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

On April 18, 2022, the Centers for Medicare & Medicaid Services (CMS) released its proposed 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 proposed rule will be published in the *Federal Register* on May 10, 2022. **The public comment period on the rule will end on June 17, 2022.**

The payment rates and policies described in the IPPS/LTCH proposed rule (CMS-1771-P) affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in LTCHs paid under their respective prospective payment systems. The proposed rule also sets forth rate-of-increase limits for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals, and religious nonmedical health care institutions, which are paid based on reasonable costs. Unless otherwise specified, policies will be effective October 1, 2022.

The proposed rule includes requests for information (RFI) on:

- The impact of climate change on outcomes, care, and health equity;
- Measuring healthcare quality disparities across CMS quality programs;
- The use of fast healthcare interoperability resources (FHIR) in CMS quality programs; and
- Payment adjustments under the IPPS and outpatient prospective payment system for domestically manufactured N95 respirator masks.

CMS also proposes:

- To require 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;
- Changes to how section 1115 waiver days are counted for determining the Medicare disproportionate share percentage (DSH) percentage; and
- Revisions to Medicare's direct graduate medical education (DGME) regulations in response to adverse litigation against the agency.

CMS makes many data files available to support analysis of the proposed rule. These data files are generally available at: FY 2023 IPPS Proposed Rule Home Page | CMS. Numbered tables that were historically included in the IPPS/LTCH rule are now only available on the CMS website at the above hyperlink.

Table of Contents

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

CMS estimates that the proposed rule will decrease FY 2023 combined operating and capital payments to approximately 3,141 acute care hospitals paid under the IPPS by an estimated $0.4 billion. This net impact results from:

Combined Expenditure Change Estimate ($ in Billions)[1]	
Operating Payments, excluding DSH and UCP	$1.4
Operating DSH	-0.18
UCP	-0.65
Indian Health Service/Tribal/Puerto Rico Supplemental Payments	0.09
Capital Payments	-0.02
NTAP	-0.83
Expiration of the low-volume payment adjustment	-0.41
Proposed change to the DGME weighting methodology	0.17
Total	**-0.4**

[1] This information differs from what CMS provided in the proposed rule. It reflects information provided to HPA from CMS and corrects what CMS indicates are typographical errors in the proposed rule. The individual items in the table are explained in more detail below.

A. Inpatient Hospital Operating Update

The above are changes to IPPS payments. The estimated percentage increase in IPPS *payment per service* is estimated at 3.2 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 3.2 percent rate increase is the

net result of a market basket update of 3.1 percent less 0.4 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) and MDHs are paid. However, the documentation and coding adjustment does not apply to the hospital-specific rates resulting in a 2.7 percent increase rather than a 3.2 percent increase for SCHs and MDHs.

Factor	Percent Change
FY 2023 Market Basket	3.1%
Total Factor Productivity	-0.4
MACRA Documentation and Coding Adjustment	+0.5
Net increase before application of budget neutrality factors	3.2%

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	3.1%	2.7%	-0.775	1.925%	25
No EHR	75% of the MB	3.1%	2.7%	-2.325	0.375%	158
No IQR/EHR	100% of the MB	3.1%	2.7%	-3.1	-0.4%	19

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2023 payments increasing 1.4 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	+3.1[1]
Imputed and Frontier Wage Index Floors and Outmigration Adjustment	+0.3[2]
Expiration of the MDH Program	-0.2[3]
Outliers	-1.8[4]
Total	+1.4

[1]Weighted average of hospital-specific rate update of 2.6 and 3.2 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 1.8 percent more than the amount targeted in FY 2022. As a result, CMS estimates total payments will decline by 1.8 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 proposed rule (reproduced in the Appendix to this summary). The following table summarizes the impact by selected hospital categories.

Hospital Type	All Proposed Rule Changes
All Hospitals	1.4%
Urban	1.4%
Rural	1.1%
Major Teaching	1.3%

To the extent the impact on a given hospital category deviates from the national average of 1.4 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 is made budget neutral through an adjustment to hospital wage indexes.

The largest deviation from the average increase of 1.4 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 120 hospitals and decrease spending $219 million.

Other provisions having an impact include:

Rural Floor. The proposed rural floor raises the wage index of 192 urban hospitals so that it is not below the wage index for the rural area of its state. CMS calculates a proposed national rural floor budget neutrality adjustment factor of 0.993656 (-0.63 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 3.3 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 (ARPA) 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 69 hospitals by $140 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 $64 million to 44 hospitals and the outmigration adjustment that increases payments about $55 million to 245 hospitals.

NTAP. NTAP payments are not subject to budget neutrality. CMS is proposing to continue NTAP payments for 15 technologies that remain eligible. These technologies are estimated to receive $612 million in FY 2023. As CMS estimated FY 2022 NTAP payments of $1.4 billion, the proposed rule estimates a reduction in NTAP payments of $800 million. However, these estimates do not account for FY 2023 NTAP applications for which CMS will make a determination in the final rule.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by 9.1 percent or about $654 million. However, about $91.6 million of this reduction is offset by supplemental payments to Puerto Rico, Indian Health Service and Tribal Hospitals that CMS proposes as a replacement of the low-income insured days proxy to calculate uncompensated care payments for these hospitals. More detail on these calculations is in section IV.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2023 payments to an estimated 2,364 hospitals or 81.6 percent of all hospitals eligible to receive a readmissions penalty. The proposed readmissions penalty is estimated to affect 0.50 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 will redistribute 2 percent of base operating MS-DRG payments based on hospitals' performance scores. CMS includes an unnumbered table in the impact section that illustrates the proposed average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural, etc.) in FY 2023.

Hospital Acquired Conditions (HAC) Reduction Program. CMS is proposing not to apply any HAC penalties in FY 2023. If the proposal is finalized, no hospitals will receive a payment reduction in the FY 2023 due to being in the worst performing quartile for a given HAC measure. Tables 1 and 2 in the HAC impact section of the proposed rule show the number of hospitals participating the program and the number and percent of hospitals that would be in the worst performing quartile by hospital category if CMS did not suppress HAC program measures.

DGME. In response to adverse litigation, CMS is proposing to change 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 proposed 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 $71.9 million for FY 2023 and $35.9 million using reconciled cost reports for FY 2017 when no budget neutrality adjustment was applied. CMS proposes applying a budget neutrality adjustment to the IPPS standardized amounts based on total costs of $107.9 million in FY 2023.

C. IPPS Standardized Amounts

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

	Update
Full Update	2.7%
No IQR	1.925%
No EHR	0.375%
No EHR/IQR	-0.4%

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, 1.000491 (an increase of 0.05 percent);
- MS-DRG recalibration cap, 0.999765 (a decrease of 0.02 percent)
- Wage index, 1.001303 (an increase of 0.13 percent);
- Geographic reclassification, 0.985346 (a reduction of 1.47 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.998205 or -0.18 percent;
- 5 percent cap on wage index reductions, 0.999563 or -0.04 percent;
- The outlier offset factor is 0.949 or -5.1 percent;
- The rural community hospital demonstration program adjustment is 0.998925 or -0.11 percent;

Of the adjustments above, MS-DRG recalibration and wage index is 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	2.7%
DRG Recalibration	0.05%
DRG Recalibration Cap	-0.02%
Wage Index	0.13%
Geographic Reclassification	-0.14%

Factor	Net Change
25th Percentile	0.02%
5% Cap on Wage Index Reductions	-0.03%
Outlier	0.00%
Rural Community Hospital	-0.04%
Doc and Coding	0.50%
Net Change*	3.1%

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

The proposed increase in the capital rate is 1.63 percent from $472.59 to $480.29. The combined increase in the proposed operating standardized amount and the capital rate will be 3.06 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=2.7%	**Reduced Update Failed IQR = 1.925%**	**Reduced Update Failed EHR =0.375%**	**Reduced Update Failed IQR and EHR = -0.4%**
Wage Index >1.0				
Labor (67.6%)	$4,269.46	$4,237.24	$4,172.80	$4,140.59
Non-Labor (32.4%)	$2,046.31	$2,030.87	$1,999.98	$1,984.54
WI<=1.0				
Labor (62%)	$3,915.78	$3,886.23	$3,827.12	$3,797.58
Non-Labor (38%)	$2,399.99	$2,381.88	$2,345.66	$2,327.55
National Capital Rate (All Hospitals)	$480.29			

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 proposes 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. CMS projects that the proposed outlier threshold for FY 2023 will result in outlier payments equal to 5.1 percent of operating DRG payments and 5.55 percent of capital payments. Accordingly, CMS is applying

adjustments of 0.949 to the operating standardized amounts and 0.944536 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 December 2021 update to the FY 2021 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data is the December 2021 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 proposes 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 is proposing 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.

