Modifications to Regulatory Text and Overview of Objectives and Measures for the Medicare PIP for the EHR Reporting Period in 2023

Table IX.H.-06 contains the proposed modifications and additions to the regulatory text in section 495.24 of the regulations. CMS seeks to ensure that the objectives and measures are described consistently in the preamble as well as in the regulatory text. It proposed to remove the text of those objectives and measures from paragraph (e) of section 495.24 (which it insists does not include any policy changes) and to establish a new paragraph (f) of that section as described in Table IX.H.-06. No comments were received on the proposal, which the agency finalizes without modification.

Table IX.H.-07 lists the objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2023 as revised to reflect the proposals adopted in the final rule. Table IX.H.-08. lists the 2015 Edition certification criteria required to meet the objectives and measures.

8. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Background

Tables IX.H.-09 through IX.H.-11 of the final rule summarize the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare PIP for the 2022 reporting period, the 2023 reporting period, and the 2024 reporting period and subsequent years. The tables include the Safe Use of Opioids – Concurrent Prescribing measure (NQF #3316e), which was finalized as mandatory for reporting beginning with the 2022 reporting period.

b. eCQM Adoptions

CMS intends to continue to align the Medicare PIP eCQM reporting requirements with similar requirements under the Hospital IQR Program. To that end, it proposed to adopt four new eCQMs for the Medicare PIP eCQM measure set.

Beginning with the 2023 reporting period, CMS proposed to add the following eCQMs:

- Severe Obstetric Complications eCQM (NQF NA); and
- Cesarean Birth eCQM (NQF NA).

Mandatory reporting of these two eCQMs would be required for the 2024 reporting period and for subsequent years. CMS declines to adopt suggestions to delay mandatory reporting until the 2025 reporting period. It acknowledges concerns that the measures do not have NQF endorsement, but it believes that the measures are a key activity in prioritizing the improvement of maternity care, particularly to reduce morbidity and mortality during inpatient births. The proposals are finalized without modification.

Beginning with the 2024 reporting period, CMS finalizes its proposal to adopt the following two eCQMs which hospitals may self-select to report:

- Hospital Harm-Opioid-Related Adverse Event eCQM (NQF #3501e); and
- Global Malnutrition Composite Score eCQM (NQF #3592e).

Tables IX.H.-12 and IX.H.-13 show the finalized eCQMs for the 2023 and 2024 reporting periods, respectively.

c. eCQM Reporting and Submission Requirements for the 2024 Reporting Period and Subsequent Years

As part of being a meaningful user under the Medicare PIP, eligible hospitals and CAHs must report on eCQMs selected by CMS. For the 2023 reporting period, CMS previously finalized a requirement that eligible hospitals and CAHs must report four calendar quarters of data from 2023 and each subsequent year for (i) the Safe Use of Opioids-Concurrent Prescribing eCQM and (ii) three self-selected eCQMs from the measure set for 2023 and each subsequent year. These requirements are in alignment with those for eCQM reporting under the Hospital IQR Program. CMS did not propose any changes the data reporting and submission requirements for the 2023 reporting period.

For the 2024 reporting period and subsequent years, CMS finalizes its proposal to increase the number of eCQMs that must be reported to six. Eligible hospitals and CAHs must report four calendar quarters of data for each of the following eCQMs: (i) the Safe Use of Opioids-Concurrent Prescribing eCQM, (ii) the Severe Obstetric Complications eCQM, (iii) the Cesarean

Birth eCQM, and (iv) three self-selected eCQMs from the measure set for 2024 and each subsequent year.

Because CMS adopts the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM in this final rule, those measures are available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the 2023 reporting period. Beginning with the 2024 reporting period and for subsequent years, all eligible hospitals and CAHs must report these two eCQMs.

CMS acknowledges many concerns expressed by commenters about these new requirements, including lack of frequent and actionable eCQM performance feedback, difficulties extracting data from production ready eCQM products delivered by developers, insufficient time for vendor design and development and for hospitals to complete testing, validation, staff education before required reporting, and the costly and prolonged process of eCQM health care provider adoption. However, those concerns did not persuade the agency to modify their proposals, including the timeline by which mandatory reporting is required.

9. Patient Access to Health Information Measure — Request for Information

CMS describes the benefits of the use of patient portals for individuals to access their health information, but it is concerned with the low uptake rate and use of patient portals. For example, close to two thirds of hospitals have less than one quarter of their patients activate access to the hospitals' patient portals in 2017. Study results have indicated that health care providers and staff may positively influence patient use of a portal.