	Operating	Capital	% Change	Factor
March 2019 PSF	0.254027	0.0207300	-2.55%	0.974495
March 2020 PSF	0.247548	0.0019935	-3.84%	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 be $58,798.

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 proposed rule, CMS is using the December 2021 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 2022). 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.

In the proposed rule, CMS estimates that reconciliation in FY 2017 resulted in 10 hospitals being owed $11.940 million or -0.013508 percent of total operating IPPS payments. This figure rounds to -0.01 percent. Subtracting -0.01 percentage points from 5.10 percent is 5.11 percent. CMS will target 5.11 percent of operating payments as outliers assuming that -0.01 percentage points of that amount will be repaid to hospitals under the reconciliation process. Reconciliation will have the effect of slightly decreasing the proposed outlier threshold (from $43,292 to $43,214) 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 the ratio of reconciled outlier payments to total payments is -0.01 percent based $759,949 in reconciled capital outlier payments owed to hospitals (the proposed rule does not specify the number of hospitals owed capital outpatient reconciliation payments in FY 2017).

FY 2021 Outlier Payments. CMS' current estimate, using available FY 2021 claims data, is that actual outlier payments for FY 2021 were approximately 5.62 percent of actual total MS-DRG payments or 0.52 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 this proposed rule, CMS estimates that, using FY 2021 data, outlier payments will be 1.8 percentage points higher (or 6.9 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 to offset prior negative ones through FY 2023. For FY 2023, consistent with MACRA, CMS is proposing to implement a positive 0.5 percentage point adjustment to the standardized amount.

This proposed 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 proposed adjustment will result in 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.

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.[1] 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] 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.

To allow the public to better analyze and understand the impacts of the proposals in this rule, CMS is posting a test version of the ICD-10 MS-DRG GROUPER Software, Version 40 on its website. This test software reflects the proposed GROUPER logic for FY 2023; it includes the new diagnosis and procedure codes effective for FY 2023 and does not include the diagnosis codes that are invalid beginning in FY 2023. CMS is also making available a supplemental file in Table 6P.1a that includes the mapped Version 40 FY 2023 ICD-10-CM codes and the deleted Version 39.1 FY 2022ICD-10-CM codes for testing purposes with users' available claims data. All this information is available at https://www.cms.gov/MEdicare/MEdicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

This section of the preamble discusses changes that CMS proposes 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.

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.[2] 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-DRGs.

The table below, reproduced from the rule, illustrates all five criteria and how they are applied to each CC. For FY 2022, CMS applied these criteria to each of the MCC, CC, and NonCC subgroups.

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-

[2] 85 FR 58448

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.

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 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 proposes 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). CMS intends to address the application of the NonCC subgroup criteria in 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, CMS provides 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 table below summarizes this information. CMS notes that if a procedure code is assigned to the logic for MS-DRG and is not listed in the table no cases were found for that procedure code.

MS-DRG 018: Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies				
ICD-10-PCS Code	**Number of Cases**	**Average Length of Stay**	**Average Costs**	**Secondary Diagnosis Z00.6**
All cases	558	16.5	$194,717	185
XW033C7 - Introduction of autologous engineered chimeric antigen receptor t-cell	50	13.2	$212,265	16

MS-DRG 018: Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies				
ICD-10-PCS Code	**Number of Cases**	**Average Length of Stay**	**Average Costs**	**Secondary Diagnosis Z00.6**
immunotherapy into peripheral vein, percutaneous approach, new technology group 7				
XW033M7 - Introduction of brexucabtagene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	11	14.1	$157,950	4
XW033N7 - Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	4	11.3	$310,561	1
XW043C7 - Introduction of autologous engineered chimeric antigen receptor t-cell immunotherapy into central vein, percutaneous approach, new technology group 7	435	16.7	$186,038	152
XW043M7 - Introduction of brexucabtagene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 7	\43	20.3	$264,932	7
XW043N7 - Introduction of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7	15	14.2	$182,700	5

The data shows 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). CMS believes this is 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.

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

a. Laser Interstitial Thermal Therapy (LITT)

In the FY 2023 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.[3] 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 redesignation of these two LITT procedures from extensive O.R. procedures to non-extensive O.R. procedures.

[3] 86 FR 44812 through 44814

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 summarizes the information and data analysis submitted by both requestors.

Medtronic and Monteris Medical also submitted a joint code proposal requesting an overall change is 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.[4] Public comments in response to the code proposal were due by April 8, 2022.

CMS acknowledges 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, CMS discusses 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 are not approved.

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

The code proposal is 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 is to reclassify LITT procedures to the root operation Destruction[5]. 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 believes it is 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 reviews 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 procedure codes and associated MS-DRG assignments are summarized in a table in the proposed rule, reproduced below. Additional information about these potential new procedure codes is included in Table 6P.2a associated with this proposed rule.

[4] 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.

[5] 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.

ICD-10-PCS Code	Description	MS-DRG
00500ZZ	Destruction of brain, open approach	023-027
00503ZZ	Destruction of brain, percutaneous approach	
00504ZZ	Destruction of brain, percutaneous endoscopic approach	
005W0ZZ	Destruction of cervical spinal cord, open approach	028-030
005W3ZZ	Destruction of cervical spinal cord, percutaneous approach	
005W4ZZ	Destruction of cervical spinal cord, percutaneous endoscopic approach	
005X0ZZ	Destruction of thoracic spinal cord, open approach	
005X3ZZ	Destruction of thoracic spinal cord, percutaneous approach	
005X4ZZ	Destruction of thoracic spinal cord, percutaneous endoscopic approach	
005Y0ZZ	Destruction of lumbar spinal cord, open approach	
005Y3ZZ	Destruction of lumbar spinal cord, percutaneous approach	

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

CMS summarizes 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. The data demonstrates that since the implementation of ICD-10, a shift in the reporting of brain and brain stem procedures has occurred. The MedPAR data for FYs 2016 – 2018 indicates that number of cases for which LITT of brain or brain stem were reported as a standalone procedure was higher in comparison to the number of cases reported with another procedure. Conversely the MedPAR data for FYs 2019 – 2021 indicates that the number of cases for which LITT of brain or brain stem procedures reported as a standalone procedure is lower in comparison to the number of cases reported with another procedure. The data also indicates that the average length of stay is shorter and the average costs are lower for cases reporting LITT of brain or brain stem as a standalone procedure in comparison to cases reported with another procedure. CMS notes that the number of cases for which LITT of brain or brain procedures was performed is relatively stable at over 100 cases.

CMS also identified a limited number of cases reporting LITT procedures for other anatomic sites and is interested in comments regarding the use of and experience with LITT for these other anatomic sites.

Based on its analysis of the FY 2021 MedPAR claims data for cases reporting LITT of brain or brain stem, CMS agrees 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 believes 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 recognizes 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 concludes 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 proposes 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 proposes 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 notes it did not receive any comments or requests to reconsider those assignments.

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 seeks 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.[6] 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.

CMS summarizes 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 summarizes 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 concludes there is 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 do not think it would be

[6] 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.

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 will continue to evaluate this issue as data becomes available in future rulemaking.

CMS is proposing 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.

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 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 proposes to add these 24-ICD-PCS codes to MS-DRGs 040 – 042.

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 proposes 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.

3. 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.

CMS summarizes its review of this request. CMS first examined the September 2021 update of the FY 2021 MedPAR file for MS-DRG to examine the number of cases with a principal diagnosis of CRAO or BRAO with and without administration of a thrombolytic agent or HBOT. CMS also examined claims data from the same MedPAR file for MS-DRGs 061 – 063. These

results are summarized in tables in the proposed rule. Based on this data analysis, CMS does not believe that the small subset of patients with a diagnosis of CRAO or BRAO receiving a thrombolytic agent or HBOT warrant a separate MS-DRG or reassignment. CMS' clinical advisors agreed. The clinical advisors also believe that CRAO and BRAO describe ischemia affecting the retina and these diagnosis codes are 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, summarized in the proposed rule, indicates that the current base MS-DRG 123 maintains the overall accuracy of the IPPS and that claims data do 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 is not proposing 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.

4. 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 proposes to reassign cases reporting ARDS (code J80) as a principal diagnosis form MS-DRG 204 to MS-DRG 189

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

a. Percutaneous Transluminal Coronary Angioplasty (PTCA) Logic

CMS discusses 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.

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

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 proposes 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). CMS summarizes 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.

CMS summarizes 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. These results are summarized in a table in the proposed rule. Only three cases reported procedure codes describing the implantation of a BAROSTIM NEO System; the claims data indicates 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 concludes 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. These results are summarized in a table in the proposed rule. This analysis found 12 cases in MS-DRG 252 and 4 cases in MS-DRG 253. CMS concludes it does not have sufficient claims data to evaluate any proposed changed to the current MS-DRG assignment.

In response to the requestors 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. CMS notes that when BAROSTIM NEO applied for new technology add-on payment the requestor noted that the technology could be uniquely identified using a combination of existing ICD-10-PCS codes that were already assigned to MS-DRGs.

For FY 2023, CMS proposes 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.

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. For FY 2023, CMS proposes 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 summarizes its review of this issue in the proposed rule. For FY 2023, CMS proposes the reassignment of procedure code 02K80ZZ from MS-DRGs 246 – 251 to MS-DRGs 273 and 273 (Percutaneous and Other Intracardiac Procedures). CMS notes that this proposed reassignment it not reflected in the test version of the ICD-10 MS-DRG GROUPER Software, 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.[7] 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.

[7] 86 FR 44836 through 44848

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

6. 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). CMS notes this topic has been previously discussed in both FY 2019 and FY 2021 rulemakings and summarizes its previous decisions.[8] 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 proposed rule (reproduced below).

Proposed ICD-10-CM Code	Description
K35.200	Acute appendicitis with generalized peritonitis, without perforation or abscess
K35.201	Acute appendicitis with generalized peritonitis, with perforation, without abscess
K35.209	Acute appendicitis with generalized peritonitis, without abscess, unspecified as to perforation
K35.210	Acute appendicitis with generalized peritonitis, without perforation, with abscess
K35.211	Acute appendicitis with generalized peritonitis, with perforation and abscess
K35.219	Acute appendicitis with generalized peritonitis, with abscess, unspecified as to perforation

CMS notes that the deadline for submitting public comments to this proposal is May 9, 2022.

7. 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

[8] 83 FR 41230, 85 FR 32500 through 32503, and 85 FR 58484 through 58488.

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 proposes 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.

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 requests feedback on this and any alternative recommendations via MEARIS by October 20, 2022 for future consideration**.

8. 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.

CMS summarizes 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 proposes to maintain the current MS-DRG assignments. As discussed below (section D.18), CMS is exploring alternative to address rare diseases and conditions that are represented by low volumes in the claims data.

9. 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).

CMS summarizes 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 notes 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 proposes 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.

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 proposes to reassign ICD-10-CM diagnosis codes P07.00, P07.20, and P07.26 to MS-DRG 790.

10. 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 proposed rule for a discussion of the following:

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

11. 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.

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 are 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 proposed 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

12. Proposed 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[9], 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.[10] 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 a comprehensive CC/MC analysis 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 explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

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 is soliciting public comment on how the reporting of diagnosis codes in categories Z55-Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances) may improve its ability to recognize severity of illness, complexity of illness, and utilization of resources under the MS-DRGs. 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 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.

CMS seeks comments on the following questions:

- How the reporting of certain Z-codes – and if so, which Z codes[11] - 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 is interested in hearing the perspective of large urban hospitals, rural hospitals, and other hospital types in regard to their experience. CMS is 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.

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.

CMS is also interested in comments on ways the MS-DRG classification can 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 is interested in learning about the potential benefits and challenges associated with the collection of SDOH data in the inpatient setting. CMS will consider comments in future policy development.

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

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

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

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

c. Proposed 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 proposed additions and deletions to the CC Exclusion list:

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

13. Proposed 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 6E	Revised Diagnosis Title
Table 6G.1	Proposed Secondary Disorders Order Additions to the CC Exclusion List
Table 6G.2	Proposed Principal Disorders Order Additions to the CC Exclusion List
Table 6H.1	Proposed Secondary Disorders Order Deletions to the CC Exclusion List
Table 6H.2	Proposed Secondary Disorders Order Deletions to the CC Exclusion List
Table 6I.1	Proposed Additions to the MCC List
Table 6I.2	Proposed Deletions to the MCC List
Table 6J.1	Proposed Additions to the CC List
Table 6J.2	Proposed Deletions to the CC List

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

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

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedures, and demographic information are entered into the Medicare claims processing systems and subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS-DRG. The link to the MCE 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 proposed 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.

15. Proposed Changes to Surgical Hierarchies

The surgical hierarchy is an ordering of surgical classes from most resource-intensive to least resource-intensive. It ensures that cases involving multiple surgical procedures are assigned to the MS-DRG associated with the most resource-intensive surgical class. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS-DRG by frequency to determine the weighted average resources for each surgical class.

Based on the changes CMS is proposing for FY 2023, it is proposing to maintain the existing surgical hierarchy for FY 2023.

16. 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 proposed rule).
CMS notes that for FY 2023, there are 72,750 diagnosis codes and 78,229 procedure codes. At this time, there are 1,176 new diagnosis codes and 45 new procedure codes finalized for FY 2023.

17. Replaced Devices Offered without Cost or with a Credit

In the FY 2008 final rule with comment period[12], 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,[13] 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 is not proposing to add any MS-DRGs to the policy for replaced devices offered without cost or with a credit. The table below, reproduced from the proposed rule, lists the existing MS-DRGs subject to this policy

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

[12] 72 FR 47246 through 47251
[13] 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 DRG**	**MS-DRG Title**
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC
MDC 5	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC
MDC 5	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC
MDC 5	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC
MDC 5	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC
MDC 5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC
MDC 5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC
MDC 5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC
MDC 5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC
MDC 5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
MDC 5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
MDC 5	242	Permanent Cardiac Pacemaker Implant with MCC
MDC 5	243	Permanent Cardiac Pacemaker Implant with CC
MDC 5	244	Permanent Cardiac Pacemaker Implant without CC/MCC
MDC 5	245	AICD Generator Procedures
MDC 5	258	Cardiac Pacemaker Device Replacement with MCC
MDC 5	259	Cardiac Pacemaker Device Replacement without MCC
MDC 5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
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

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

CMS is soliciting comments to explore possible mechanisms through which it can address rare diseases and conditions that are represented by low volumes in the claims data. 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 describes 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 summarizes prior rulemaking requests and decisions for Panhematin[14] used in treating acute porphyria attacks ANDEXXA[15] 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[16] used for postpartum depression in adults.

CMS is soliciting 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. It is also interested in comments on ways it may potentially improve access to treatment for postpartum depression. CMS is interested in hearing the perspective of large urban hospitals, rural hospitals, and other hospital types. CMS is also interested in how factors such as hospital size and type might impact a hospital's ability to develop protocols to better address these conditions. CMS will take comments 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 ratesetting year (e.g., FY 2021 for FY 2023). It also uses Medicare cost report data from the 3rd year preceding the ratesetting year (e.g., FY 2020 for FY 2023).

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 proposes 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

[14] 77 FR 53311, 79 FR 49901, and 83 FR 41200
[15] 86 FR 44869
[16] 85 FR 32672 through 32676 and 85 FR 58709 through 58715

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 proposes to use:

- FY 2021 MedPAR data: Bills received through December 31, 2021 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 7,417,999 million Medicare discharges regrouped using the FY 2023 proposed MS-DRG classifications.
- FY 2020 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2020 cost reporting periods, using the December 31, 2021 update of the FY 2019 HCRIS.

For FY 2023, CMS is not proposing any changes to its methodology and will calculate MS-DRG weights using national averages for the 19 CCRs. Accompanying the proposed rule, CMS posted the version of HCRIS cost report data file which it used to calculate the 19 CCRs for FY 2023, available at FY 2023 IPPS Proposed Rule Home Page | CMS. (Select file #4 under FY 2023 Proposed Rule Data files, "FY 2023 Proposed Rule: HCRIS Data File (ZIP)".)

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

Group	FY 2022 CCR	Proposed FY 2023 CCR
Routine Days	0.422	0.421
Intensive Days	0.345	0.342
Drugs	0.187	0.187
Supplies & Equipment	0.297	0.307
Implantable Devices	0.293	0.286
Inhalation Therapy	0.147	0.150
Therapy Services	0.288	0.286
Anesthesia	0.071	0.076
Labor & Delivery	0.359	0.347
Operating Room	0.167	0.168
Cardiology	0.094	0.095
Cardiac Catheterization	0.100	0.104
Laboratory	0.106	0.108
Radiology	0.136	0.138
MRIs	0.070	0.072
CT Scans	0.034	0.035
Emergency Room	0.147	0.155
Blood and Blood Products	0.270	0.265
Other Services	0.344	0.362

Relative Weight Calculation for CAR-T cell Therapy (MS-DRG 018). In some cases, the 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 in drug costs—from the relative weight calculation.

CMS proposes 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 ($61,356) were 20 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($299,460). Accordingly, CMS is proposing to adjust the transfer-adjusted case count for MS-DRG 018 by applying an adjustor of 0.20 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 proposes to apply this same adjustor for the applicable cases that group to MS-DRG 018 for purposes of budget neutrality and outlier simulations.