Under the Patient Exchange Objective in the Medicare PIP, in response to stakeholder input, CMS removed the View, Download, or Transmit (VDT) measure because of the difficulties providers face with measures that require patient action. CMS made changes to the Provide Patients Electronic Access to Their Health Information measure to require hospitals to provide timely access for viewing, downloading or transmitting their health information for at least one unique patient discharged using any application of the patient's choice that is configured to meet the technical specifications of the API in the provider's CEHRT. The emphasis of the measure was timely access rather than holding providers accountable for patient action.

CMS is balancing the barriers and challenges of the VDT measure with advancements in the health IT industry, and it sought comment on how to promote equitable patient access and use of their health information without adding unnecessary burden on providers as well as information on a number of issues.

The agency received feedback on various aspects of its request. Many commenters supported patient contributions to their own records as a way to promote patient access to and engagement with their health information, but they noted concerns with potentially duplicative or erroneous information being added, and the need for clinical review of information entered by individuals before inclusion in the medical record. Some recommended including beneficial capabilities within the patient portal to promote patient access, such as appointment scheduling, prescription refills, immediate release of lab results, push notifications to patients, and secure physician messaging.

A number of comments mentioned the importance of developing educational materials for health care providers to reduce stigmatizing language, including providing guidance on the information blocking regulations so health care providers are aware of requirements for patient access to clinical notes, and provide patient-facing resources to address questions when reviewing records. Other commenters emphasized the importance of accurate translation of health information from other languages and how technology can provide reliable real-time translation of information contained in a portal.

With respect to barriers to patient access, potential barriers included individuals having limited access to technology or insufficient understanding of how to use health technology when encountering difficulties navigating portals. Several commenters stated that racial and ethnic minority groups, socioeconomically disadvantaged, rural, elderly, and people who are at risk of poor health outcomes lack physical tools including computers, email addresses, smartphones, and inconsistent internet access.

Providers noted the challenges and burdens they face, including cumbersome and decentralized processes for requesting records as well as the manual workflows for health information professionals fulfilling requests. Other comments noted the importance of continued collaboration with OCR and ONC to develop guidance regarding HIPAA requirements, particularly in the context of health information exchanges and networks, as well as guidance regarding the lack of HIPAA protections when data moves to third-party applications.

While a few commenters supported adding a measure for patient access to their health information, others did not support adding a new measure of patient access noting lack of control, unnecessary burden, and existing patient access barriers. CMS will take the input into account in future rulemaking.

X. Changes for Hospitals and Other Providers

A. Qualified and Non-Qualified Deferred Compensation Plans

1. Background

Currently, certain costs incurred on behalf of deferred compensation plans may be allowable costs under Medicare to the extent such costs are related to the reasonable and necessary cost of providing patient care and represent costs actually incurred by the provider submitting the cost report. Reasonable cost principles pertaining to deferred compensation plans are in section 2140.1 of the Provider Reimbursement Manual - Part 1 (PRM-1).

As part of its continuing efforts to codify sub-regulatory guidance in regulations following the *Azar v. Allina* Supreme Court case, CMS proposed to codify and clarify additional policies relating to deferred compensation plans in a new CFR section in part 413, subpart F. The rule did not propose any changes to current sub-regulatory policies or how those costs are audited.

2. Principles (§413.99(b))

A formal deferred compensation plan is an agreement between the provider of services and its participating employees, in which the agreeing parties can make contributions to the plan for the exclusive benefit of its participating employees. Deferred compensation is salary earned in the current period that is not received until a subsequent period, usually after retirement. Defined contribution plans and defined benefit plans generally specify contributions and benefits as a percentage of employee salary, respectively. Deferred compensation based on unallowable compensation is also unallowable. CMS provides more details regarding how these principles apply to deferred compensation arrangements involving physicians but indicate that there are no policy changes—just codification of provisions previously only found in PRM-1.

3. Requirements for Non-Qualified and Qualified Deferred Compensation Plans (§413.99(c))

Employer contributions for the benefit of employees under a deferred compensation plan are allowable when, and to the extent that, such costs are actually incurred by the provider. Contributions to a funded deferred compensation plan are allowable costs when they are made to the plan, to the extent they fall under a computed limit. Benefits paid for an unfunded deferred compensation plan are allowable costs only when actually paid to the participating employees (or their beneficiaries), and only to the extent considered reasonable. CMS specifies where the requirements for non-qualified and qualified deferred compensation plans can be found in the regulations as well as detailing the requirements themselves.