Proposed 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 is proposing 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 relative weight for MS-DRG 871 (Septicemia or Severe Sepsis Without MV >96 Hours with MCC) will be 1.9549 compared to 1.9544 without any special intervention. CMS is making available supplemental information, including the relative weights, average length of stay, and geometric mean length of stay, calculated both with and without COVID-19 cases.

Proposed Cap for 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 cites its statutory authority under sections 1886(d)(4)(B) and (C) and 1886(d)(5)(I)(i)[17] 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 proposes 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 will affect 27 MS-DRGs, based on the FY 2021 claims data used for this 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 proposes that the limit would not apply.

Other Issues. The proposed rule relative weights were normalized by an adjustment factor of 1.947540 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself does not increase or decrease total payments under the IPPS.

For very low volume MS-DRGs (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 Payment 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[18]; 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.[19] Also, beginning with FY 2022, a drug approved under FDA's Limited

[17] 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.

[18] 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).

[19] 84 FR 42292 through 42297; regulations at § 412.87(c) and (d)

Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway), may also qualify for a new technology add-on payment under an alternative pathway.[20]

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[21]:

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

If a technology meets all three of the criteria, CMS considers it substantially similar to an existing technology and for purposes of the new technology add-on payments, CMS would not consider the medical service or technology "new". CMS first determines whether a medical service or technology is new; if CMS determines the medical service or technology is considered new, then it 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 are included in the data files associated with the FY 2023 proposed rule on the CMS website.[22]

Because of the PHE, for FY 2022 ratesetting, 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 ratesetting, CMS proposes to use the FY 2021 MedPAR claims data for FY 2023 with certain proposed modifications to its relative weight setting and outlier methodologies. For the FY 2024 threshold values, CMS proposes to use the FY 2021 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2024. In addition, to account for the anticipated decline in COVID-19 hospitalizations of Medicare beneficiaries as compared to FY 2021, CMS is proposing to use an averaging approach for calculating the FY 2023 relative weights. (This proposal is discussed above in this summary and in section II.E.1 in

[20] 85 FR 58736
[21] 74 FR 43813 and 43814
[22] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

the preamble of this proposed rule.) 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 is also proposing to average the data in the steps of the calculation that uses charge data from the calculation of the MS-DRG weights.

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[23], 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
    - 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.

[23] 84 FR 42288 through 42292

- 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[24], 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.

[24] 84 FR 42297 through 42300

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.[25]

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 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.[26] 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.

[25] 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.

[26] 85 FR 58739 through 58742

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.[27] 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 will consider the presentations made at the town hall meeting and written comments received by December 27, 2021. Where applicable, CMS summarizes comments at the end of each discussion of the individual applications in this proposed rule. Comments that are unrelated to the "substantial clinical improvement" criterion are not summarized in this proposed rule. Commenters can resubmit their comments in response to proposals in this proposed rule.

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 proposing 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 beginning with a transitional period in FY 2023.

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.[28] 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

[27] Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108-73.
[28] 85 FR 71155

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. Proposed 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.[29]
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. CONTEPO has not yet obtained FDA approval and CMS discusses the FY 2022 options for CONTEPO:

- If CONTEPO receives FDA marketing authorization before July 1, 2022, the new technology add-on payment for cases using this technology would be effective for discharges beginning in the first quarter after FDA marketing authorization is granted.
- If FDA marketing authorization is received on or after July 1, 2022, no new technology add-on payments would be made for cases involving the use of CONTEPO for FY 2022.

For FY 2023, CMS proposes the following options:

- If CONTEPO receives FDA marketing authorization prior to July 1, 2022, CMS proposes to continue new technology payments for FY 2023.
- If CONTEPO does not receive FDA marketing authorization by July 1, 2022, in addition to not being eligible for new technology add-on payments for FY 2022, it would not be eligible for add-on payments for FY 2023. CMS notes that 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.

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

CMS proposes to continue the new technology add-on payments for FY 2023 for technologies approved in FY 2022 and which it would still consider "new" for FY 2023. CMS proposes to

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

discontinue the new technology add-on payments for FY 2023 for technologies approved in FY 2022 and which it would no longer consider "new" for FY 2023.

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 II.F.-01 in the proposed rule (see table extract below) lists the eleven technologies CMS proposes to discontinue 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.

Proposed 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
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

Table II.F.-02 in the proposed rule (see table extract below) lists the fifteen technologies CMS proposes to continue 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.

Proposed 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**
1	Rybrevant™	05/21/2021	10/1/2021	5/21/2024
2	Cosela™	02/12/2021	10/1/2021	2/12/2024
3	ABECMA®	03/26/2021	10/1/2021	3/26/2024
4	StrataGraft®	06/15/2021	10/1/2021	6/15/2024
5	TECARTUS®	07/4/2020	10/1/2021	7/4/2023
6	VEKLURY®	07/1/2020*	10/1/2021	7/1/2023*
7	Zepzelca™	06/15/2020	10/1/2021	6/15/2023
8	aprevo® Intervertebral Body Fusion Device	12/03/2020 (ALIF and LLIF) 6/30/2021(TLIF)	10/1/2021	12/03/2023 (ALIF and LLIF) 6/30/2024 (TLIF)
9	aScope® Duodeno	07/17/2020	10/1/2021	7/17/2023
10	Caption Guidance™	09/15/2020	10/1/2021	9/15/2023
11	Harmony™ Transcatheter Pulmonary Valve (TPV) System	03/26/2021	10/1/2021	3/26/2024
12	Intercept® (PRCFC)	05/05/2021	10/1/2021	5/05/2024
13	ShockWave C2 Intravascular Lithotripsy (IVL) System	02/12/2021	10/1/2021	2/12/2024
14	Fetroja® (HABP/VABP)	09/25/2020	10/1/2021	9/25/2023
15	Recarbrio™ (HABP/VABP)	06/04/2020	10/1/2021	6/04/2023

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.[30] 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.[31] Based on this information, CMS believes that cost data may not have been available until after the donation period, when the

[30] 86 FR 45104 through 45107

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

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

CMS continues to consider comments previously received regarding the newness period for products available through an EUA for COVID-19 and welcomes additional comments in response to this proposed rule.

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 continues to welcome comments as to the appropriate method to determine a cost per case for technologies sold on a subscription basis**. CMS seeks comments on whether it should continue to estimate the cost per case based on subscriber hospital data and if whether the cost analysis should be updated based on the most recent subscriber data for each year the technology may be eligible for new technology add-on payment.

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 proposes to use this data for ratesetting 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 proposed rule (see table extract below) lists the 15 technologies CMS proposes to discontinue the new technology add-on payments for FY 2023.

Proposed 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
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

Proposed 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**
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 US10/04/2018	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. The summary below provides a high-level discussion of the remaining 13 new technology assessment; readers are advised to review the proposed rule for more detailed information. **CMS invites public comment on whether these technologies meet the newness, cost and substantial clinical improvement criteria.**

a. CARVYKTI™ (Ciltacabtagene autoleucel)

Janssen Biotech submitted an application for CARVYKTI (Ciltacabtagene autoleucel)[32], 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).[33] CARVYKTI is a unique, structurally differentiated BCMA-targeting chimeric antigen receptor with two distinct BCMA-binding domains that can identify and eliminate myeloma cells.

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

[33] 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).

MM is typically characterized by neoplastic proliferation of plasma cells producing a monoclonal immunoglobulin. Introduction of new treatment options have extended the median survival but most patients will relapse after first-line treatment and require further treatment. The applicant stated that relapsed and refractory MM (r/rMM) patients who have received at least 3 prior lines of therapy lack a standard treatment option. Approximately 50% of relapsed patients survive after 5 years.

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 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, CMS states it is unclear how the additional BCMA binding domain represents a change in the mechanism of action of this therapy. CMS believes that the mechanism of action for CARVYKTI may be the same or similar to ABECMA. CMS also notes 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 questions whether CARVYKTI treats a new patient population.

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 is interested in information on how these two technologies may differ with respect to the substantial similarity and newness criterion.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion and requests clarification of whether the cases identified differentiate between patients treated with one, two, three, and four prior lines of therapy. CMS reiterates its prior concerns related to the variability in provider billing and charging practices for CAR-T cell therapy and requests submission of the cost analyses with the national average drug CCR.

Substantial Clinical Improvement. The applicant stated that CARVYKTI offers a treatment option for a patient population with limited options and provides a significantly improved outcome relative to other therapies for r/rMM. CMS summarizes the information provided by the applicant, including results from the CARTITUDE-1 Study (a Phase 1b/2 open-label, multicenter, multi-national study (including the U.S.)) to evaluate the safety and efficacy of CARVYKTI and the LEGEND-2 study (an ongoing Phase1, single-arm, open-label, multicenter trial in patients with RRMM (using LCAR-B38M in China)). The applicant also discussed multiple unpublished studies using matching-adjusted indirect treatment comparison (MAIC) and other matching techniques to compare CARVYKTI to other existing therapies. CMS summarizes the information submitted and notes that many of the studies are in abstract or presentation format with limited information on the overall design and methodology used. CMS discusses concerns with the LEGEND-2 study, including whether the results are generalizable to the Medicare population when only 19% of respondents were 65 and older. CMS also asks for clarification on potential inconsistencies between statements in the application and the citation which explains the LEGEND-2 study. Given that CARVYKTI was recently FDA approved with an indication for patients with at least four prior lines of therapy, CMS welcomes additional clarification on any differences between CARVYKTI and existing therapies with respect to the patient populations indicated for treatment.

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.[34] 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,[35] 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.

Cost. CMS summarizes the analysis provided to demonstrate the technology 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. CMS summarizes 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.

CMS discusses 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 notes that during the New Technology Town Hall meeting, the applicant clarified that all

[34] 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.
[35] NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain amyloidosis (Version 1.2022). National Comprehensive Cancer Network.www.nccn.org. Published June 2021.

subjects in the ANDROMEDA trial received DARZALEX FASPRO in the outpatient setting. CMS questions whether the results for this outpatient population are generalizable to patients who require hospitalization. CMS also is concerned that the secondary endpoints used for the quality-of-life assessments and hematologic responses are not appropriate to measure outcomes. The applicant provided a supplemental written response pertaining to data from the ANDROMEDA trial. CMS will review this information when deciding to approve the new technology add-on payment.

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.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS questions 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.

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. CMS summarizes 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 discusses several concerns regarding whether the Hemolung RAS meets the substantial clinical improvement criterion. CMS is concerned that the evidence includes small, non-randomized studies without the use of comparators or controls and case studies without comparative data. CMS notes 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 notes that the background studies supporting substantial clinical improvement did not utilize the Hemolung RAS.

The applicant submitted two public comments in support of the use of Hemolung RAS. CMS will consider these comments when deciding whether to approve the new technology add-on payment.

d. Lifileucel

Iovance Biotherapeutics submitted an application for lifileucel, a one-time, autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for treatment of patients with unresectable or metastatic melanoma.[36] TIL therapy with lifileucel involves the adoptive cell transfer of autologous T-cells directly isolated from the tumor tissue and expanded *ex vivo* without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state and low numbers prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them, the lifileucel manufacturing process produces large numbers of reinvigorated T-cells. Following the infusion of lifileucel, the TIL migrates back into the tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens.

Newness. The applicant submitted a BLA to FDA for lifileucel as an autologous TIL immunotherapy indicated for the treatment of patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy, including a PD-1 blocking antibody and, if BRAF V600 mutation positive, a BRAF inhibitor or BRAF inhibitor with MEK inhibitor. The applicant stated that lifileucel has been granted Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug and Fast Track designations. Two unique ICD-10-PCS codes identify the administration of lifileucel (XW033L7 and XW043L7).

For the first criterion (same or similar mechanism of action), the applicant stated that lifileucel uses a novel and distinct mechanism of action which delivers a highly customized, personalized, and targeted treatment for unresectable or metastatic melanoma. The applicant discussed the difference between this therapy and current treatments, including CAR T-cell therapies. The applicant stated that CAR T-cell therapies mainly targets only single/surface tumor antigens and TIL cell therapy targets multiple tumor antigens. For the second criterion (same or different MS-DRG), the applicant stated that cases would be assigned to Pre-MDC MS-DRG 018 (CAR T-cell and Other Immunotherapies). For the third criterion (same or similar disease or patient population), the applicant stated that upon FDA approval, lifileucel will be the first and only cell therapy indicated for these patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy.

CMS notes that in regard to the MS-DRG assignment, lifileucel maps to a different MS-DRG that existing treatments for metastatic melanoma. CMS also notes that there are currently other therapies for the treatment of metastatic melanoma and it questions whether the distinction of being the first cellular treatment is relevant to the third criterion (same or similar disease or patient population).

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS reiterates its concerns related to the variability in provider billing and charging practices for CAR-T cell therapy and it is not sure how representative this data is for calculating a CCR for CAR T-cell therapies and TIL.

[36] Iovance Biotherapeutics previously submitted an application for new technology add-on payments for Lifileucil for FY 2022 (86 FR 25272 through 25282) and withdrew that application prior to the FY 2022 IPPS PPS final rule.

Substantial Clinical Improvement. The applicant stated that when approved by FDA, lifileucel will provide a treatment option for patients with advance melanoma who relapse on or do not tolerate treatment with immune checkpoint inhibitors and BRAF-targeted therapies and who respond poorly to a subsequent round of therapy with these agents or chemotherapy. CMS discusses the information presented by the applicant which included data from an ongoing phase 2, multicenter study (NCT02360579); results from the C-144-01 study (a phase II open label, single arm multicenter study); one article; and two presentations with abstracts. CMS also references the evidence previously submitted and summarized in the FY 2022 IPPS PPS proposed rule. CMS also summarizes the information the applicant provided to address CMS' prior concerns about the use of overall response rate (ORR) as the primary outcome and the use of historical controls.

CMS is concerned that the majority of the evidence supporting the substantial clinical improvement criterion are based on the C-144-01 trial which has a small sample size and questions whether there are methods to compare lifileucel to existing treatments used to construct the historical controls. Specifically, CMS is concerned that the differences in the studies, the samples, and the time period in which the studies were done may account for differences in the ORR as opposed to the use of lifleucel. CMS states it is difficult to determine if the results are due to treatment, random occurrences, or bias. CMS is also concerned that it is not clear how the impact of high-dose IL-2, which has been used to treat metastatic melanoma and is given as a post-treatment to lifileucel, impact the treatment effects and adverse effects reported for lifileucel.

In response to CMS' question at the New Technology Town Hall meeting, the applicant described IL-2 and its approved therapeutic use. CMS will consider these comments when deciding whether to approve the new technology add-on payment.

e. 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.

Cost. CMS summarizes the analysis provided to demonstrate the technology 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. CMS summarizes 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 discusses its concerns regarding whether LIVTENCITY meets the substantial clinical improvement criterion. It is concerned that the SOLTICE study resulted in similar rates of mortality and new-onset CMV between the 2 treatment groups. CMS requests 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.

f. Mosunetuzumab

Genetech submitted a new technology add-on payment application for mosunetuzumab, an investigational drug that is anticipated to be a novel first-in class therapy for the treatment of any non-Hodgkin lymphoma (NHL). Mosunetuzumab is a humanized bispecific monoclonal antibody that binds to patients' T cells (CD 3) and CD 20-expressing tumor cells; linking these cells causes a cytotoxic T-cell response against CD20-expressing tumor B cells. The applicant is seeking FDA approval for the use of mosunentuzumab in adults with relapsed or refractory (r/r) follicular lymphoma (FL) who have received at least two prior systemic therapies.

FL is the second most prevalent form of NHL. The vast majority of patients will have an initial response to therapy with 40 to 80 percent demonstrating a complete response; patients are expected to have relapses. The applicant states there is a high unmet need for patient with r/r FL who have receive 2 or more prior therapies, especially for patients' refractory to different classes of agents or are at risk for serious side effects.

Newness. Mosunetuzumab was granted Breakthrough Therapy designation by the FDA and the applicant anticipates FDA approval by June 30, 2022. The applicant stated there may be limited product immediately available following FDA approval. The applicant stated there are currently no ICD-10-PCS codes to identify the administration of mosunetuzumab and the applicant has submitted a request for a unique ICD-10-PCS procedure code. The proposed rule lists a table of 70 diagnosis codes that could be used to identify the indications associated with the technology.

For the first criterion (same or similar mechanism of action), the applicant stated that mosunetuzumab's mechanism of action is different from other therapies approved for the treatment of third line (3L+) r/r FL. The applicant stated that mosunetuzumab binds to CD3 on T cells and CD20 on malignant B cells; the crosslinking leads to T cell activation which results in the elimination of malignant B cells. According to the applicant, an ammino acid substitution in the Fc region of mosunetuzumab reduces binding to FC-gamma receptors and reduces FC effector function. The applicant summarizes the mechanism of action of eight currently available treatments. For the second criterion (same or different MS-DRG), the applicant stated that with the exception of CAR T-cell therapies, mosunetuzumab may be assigned to the same MS-DRG as existing treatments. For the third criterion (same or similar disease or patient population), the applicant stated that mosunetuzumab will treat 3L+ r/r FL patients, a population that has no FDA approved treatment indication.