4. Recognition of Contributions or Payments to Qualified and Non-Qualified Deferred Compensation Plans (§413.99(d))

Rules and requirements that determine when payments or contributions are recognized and included in allowable costs will vary depending on whether a plan is qualified or non-qualified. In addition, certain special rules apply to contributions to qualified and non-qualified deferred compensation plans that are deposited into trusts. CMS restates these rules that are proposed to be codified at §413.99(d) without any change in policy.

5. Documentation Requirements (§413.99(e))

CMS proposed to codify at §413.99(e) that a provider of services must maintain and make documentation available upon request to substantiate the costs incurred for deferred compensation plans included in its Medicare cost report. The requirements for documentation are based on the existing regulatory requirements at §413.20, which require providers of services to maintain sufficient financial records and statistical data for proper determination of costs payable under the program.

6. Administrative and Other Costs Associated Deferred Compensation Plans (§413.99(f))

CMS proposed to codify in §413.99(f) current policies set forth in sections 2140, 2141, and 2142 of PRM-I, regarding the treatment of certain administrative and other costs related to deferred compensation plans.

7. Proposed Treatment of Costs Associated with the Pension Benefit Guaranty Corporation (PBGC) (§413.99(g))

Since 1974, the PBGC has protected retirement security and the retirement incomes of over 33 million American workers, retirees, and their families in private sector defined benefit pension plans. The PBGC collects insurance premiums from employers that sponsor insured pension plans, earns money from investments, and receives funds from pension plans it takes over.

Providers of services who offer a qualified defined benefit plan (QDBP) may incur costs related to the PBGC premiums. The regulations outlined in this section of the final rule establish which costs incurred by providers of services who maintain a QDBP and pay premiums for basic benefits to the PBGC are allowable under the program. CMS proposed to include these provisions on the treatment of costs associated with the PBGC in paragraph (g) of proposed §413.99.

CMS received no comments on any of the proposals related to deferred compensation plans. All proposals are being finalized without change.

B. Condition of Participation: Reporting COVID-19 and Influenza Infections

Conditions of participation (CoPs) are the patient health and safety regulations established by the Secretary for various types of providers and suppliers. The CoPs require hospitals and CAHs to have infection prevention and control program policies.

During the PHE, CMS has required hospitals and CAHs to report specific information about COVID-19 such as the number of staffed beds in a hospital and the number of those that are occupied, information about its supplies, a count of patients currently hospitalized who have laboratory-confirmed COVID-19, current inventory supplies of any COVID-19-related therapeutics that have been distributed and delivered to the hospital (or CAH) under the authority and direction of the Secretary as well as the hospital's (or the CAH's) current usage rate for these COVID-19-related therapeutics.

The rule indicates these elements are essential for planning, monitoring, and resource allocation during the COVID-19 PHE and a requirement of participation in the Medicare and Medicaid programs. However, these reporting requirements will no longer be required through the CoPs once the PHE declaration ends. Additionally, CMS is concerned that the current requirements, while appropriately focused on the current COVID-19 pandemic, are too limited in scope for potential future use. Therefore, CMS proposed to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs' CoPs to extend the current COVID-

19 reporting requirements and to establish new reporting requirements for any future PHEs related to a specific infectious disease or pathogen.

CMS proposed to require that, beginning at the conclusion of the current COVID-19 PHE declaration and continuing until April 30, 2024, a hospital or a CAH must electronically report information about COVID-19 and seasonal influenza in a standardized format specified by the Secretary. For COVID-19 reporting, hospitals and CAHs would be required to report:

- Suspected and confirmed COVID-19 infections among patients and staff.
- Total COVID-19 deaths among patients and staff.
- Personal protective equipment (PPE) and testing supplies in the facility.
- Ventilator use, capacity and supplies in the facility.
- Total hospital bed and intensive care unit bed census and capacity.
- Staffing shortages.
- COVID-19 vaccine administration data of patients and staff.
- Relevant therapeutic inventories and/or usage.

For seasonal influenza, hospitals and CAHs would be required to report:

- Confirmed influenza infections among patients and staff.
- Total influenza deaths among patients and staff.
- Confirmed co-morbid influenza and COVID-19 infections among patients and staff.

These data elements align closely with those COVID-19 reporting requirements for long-term care facilities and are representative of the guidance provided to hospitals and CAHs for current reporting. The sunset date of April 30, 2024 was selected to align with requirements on nursing homes and end reporting at the traditional conclusion of the influenza season.