CMS notes that there are FDA approved therapies for treatment of patients with rr/FL after two or more lines of systemic therapy and that CAR-T cell therapies, such as Yescarta, are FDA approved therapies. CMS believes that mosuneruzumab would be used for the same disease and same population when compared to other therapies approved to treat 3L+ r/r FL.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes that the applicant did not specify the list of ICD-10-PCS codes used for the exclusion of cases receiving chemotherapy administration and the diagnosis codes used to exclude grade IIIb FL cases.

Substantial Clinical Improvement. The applicant stated that mosunetuzumab represents a substantial clinical improvement over existing technologies because it offers a treatment option for patients with r/r FL who are relapsed or refractory to other agents and have limited treatment options. In addition, the applicant stated that mosunetuzumab significantly improves clinical outcomes relative to previously available therapies, demonstrating high overall and complete response rates, high durable responses, and safety. The support for these statements is predominately from an open-label, uncontrolled pivotal Phase II trial of 90 patients with r/r FL who had received more than 2 prior therapies. CMS summarizes the information provided and is concerned that the information from this single study is used to support all of the claims for substantial clinical improvement. CMS is concerned that comparison to other technologies is based on historical rates found in other clinical trials and no direct comparison of therapies is provided. In addition, CMS questions whether the results for the outpatient administration of this medication represents a substantial clinical improvement in the inpatient setting.

g. Narsoplimab

Omeros Corporation submitted an application for Narsoplimab, a fully human monoclonal antibody for the treatment of HSCT-TMA also known as transplant-associated thrombotic microangiopathy (TA-TMA).[37] According to the applicant, narsoplimab inhibits mannan-binding lectin serine protease 2 (MASP-2), the effector enzyme of the lectin pathway of the complement system and inhibits activation of the lectin pathway. Narsoplimab prevents complement-

[37] Omeros Corporation previously submitted an application for new technology add-on payments for Narsoplimab for FY 2022 (86 FR 25282 through 25286) and withdrew that application prior to the FY 2022 IPPS PPS final rule.

mediated inflammation and exhibits anticoagulant effects, while leaving intact the respective functions of the classical and alternative pathways of innate immunity.

The applicant stated that HSCT-TMA is a lethal complication of hematopoietic stem cell transplantation (HSCT) that results in thrombosis in the small blood vessels, leading to organ failure. The applicant stated that there are currently no FDA approved products indicated for the treatment of HSCT-TMA.

Newness. The applicant stated that it is in the process of resubmitting a BLA to the FDA for narsoplimab for the treatment of HSCT-TMA. Narsoplimab has received Orphan Drug designation Breakthrough Therapy Designation, and Priority Review for the treatment of patients with HSCT-TMA who have persistent thrombotic microangiopathy despite modification of immunosuppressive therapy. Two ICD-10-PCS codes describe procedures involving the use of narsoplimab (XW03357 and XW04357) and ICD-10-CM code M31.11 (HSCT-TMA) is used to identify the indication for narsoplimab.

For the first criterion (same or similar mechanism of action), the applicant stated that narsoplimab is the first therapeutic to target MASP-2 and the first treatment to inhibit the lectin pathway of the complement system. The applicant stated that narsoplimab is the only drug that addresses all the components of HSCT-TMA and is the only product that inhibits complement activation and has anticoagulant activity. The applicant asserted that the mechanism of action of narsoplimab differs from that of products occasionally used off-label for treatment of HSCT-TMA. For the second criterion (same or different MS-DRG), the applicant stated that patients will be assigned to the same MS-DRGs as patients who are diagnosed with HSCT-TMA/transplant-associated thrombotic microangiopathy (TA-TMA) regardless of treatment. For the third criterion (same or similar disease or patient population), the applicant states that upon FDA approval, narsoplimab will be the first technology specifically indicated to treat HSCT-TMA patients. The applicant also discussed the FDA indications for the existing products that are used off-labeled for treatment of HSCT-TMA and the differences between HSCT-TMA and other diseases, including hemolytic uremic syndrome (HUS) and thrombocytopenic purpura (TTP).

CMS requests comments on whether narsoplimab has a unique mechanism of action and whether HSCT-TMA is a similar disease to other forms of TMA.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion.

Substantial Clinical Improvement. The applicant discussed the reasons why narsoplimab represents a substantial clinical improvement over existing technologies. The applicant stated that if approved by FDA, Narsoplimab will be the only drug or biological approved for the treatment of HSCT-TMA. The applicant's information supporting these statements includes results of the pivotal trial (a single arm trial of 28 adult HSCT-TMA patients); a systematic literature review evaluating clinical outcomes in adult patients with HSCT-TMA following allogeneic transplant; and three abstracts from a single-arm open-label pivotal trial involving 28 patients (NCT02222545). CMS reiterates its concerns discussed in the FY 2022 IPPS PPS

proposed rule that the information is too limited to determine substantial clinical improvement and whether these results are generalizable to the greater Medicare population. CMS also discusses concerns about the study design of the pivotal trial including the fact that the trial was not designed for comparisons with other treatments. CMS appreciates the information provided by the systematic review, but it is concerned about how the review was designed and performed and whether this review sufficiently establishes differences in outcomes due to treatment as opposed to study design.

h. Spesolimab

Boehringer Ingelheim Pharmaceutical submitted an application for spesolimab, a humanized antagonistic monoclonal immunoglobulin antibody blocking human IL-36R signaling under investigation for the treatment of flares in adult patients with generalized pustular psoriasis (GPP). The applicant stated that binding of spesolimab to IL-36R prevents the activation of IL36R and downstream activation of pro-inflammatory and pro-fibrotic pathways. The applicant also states that genetic human studies have established a strong link between IL36R signaling and skin inflammation.

GPP is a rare, heterogeneous and potentially life-threatening skin disease with an estimated prevalence of 1/10,000 in the U.S. Flares are characterized by widespread pustules with or without systemic inflammation. The applicant stated that GPP can be distinguished from plaque psoriasis based on clinical, pathologic and genetic features.

Newness. The applicant expects to receive FDA approval prior to July 1,2022. The applicant stated there are currently no ICD-10-PCS procedure codes to identify spesolimab and the applicant submitted a request for approval of a unique ICD-10 PCS code to identify cases involving the administration of spesolimab.

For the first criterion (same or similar mechanism of action), the applicant stated that spesolimab's inhibition of IL-36R signaling is different from other immune mediated inhibitors. The applicant also discussed first line and second line therapies for psoriasis and stated there is limited evidence on the efficacy and safety of these therapies in the treatment in GPP. The applicant stated spesolimab will be the first FDA approved treatment for GPP. For the second criterion (same or different MS-DRG), the applicant stated there is no MS-DRG specific for spesolimab but indicated that spesolimab maps to four MS-DRGs. For the third criterion (same or similar disease or patient population), the applicant stated that GPP is a distinct disease entity from plaque psoriasis which is managed by existing therapies.

CMS requests additional information about the possibility that any treatments indicated for psoriasis could also be considered on-label for subtypes of psoriasis, such as GPP. CMS also believes that the list of four MS-DRGs identified by the applicant are the same MS-DRGs that would be used for all treatments for GPP.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is interested in the applicant providing details about why it decided not to remove charges for prior technology from the cost analysis.

Substantial Clinical Improvement. The applicant stated that spesolimab represents a substantial clinical improvement because it offers a treatment option for a patient population unresponsive to, or ineligible for, current treatments and significantly improves clinical outcomes relative to current treatments. CMS discusses the information presented which includes a structured survey of 29 dermatologists about GPP treatment options; a published letter to the editor describing a phase I, proof-of-concept trial in 7 patients; a published study protocol describing Effisayil-1 (a phase 2, randomized, placebo-controlled trial); and summarized unpublished data from Effisayil-1.

CMS is concerned that the results of the Effisayil-1 trial are not included in the application and that it needs to rely entirely on the applicant's summary of the unpublished trial. CMS also notes that the dermatology survey results seem to indicate that there is perceived efficacy in current treatments since dermatologists indicated that treatment options for all flares were adequate "most" (79%) or "all" (14%) of the time. Given this finding, CMS wonders whether if a placebo is the most appropriate comparator for spesolimab as dermatologist indicate there are currently available treatments for GPP.

The applicant provided supplemental written response to questions raised by CMS during the Town Hall Meeting. CMS will consider these comments when deciding whether to approve the new technology add-on payment.

i. Teclistamab

Jansen Pharmaceutical submitted an application for teclistamab, a bispecific antibody (bsAB) that binds to CD3 on T cells and B cell maturation antigen (BCMA) on myeloma cells. This dual binding brings T cells into proximity with target myeloma cells and triggers T cell activation which leads to a series of events resulting in an anti-tumor response.