To more effectively respond to future crises, CMS proposed to require hospitals and CAHs to report specific data elements to the Center for Disease Control's (CDC) National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements would apply during local, state, and national PHEs as declared by the Secretary of Health and Human Services. Relevant to the declared PHE, CMS proposed requiring reporting of the following items on a daily basis to NHSN or other CDC-supported surveillance systems:

- Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.
- Total deaths attributed to the relevant infectious disease pathogen among patients and staff.
- Personal protective equipment and other relevant supplies in the facility.
- Capacity and supplies in the facility relevant to the immediate and long-term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.
- Total hospital bed and intensive care unit bed census, capacity, and capability.

- Staffing shortages.
- Vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.
- Relevant therapeutic inventories and/or usage.
- Isolation capacity, including airborne isolation capacity.
- Key co-morbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest that are captured with interoperable data standards and elements.
- Person level information such as medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients.

While CMS proposed daily reporting, it may specify less frequent reporting contingent on the state of the PHE and ongoing risks. Such decisions would balance the need for the information with the recognition of provider burden. In the proposed rule, CMS indicated it would be particularly interested in comments on whether there is duplication of reporting of these items with those that may be required elsewhere. CMS acknowledged the uncertainties in planning for future emergencies and requested public comment on how to best align and incent preparedness, while also reducing burden and costs on regulated entities, and ensuring flexibility.

The proposed rule indicated that CMS considered requiring the data elements that proved most informative and actionable over the course of the COVID-19 PHE. CMS proposed to include vaccine administration because of the current inability to match patient COVID-19 vaccination status with hospitalization or ICU admission status. The categories are intended to close many of the gaps identified throughout the COVID-19 pandemic and answer the call for U.S. public health agencies to have much more timely, complete, and consistent data for future pathogens of concern.

With regard to "person-level information," CMS indicated these elements are necessary to address issues of health equity and response management. An important gap raised during the COVID-19 pandemic was the inability to follow patients with COVID-19 through the health care system, especially the important transfers that often occur between acute and long-term care facilities.

CMS further explained that hospitals are already reporting quality data to NHSN. Access to NHSN data is restricted. The information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with sections 304, 306, and 308(d) of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m(d)).

CMS distinguished the health care facility reporting requirements proposed from those conducted by state and local health departments. This proposed rule aimed to create a framework for hospital and CAH reporting that would ensure the federal government has the information necessary to identify and respond to hospitals and CAHs in need of additional support and guidance and to monitor and assess the capacity of hospitals and CAHs to provide safe care during a declared PHE (national, regional, or local).

CDC's NHSN also provides ready access to data to state and many local public health agencies for the facilities in their jurisdictions. Ultimately, CMS expects reporting requirements under this section will become increasingly automated and real-time as data systems and standards continue to mature and become more interoperable. To accommodate variable reporting capabilities, the person-level reporting requirements under this provision would leverage established national standards and interoperability requirements of ONC to reduce burden and promote standardization, and would include minimal data elements necessary for public health, safety, and infection control purposes.

CMS received 757 comments that they organized into the following three categories: 1. General Comments; 2. Continued COVID-19 Reporting; and 3. Data Reporting for a Future PHE Declaration.

1. General Comments

All of the commenters were supportive of CMS expressed goals but many expressed concerns these proposals would place undue burden on facilities taking time away from patient care, infection prevention and control, and quality improvement activities. Commenters also raised concerns regarding duplicative reporting and encouraged increased coordination at the local, state, and federal level to ease the burden on providers and limit the need to report the same information through multiple streams. Commenters also suggested reviewing the use case for each data category and eliminating those that are not providing valuable information. A few commenters requested additional payment for more reporting.

CMS responds that it did review the use case for each data category. Its analysis is discussed in greater detail below. The remainder of CMS' response outlines how the CDC and the Assistant Secretary for Preparedness and Response (ASPR) are working with states and other jurisdictions to ensure that states have access to the data reported directly to the federal government. According to ASPR, approximately half of the states currently submit data on behalf of the hospitals in their jurisdictions, and many have expressed their interest in continuing this capability. CDC, CMS, and ASPR will continue to leverage this capability so that they may receive the data directly from hospitals to fulfill local jurisdictional reporting requirements and then pass the data to the federal government to alleviate the burden of hospitals reporting to both state health departments and the federal government.

There were a number of comments about the lack of resources and IT expertise to establish and maintain the necessary system interfaces to report data electronically. Commenters recommended use of NHSN as a single pathway for data reporting. Some commenters suggested that the data reporting pathways currently in place for the COVID-19 PHE should remain available for continued COVID-19-related reporting after the PHE ends and in the event of a future PHE declaration. CMS responded that the CDC is increasing automation capabilities of NHSN, and its ability to connect with other systems (87 FR 28622).

Some commenters stated there was a lack of transparency in why CMS would need the data, and by whom and how the data would be used. These commenters also indicated that there should be

a bi-directional flow of the information reported and that the data should be accessible to all health partners to both increase transparency and inform emergency management efforts.

Throughout the COVID-19 pandemic, HHS and state and local agencies used these data to provide resources (such as PPE, staffing, strike teams, financial resources) to hospitals. The data were also used to update guidance on the provision of care to patients during periods of scarce staffing, PPE, and limited hospital capacity. NHSN provides ready access to data to state and local public health agencies for the facilities in their jurisdictions via their NHSN accounts and contributes aggregate data to multiple public-facing platforms, including HHS Protect and CMS Care Compare.

Public commenters suggested implementation approaches that CMS could take to support compliance with the proposed reporting policies. Commenters emphasized that the data definitions across facility types and different reporting organizations need to be clearly defined and consistent. CMS provides several examples of these suggestions and indicated that it will consider these comments when developing the interpretive guidance implementing these policies.

2. Continued COVID-19 Reporting

Some commenters found the proposal for continued COVID-19-related reporting to be unclear because it indicated that hospitals and CAHs would report data in a standardized format specified by the Secretary but did not specify a system. CMS responded that it is taking this approach because it affords flexibility to adapt data reporting requirements in response to changing circumstances without having to go through rulemaking. Throughout the COVID-19 PHE, CMS notified hospitals and CAHs of the reporting requirements using sub-regulatory guidance and it expects to do the same for the COVID-19-related data reporting requirements finalized in this rule.

There were commenters that did not see a purpose in continued COVID-19-related reporting beyond the current PHE declaration—only if another PHE is declared. CMS believes that continuing COVID-19-related data reporting is necessary to protect the health and safety of hospital and CAH patients as well as the communities in which the hospitals and CAHs are located. Timely and actionable surveillance will enable CMS to continue to respond to facilities in need of additional technical support and oversight should they experience increased cases or outbreaks of COVID-19 and/or influenza.

A number of comments suggested options for reducing burden by eliminating reporting of suspected and confirmed cases among staff, staff vaccination, and staffing shortages as these have already been made optional or retired from current reporting requirements under the PHE. CMS agreed and will not require reporting of: suspected COVID-19 infections among patients and staff, confirmed COVID-19 and influenza infections among staff, confirmed co-morbid influenza and COVID-19 infections among staff, and COVID-19 and influenza deaths among staff.

As indicated in the proposal, CMS does not expect continued daily reporting for COVID-19 or influenza outside of a declared PHE. Moreover, the rule allows for the scope of data categories and frequency of data collection and reporting to be reduced and limited, as determined by the Secretary, responsive to evolving clinical and epidemiology circumstances. These requirements will not be implemented and enforced until the current COVID-19 PHE declaration concludes, and CMS will issue guidance indicating such a transition.

3. Data Reporting for a Future PHE Declaration

A few commenters questioned the appropriateness of continued data report for future pandemics as condition of participation. These commenters indicated that the COVID-19 data do not directly or indirectly reflect a facility's infection control policies or practices, but rather are descriptive of public health information (such as, infection rate, bed capacity, supplies, etc.)

There were also comments that, throughout the COVID-19 PHE, hospitals have been required to report similar (but not necessarily standardized) data elements to multiple agencies (federal, state, local) and through multiple platforms. Nearly all of these commenters called for CMS and other HHS agencies to work closely with facilities, as well as state and local agencies, to align and streamline future reporting requirements.

HHS will continue to partner with state and local jurisdictions, health care facilities, and stakeholders to coordinate data collection, sharing, and accessibility in a streamlined fashion that satisfies the needs of all stakeholders while reducing duplicative reporting requirements to the extent possible.

Data collected and reported by hospitals and CAHs during the COVID-19 PHE enabled the federal government to monitor the ability of facilities to provide safe care to patients, and these data were used by local, state, and federal government agencies to allocate resources (such as PPE, staff, strike teams, funding) to hospitals and to update guidance on the provision of care, which was particularly important during periods of staffing and PPE scarcity and limited capacity.

CMS disagrees that reporting is not appropriate for the CoPs in an effort to protect patient health and safety. However, CMS is withdrawing its proposal to require future infectious disease reporting in the event of a declared PHE. CMS will continue efforts to further enhance the infrastructure used to support the submission of data for the long term in hopes of mitigating many of the burden concerns raised by comments.