Multiple myeloma (MM) is an incurable blood cancer that affects plasma cells. Normal plasma cells are found in the bone marrow and make antibodies. The median age of onset is 66 years old and approximately 25% of patients have a median survival of two years or less.

Newness. Teclistamab was granted Breakthrough Therapy designation on May 26, 2021. The applicant is seeking accelerated approval for a BLA for the proposed indication for adult patient with relapsed or refractory (r/r) MM, who have received at least 3 prior therapies including a proteasome inhibitor (PI), an immunomodulatory agent (INiD), and an anti-CD38 monoclonal Ab. The applicant expects FDA approval by June 2022. Cases reporting the use of teclistamab would be coded with ICD-10-PCS code for introduction of other therapeutic substance into subcutaneous tissue (3E01305); 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 teclistamab uses a different mechanism of action when compared to existing treatments and compares the mechanism of action for teclistamab to these treatments. The applicant also stated that teclistamab is not substantially similar to other existing bsAB because it is the only bsAB

targeting CD3 cells and BCMA. For the second criterion (same or different MS-DRG), the applicant stated that teclistamab will use the same DRG assignments as other treatments for MM. For the third criterion (same or similar disease or patient population), the applicant stated that the proposed FDA indication is similar to other treatments approved for MM patients: belantamab and idecabtagene vicleucel.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that teclistamab offers a treatment option for patients' refractory to the three major classes of drugs currently approved for MM (IMiDs, PIs, and monoclonal Abs). In addition, the applicant stated that when compared to current treatment, teclistamab significantly improves clinical outcomes such as treatment response rates and minimal residual disease (MRD) rates. CMS discusses the information presented by the applicant which includes published papers and abstracts from the MajesTEC-1 trial (ongoing, open-label, single-arm phase 1 study in 157 patients); initial data from the phase 2 trial; and published papers that provided preclinical data regarding the development of JNJ-7957 (teclistamab).

CMS is concerned that all the evidence for substantial clinical improvement is based on one small-sized open label phase 1 study (MajesTEC-1) without control or comparator and there is limited long-term follow-up information. CMS notes that the applicant compared results to historically published data of other therapies which may be subject to sample-selection bias. CMS requests addition information of the subpopulation of patients receiving the recommended phase 2 dose. CMS is also concerned that approximately 50 percent of the patients discontinued treatment in the data presented for the phase 2 cohort. CMS also raises concerns about the age of the patients in the MajesTEC-1 trial (median age 63 years) and the safety data for patients over 75 years of age. CMS acknowledges the applicant's statement that teclistamab offers a treatment option for patients with limited access to or are ineligible for CAR T-cell therapy, but it notes that other available treatments are available to treat r/r MM.

j. TERLIVAZ® (terlipressin)

Mallinckrodt Pharmaceuticals submitted an application for TERLIVAZ, a synthetic, systemic vasoconstrictor with selective activity at vasopressin-1 receptors used in the treatment of adults with hepatorenal syndrome type 1 (HRS-1).[38] TERLIVAZ is a pro-drug for the endogenous/natural porcine hormone lysine-vasopressin and a synthetic vasopressin analog derived from the natural/endogenous human hormone [Arg8]-vasopressin. According to the applicant, TERLIVAZ has greater selectivity for the vasopressin receptors (V1) versus vasopressin receptors (V2) and inhibits portal hypertension with simultaneous reduction of blood circulation in portal vessels.

[38] Mallinckrodt Pharmaceuticals previously submitted an application for new technology add-on payments for TERLIVAZ for FY 2022 (86 FR 25339 through 25344) and withdrew that application prior to the FY 2022 IPPS PPS final rule.

HRS-1 is a serious, life-threatening condition characterized by development of acute or sub-acute renal failure in patients with advanced chronic liver disease. The applicant stated that there are currently no FDA-approved medications available in the U.S. indicated specifically for the treatment of HRS-1; several agents are used off-label.

Newness. The applicant stated that an NDA was filed for TERLIVAZ in 2005 but a Complete Response Letter[39] (CRL) was issued by the FDA in November 2009. In April 2020, the applicant submitted the current NDA application as a Class 2 resubmission of the original NDA. The applicant anticipates FDA approval prior to July 1, 2022. There are two unique ICD-10-PCS codes for TERLIVAZ infusion (XW03367 and XW04367).

For the first criterion (same or similar mechanism of action), the applicant stated there are currently no FDA-approved treatment for HRS-1 that have a mechanism of action of selectivity for vasopressin V1 receptors. The applicant compared the characteristics of TERLIVAZ with other drugs used off-label for the treatment of HRS-1. For the second criterion (same or different MS-DRG), the applicant stated that TERLIVAZ would be assigned to the same MS-DRG as existing technologies used to treat HRS-1. The applicant stated that the MS-DRG system does not differentiate between patients with HRS and non-HRS conditions and both TERLIVAZ and existing technologies used to treat non-HRS conditions may be assigned to the same MS-DRGs. For the third criterion (same or similar disease or patient population), the applicant stated TERLIVAZ will treat the same type of disease as existing treatments, but the applicant stated TERLIVAZ will not treat the same or similar population when compared to existing technologies currently treating HRS-1. Although the FDA label will be indicated for all patients with HRS-1, the applicant claimed that TERLIVAZ will offer a treatment option for HRS-1 patients that failed to respond to standard-of-care treatment options.

CMS remains concerned that although TERLIVAZ might be the first treatment specifically indicated for the treatment of HRS-1 but, that might not mean it is providing an unmet need for HRS-1 treatment.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion.

Substantial Clinical Improvement. The applicant stated TERLIVAZ offers a treatment option for HRS-1 patients unresponsive to current treatments and significantly improves clinical outcomes among HRS-1 patients as compared to placebo and current treatments (e.g., midodrine and octreotide, and norepinephrine). CMS summarizes the information provided by the applicant, including published papers and abstract based on the results of the CONFIRM study (a randomized, double blinded study, placebo-controlled study); studies based on results from other countries; and a meta-analysis.

CMS has several concerns with the information presented in support of substantial clinical improvement. CMS discusses concerns about the CONFIRM study including the use of serum creatinine as a surrogate endpoint for an HRS reversal and wonders whether mortality would be

[39] A Complete Response Letter indicates that the review cycle for an application is complete and that the application is not ready for approval.

a more appropriate endpoint than HRS reversal. CMS questions whether serum creatinine correlated to improvements in clinical outcomes. CMS also discusses concerns regarding the information presented about the incidence of side effects from TERLIVAZ as compared to other available treatments.

k. Treosulfan

Medexus Pharma submitted an application for treosulfan, a prodrug[40] of a bifunctional alkylating agent used in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).

The applicant stated that preparative treatments for alloHSCT are often used to eradicate existing bone marrow tissue, prevent rejection by host immune cells, and help eradicate existing disease. The applicant discussed the two types of conditioning regimens currently used, myeloablative conditioning (MAC) and reduced intensity conditioning (RIC). MAC regimens generally lead to low relapse rates but are associated with high treatment-related toxicity and transplantation-related mortality (TRM). Patients who are not eligible for MAC regimens usually receive a RIC regimen. The applicant states the treosulfan will reduce treatment-related toxicity and the risk of TRM without increasing the incidence of relapse.

Newness. The applicant anticipates FDA approval by June 30, 2022. There are currently no ICD-10-PCS procedure codes to distinctly identify the administration of treosulfan; the applicant submitted a request for unique ICD-10-PCS codes. The applicant provided a list of ICD-10-CM diagnosis codes potentially applicable for the proposed FDA indications.

For the first criterion (same or similar mechanism of action), the applicant stated that treosulfan's mechanism of action is different from the existing busulfan- and melphalan-based MAC and RIC regimens. Treosulfan is a separate chemical entity that is pending FDA review as a fully separate and distinct NDA. The applicant also stated that treosulfan differs from other alkylating agents because it is a prodrug activated under specific pH conditions and has a distinct cytotoxic activity towards hematopoietic precursor cells. For the second criterion (same or different MS-DRGs), the applicant stated that treosulfan would be assigned to the same MS-DRG as other preparative treatments. For the third criterion (same or similar disease or patient population), the applicant stated that treosulfan will address a broader patient population than MAC and RIC regimens by providing access to patients who may otherwise be ineligible for MAC (e.g., the elderly and patients with comorbidities).

CMS is concerned that treosulfan is an alkylating agent and is similar to other alkylating agents, including busulfan and melphalan. CMS notes that treosulfan appears to be structurally similar to busulfan. In addition, CMS discusses that the studies provided by the applicant appear to demonstrate that a RIC regimen using treosulfan could be an option for patients who otherwise would have been treated with a busulfan regimen. Thus, CMS questions whether treosulfan is used in a broader patient population.