Public comments both supported and opposed reporting of person level data. Commenters who supported the proposal noted that person-level data would provide information about how different groups are affected by an infectious disease thereby supporting efforts focused on advancing health equity and suggested this data should include socioeconomic status. Commenters who disagreed noted concerns related to burden and indicated that such reporting would be unreasonable, particularly for larger facilities or those facilities lacking automated processes to collect and report such data.

CMS' response indicated that in the absence of person-level data, it is challenging to take actions to reduce disparities in disease incidence and severity, access, and effectiveness of relevant preventive and therapeutic services (for example, vaccines) among vulnerable or otherwise marginalized populations. CMS will continue to explore issues of when person-level data may be warranted for future PHE reporting requirements.

Many commenters supported the proposal to require facilities to report the required data to the NHSN or some other CDC-supported surveillance system but emphasized that its usage must complement, not replace, existing data collection efforts that provide awareness and inform health care practices, especially those at the local level. These commenters shared concerns regarding the likelihood that critical data would continue to be reported to both NHSN and any local surveillance systems given the resource burden that would be placed on providers.

CMS responded that it proposed reporting to the CDC's NHSN because it is a vendor-neutral, federally owned system and as such provides ready access to data to state and many local public health agencies and can accept data submitted by outside vendors contracted either by hospitals, jurisdictions, or other Federal entities to submit data on behalf of providers (87 FR 28622). Additionally, CDC is investing in increasing the NHSN's capabilities and ability to connect with other data submission techniques, vendors, and systems to further automate data collection, reduce provider burden, and increase data accessibility for stakeholders. CMS will consider these comments as it explores the most effective approaches for data reporting.

After consideration of the public comments, CMS is finalizing its proposal with modifications to not require reporting of: suspected COVID-19 infections among patients and staff, confirmed COVID-19 and influenza infections among staff, confirmed co-morbid influenza and COVID-19 infections among staff, and COVID-19 and influenza deaths among staff. CMS will also not establish reporting requirements for an infectious disease in the event of a PHE declaration as condition of participation.

C. RFI: Payment Adjustments for Domestically Made N95 Respirator Masks

In the FY 2023 IPPS proposed rule, CMS requested public comments on potential IPPS and OPPS payment adjustments for wholly domestically made National Institute for Occupational Safety & Health (NIOSH)-approved surgical N95 respirators (87 FR 28622 through 28625). Domestically manufactured NIOSH-approved surgical N95 respirators were essential in protecting hospital personnel and beneficiaries from the SARS-CoV-2 virus but were in severe short supply during the PHE.

CMS received many comments on its solicitation. These commenters were supportive of biweekly interim lump-sum payments that would be reconciled at cost report settlement, although some commenters preferred a claims-based approach. Many commenters urged CMS to minimize the administrative burden on hospitals. MedPAC and others stated that Medicare payment policy is not the most appropriate mechanism to support domestic manufacturing of medical supplies.

In the CY 2023 OPPS proposed rule, CMS proposed to make a payment adjustment under the OPPS and IPPS for the additional resource costs of domestic NIOSH-approved surgical N95 respirators for cost reporting periods beginning on or after January 1, 2023.

XI. MedPAC Recommendations

In its March 2022 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law. CMS responded that, consistent with the statute, it is adopting an applicable percentage increase for FY 2023 of 3.8 percent (before application of the documentation and coding and other adjustments), provided the hospital submits quality data and is a meaningful EHR.

TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2023

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2023 Changes (8)[9]
All Hospitals	3,142	4.2	0.0	0.0	0.0	0.0	0.3	-0.2	2.6
By Geographic Location:									
Urban hospitals	2,420	4.3	0.0	0.0	-0.1	0.0	0.3	-0.1	2.6
Rural hospitals	722	4.0	0.1	0.0	1.0	-0.2	0.1	-0.7	2.4
Bed Size (Urban):									
0-99 beds	653	4.2	0.0	0.0	-0.8	0.2	0.6	-1.6	1.1
100-199 beds	700	4.3	0.2	0.0	-0.1	0.2	0.3	-0.3	2.9
200-299 beds	411	4.3	0.1	0.0	0.1	0.0	0.3	0.0	3.0
300-499 beds	409	4.3	0.0	0.0	0.1	0.0	0.3	0.0	2.7
500 or more beds	245	4.2	-0.1	0.0	-0.2	0.0	0.2	0.0	2.4
Bed Size (Rural):									
0-49 beds	358	3.8	0.0	-0.1	0.5	-0.3	0.2	-1.6	0.9
50-99 beds	201	3.9	0.2	0.0	0.6	-0.2	0.3	-1.7	1.3
100-149 beds	84	4.0	0.3	0.0	1.3	-0.2	0.0	-0.1	3.5
150-199 beds	46	4.1	0.1	-0.1	1.0	-0.2	0.1	0.0	3.1
200 or more beds	33	4.0	0.1	0.2	1.6	-0.3	0.0	0.0	3.4
Urban by Region:									
New England	107	4.2	-0.1	-0.4	1.8	3.8	0.7	-0.2	3.2
Middle Atlantic	295	4.3	0.1	0.1	0.5	-0.4	0.4	-0.1	2.5
East North Central	373	4.3	-0.1	-0.2	-0.3	-0.4	0.1	-0.3	2.3
West North Central	156	4.2	-0.2	-0.3	-0.7	-0.4	0.8	0.0	2.2
South Atlantic	402	4.3	0.0	-0.2	-0.7	-0.4	0.3	-0.1	2.4
East South Central	140	4.3	0.1	-0.2	-0.7	-0.4	0.0	0.0	2.5
West South Central	362	4.3	0.1	0.4	-0.7	-0.4	0.0	-0.1	3.0
Mountain	176	4.2	-0.1	-0.1	0.2	1.1	0.3	0.0	4.1
Pacific	359	4.2	0.1	0.5	0.3	0.0	0.1	0.0	2.4
Puerto Rico	50	4.3	0.6	-0.5	-1.3	0.4	0.1	0.0	3.8
Rural by Region:									
New England	19	4.1	-0.2	0.6	-0.1	-0.3	0.2	-1.7	0.1
Middle Atlantic	49	4.1	0.0	-0.2	1.3	-0.2	0.0	-0.6	2.5
East North Central	113	4.0	-0.1	-0.2	1.2	-0.2	0.0	-2.5	0.1
West North Central	86	3.7	0.0	0.2	-0.1	-0.1	0.2	-0.3	2.9
South Atlantic	109	4.0	0.4	0.0	1.5	-0.2	0.1	-0.1	3.6
East South Central	141	4.1	0.4	-0.1	1.4	-0.3	0.1	-0.2	3.2
West South Central	134	4.0	0.3	0.4	1.5	-0.3	0.0	-0.4	2.8
Mountain	47	3.2	0.0	-0.7	0.1	-0.2	1.2	0.0	2.8
Pacific	24	3.9	0.2	-0.1	0.9	-0.1	0.0	0.0	3.4
By Payment Classification:									
Urban hospitals	1,861	4.3	0.0	0.0	-0.8	-0.1	0.3	0.0	2.5
Rural areas	1,281	4.2	0.0	0.0	0.9	0.1	0.2	-0.3	2.7
Teaching Status:									
Nonteaching	1,939	4.2	0.1	0.1	0.0	0.1	0.2	-0.4	2.6
Fewer than 100 residents	929	4.3	0.0	0.0	0.0	-0.1	0.3	-0.1	2.6
100 or more residents	274	4.2	0.0	0.0	0.0	0.0	0.2	0.0	2.5
Urban DSH:									

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2023 Changes (8)[9]
Non-DSH	369	4.3	-0.3	0.1	-0.3	-0.2	0.5	-0.2	2.3
100 or more beds	1,129	4.3	0.1	0.0	-0.8	-0.1	0.3	0.0	2.5
Less than 100 beds	363	4.3	0.3	0.1	-0.7	0.3	0.5	-0.4	2.7
Rural DSH:									
Non-DSH	105	4.2	-0.2	-0.3	1.2	1.1	0.2	-1.7	1.7
SCH	264	3.8	0.1	0.0	0.1	0.0	0.1	0.0	3.8
RRC	674	4.2	0.0	0.0	0.9	0.1	0.2	-0.1	2.8
100 or more beds	22	4.4	0.0	0.1	-0.1	1.1	0.0	-3.4	0.1
Less than 100 beds	216	4.2	0.1	0.0	1.1	-0.5	0.2	-4.8	-4.0
Urban teaching and DSH:									
Both teaching and DSH	663	4.3	0.0	0.0	-0.8	-0.2	0.4	0.0	2.5
Teaching and no DSH	60	4.3	-0.4	0.2	0.2	-0.1	0.5	-0.3	2.0
No teaching and DSH	829	4.3	0.2	0.0	-0.7	0.1	0.2	0.0	2.7
No teaching and no DSH	309	4.3	-0.3	0.1	-0.6	-0.2	0.6	-0.1	2.5
Special Hospital Types:									
RRC	148	4.4	0.1	-0.1	1.5	-0.2	0.3	-0.7	2.0
RRC with Section 401 Rural Reclassification	470	4.2	-0.1	0.0	1.0	0.2	0.2	-0.1	2.8
SCH	256	3.7	0.1	0.0	0.0	0.0	0.1	0.0	3.6
SCH with Section 401 Rural Reclassification	47	3.7	0.0	0.0	0.0	0.1	0.0	0.0	3.8
SCH and RRC	122	3.8	0.1	0.0	0.3	-0.1	0.0	0.0	3.5
SCH and RRC with Section 401 Rural Reclassification	39	3.9	-0.3	0.0	0.1	-0.1	0.0	0.0	3.3
Type of Ownership:									
Voluntary	1,915	4.3	0.0	0.0	0.1	0.0	0.3	-0.2	2.5
Proprietary	789	4.2	0.2	0.0	-0.1	0.1	0.2	-0.1	3.3
Government	438	4.1	0.1	0.1	-0.4	-0.2	0.1	-0.1	2.4
Medicare Utilization as a Percent of Inpatient Days:									
0-25	790	4.2	0.1	0.1	-0.4	-0.2	0.1	0.0	2.9
25-50	2,072	4.2	0.0	0.0	0.1	0.0	0.3	-0.2	2.5
50-65	225	4.2	0.1	0.1	-0.1	0.6	0.4	-0.3	2.8
Over 65	30	3.1	-1.1	-0.5	-0.7	-0.4	0.0	-1.1	0.3
Medicaid Utilization as a Percent of Inpatient Days:									
0-25	2,082	4.2	-0.1	0.0	0.1	-0.1	0.3	-0.3	2.4
25-50	942	4.2	0.1	0.0	-0.1	0.1	0.3	0.0	2.8
50-65	94	4.1	0.9	0.4	-0.7	0.5	0.2	0.0	3.5
Over 65	24	4.1	1.0	1.2	-0.9	-0.3	0.1	0.0	4.4
Hospitals with 5% or more of cases that reported experiencing homelessness	45	4.2	1.0	0.5	-0.7	-0.2	0.2	0.0	3.9
FY 2023 Reclassifications:									
All Reclassified Hospitals	1,004	4.2	0.0	0.0	1.2	0.1	0.1	-0.1	2.8
Non-Reclassified Hospitals	2,138	4.3	0.0	0.0	-1.1	-0.1	0.4	-0.2	2.4
Urban Hospitals Reclassified	840	4.2	-0.1	0.0	1.1	0.1	0.2	-0.2	2.7
Urban Non-Reclassified Hospitals	1,594	4.3	0.0	0.0	-1.3	-0.1	0.4	0.0	2.5
Rural Hospitals Reclassified Full Year	282	4.1	0.2	-0.1	1.9	-0.2	0.1	-0.5	2.8
Rural Non-Reclassified Hospitals Full Year	426	3.8	0.1	0.1	-0.5	-0.2	0.2	-0.9	1.9
All Section 401 Rural Reclassified Hospitals	615	4.2	-0.1	0.0	0.9	0.2	0.2	-0.2	2.7

	Number of Hospitals[1]	Hospital Rate Update and Adjustment under MACRA (1)[2]	FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All FY 2023 Changes (8)[9]
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	4.2	0.2	0.0	3.0	-0.4	0.2	-2.0	0.6

[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 2021, and hospital cost report data are from the latest available reporting periods.
[2] This column displays the payment impact of the hospital rate update and other adjustments, including the 3.8 percent update to the national standardized amount and the hospital-specific rate (the 4.1 percent market basket update reduced by 0.3 percentage point for the productivity adjustment), and the 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.
[3] This column displays the payment impact of the changes to the Version 40 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2021 MedPAR data as the best available data, and the permanent 10-percent cap where the relative weight for a MS-DRG would decrease by more than 10 percent in a given fiscal year. This column displays the application of the recalibration budget neutrality factors of 1.000509and 0.999764.
[4] This column displays the payment impact of the update to wage index data using FY 2019 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor. The wage budget neutrality factor is 1.000968.
[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2023 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2023. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.984399.
[6] This column displays the effects of the rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.991909.
[7] This column shows the combined impact of (1) the imputed floor for all-urban states (2) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (3) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.
[8] This column displays the impact of the expiration of MDH status for FY 2023, a non-budget neutral payment provision.
[9] This column shows the estimated change in payments from FY 2022 to FY 2023.