[40] A prodrug is an inactive medication that chemicals or enzymes activate after the medication enters the body.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes that the analysis does not exclude PPS-exempt hospitals which typically have higher charges than hospitals paid under IPPS. CMS also notes that the leukemia patients in treosulfan's clinical evidence were in remission and the analysis should only include these patients.

Substantial Clinical Improvement. The applicant stated that treosulfan represents a substantial clinical improvement because it was designed to improve alloHSCT conditioning outcomes for patients otherwise ineligible for MAC regimens and without the increase risk of relapse that occurs with RIC regimens. The applicant also stated that treosulfan significantly improves clinical outcomes relative to other preparatory regimens. CMS notes that although the applicant indicates that treosulfan offers a treatment option for patients' ineligible for MAC, the proposed FDA indications for treosulfan do not limit use to patients' ineligible for MAC. CMS summarizes the information provided by the applicant, including published studies and an abstract based on the results of the phase 3 open-label, non-inferiority randomized study in 5 European countries.

CMS has several concerns with the information provided by the applicant, including the lack of evidence indicating the lack of a significant difference in cumulative incidence of relapse between treosulfan and busulfan treatment groups. CMS discusses several concerns about the design of the phase 3 trial and states that because it is a non-inferiority trial it is not designed to demonstrate superiority over other regimens. CMS also notes that the studies were not powered to show improved outcomes for patients 65 and older and is concerned that the results may not be generalizable to the Medicare population. CMS is also concerned that treosulfan was only compared to busulfan, and requests addition information comparing treosulfan to other MAC regimens.

l. 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.

CMS is concerned that UPLIZNA treats 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.

Cost. CMS summarizes the analysis provided to demonstrate the technology 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.

CMS has several concerns with the information presented including the lack of information demonstrating improved outcomes for UPLINZA as compared to existing treatments. CMS reiterates 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 is not sure that treatment regimen requirements identify a separate patient population ineligible for currently available treatments and notes that ENSPRYNG has a similar treatment schedule as UPLINZA. CMS is 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.

m. XENOVIEW (hyperpolarized Xenon-129 [HP ^{129}Xe] gas for inhalation)

Polarean and The Institute for Quality Resource Management (collectively referred to as "applicant") submitted an application for XENOVIEW, a gas blend (89% Helium, 10% Nitrogen, and 1% Xenon) used in chest MRI. The applicant stated that the 1% Xenon (Xe) is hyperpolarized to create ^{129}Xe which allows for high resolution 3-dimensional images of the lungs and assessment of lungs' functional status when inhaled by a patient during a pulmonary MRI scan. The applicant stated that XENOVIEW can be used for longitudinal therapeutic evaluation and assessment of disease progression in a range of pulmonary disease including asthma, cystic fibrosis, chronic obstructive pulmonary disease and patients recommended for surgical lung resection.

Newness. The applicant submitted an NDA for XENOVIEW as a drug/device combine for the evaluation of pulmonary function and imaging of the lungs using MRI. The applicant received a CRL from the FDA on October 5, 2021 and it anticipates FDA approval by July 1, 2022. The applicant submitted a request for a unique ICD-10-PCS procedure code for XENOVIEW. For the first criterion (same or similar mechanism of action), the applicant discussed how HP ^{129}Xe identifies regional function in the lung and how it is different from traditional MRI imaging and other imaging technologies. For the second criterion (same or different MS-DRG), the applicant identified five MS-DRGs for patients with pulmonary disease and stated XENOVIEW would map to the same MS-DRGs as existing technologies. For the third criterion (same or similar disease or patient population), the applicant discussed how XENOVIEW would allow MRI imaging for a new population of patients whose underlying morbidities impact their ability to tolerate standard lung imaging. The applicant stated that XENOVIEW addresses an unmet medical need for a diagnostic agent that evaluates pulmonary function without requiring patients to be exposed to radiation or nephrotoxicity.

CMS believes that cases involving XENOVIEW would be assigned to the same MS-DRGs as cases involving the use of other MRIs and imaging modalities for pulmonary function and imaging of the lungs. CMS is concerned that XENOVIEW may use the same or similar mechanism of action as other inhaled gases (^{133}Xe) and oxygen-enhanced pulmonary imaging.

CMS notes that the proposed FDA indication for XENOVIEW is not unique to this technology and it does not mention the subset of patients with comorbidities identified by the applicant as a new patient population.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is concerned that the applicant did not remove any charges to account for prior technologies that XENOVIEW would be replacing.

Substantial Clinical Improvement. The applicant stated that XENOVIEW is a substantial clinical improvement because it provides a new service for patients with early symptoms of breathing difficulties, including those with an uncertain diagnosis that are unresponsive to current

treatments; ability to diagnose a medical condition in a patient population where the condition is undetectable; ability to diagnose a medical condition earlier; improved outcomes; and the ability to safely monitor unexplained dyspnea. CMS summarizes the information provided by the applicant including a narrative review, a study in children, background studies, and case studies. CMS has several concerns with the information presented in support of substantial clinical improvement. CMS notes that XENOVIEW is a diagnostic test and does not offer any treatment option for patients. CMS is concerned that some of the evidence utilizes a pediatric population which is largely distinct from the Medicare population and that many of the articles have contributors outside the U.S. and these countries might have differing standards of care. CMS is also interested in additional evidence that XENOVIEW changes patient disease management as well as improved clinical outcomes as compared to existing technologies.

CMS also summarizes the additional written comments the applicant provided in response to questions raised at the New Technology Town Hall meeting. This included responses to whether there are studies in the medical literation showing early detection of disease and better outcomes using XENOVIEW and any information comparing XENOVIEW to available technologies. CMS notes the applicant stated there are no published studies reporting early detection of disease using XENOVIEW that followed longitudinally reported outcomes. CMS is also concerned that many of the articles submitted were not about XENOVIEW and used HP ^{3}He MRI. CMS reiterates its concern that the many of the results would not be generalizable to the Medicare population.

7. Proposed 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.[41] 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; 1 has a pending Breakthrough Device designation

[41] 85 FR 58737 through 58742

from FDA; and 1 has been designated as a QIDP and is also requesting approval under the LPAD pathway from FDA. CMS provides background information on each application and proposes whether or not each technology would be eligible for new technology add-on payment for FY 2023 based on whether the technology meets the cost criterion. For the Breakthrough Devices Program, the new technology add-on payment is the less of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case. For QIDPs and LPADs, the new the new technology add-on payment is the less of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS-DRG payment for the case.

The summary below provides a high-level discussion of applications; readers are advised to review the proposed rule for more detailed information. **CMS invites public comment on whether these technologies meet the cost criterion.**

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.[42] 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.

Subject to CERAMENT G receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2022, CMS proposes to approve CERAMENT G for new technology add-on payments for FY 2023. Based on preliminary information provided by the applicant the cost of CERAMENT G is $7,567 per procedure. CMS proposes the maximum new technology add-on payment for a case involving the CERAMENT G would be $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 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).

[42] 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.

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.[43] 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.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes 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 questions if these results are generalizable to the cost analysis performed and to the greater Medicare population. CMS also notes the applicant did not specify the revenue codes used to identify and remove intensive care unit charges. In addition, CMS is concerned the applicant listed two ICD-10-PCS codes (03S43ZZ and 03SQ3ZZ) in their analysis which are percutaneous procedures and questions whether these codes are appropriate as the device currently require open surgery. CMS also questions whether the cases identified are appropriately representative of case eligible for treatment with CORE TAG TBE.

Subject to the applicant adequately addressing CMS' concerns, CMS would agree that the technology meets the cost criterion. If the GORE TAG TBE device receives FDA marketing approval consistent with its EPA by July 1, 2022, CMS proposes to approve the device for new technology add-on payments for FY 2023. Based on preliminary information provided by the applicant the cost of GORE TAG TBE device is $42,780. CMS proposes 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 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.

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

Subject to the iFuse Bedrock Granite Implant System receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by July 1, 2022, CMS proposes to approve this technology for new technology add-on payment for FY 2023. Based on preliminary information from the applicant, the cost of the iFuse Bedrock Granite Implant System is $15,120. CMS proposes the maximum new technology add-on payment for a case involving the use of this technology would be $9,828 for FY 2023.

(4) LigaPASS 2.0 PJK Prevention System

Medtronic submitted an application for the LigaPASS 2.0 PJK Prevention System which is intended to mitigate the risk of post-operative proximal junctional kyphosis (PJK) and proximal junctional failure (PJK) in patients with spinal deformities. The device consists of a polyester band and titanium alloy medical open connector with two set screws.

The LigaPASS 2.0 PJK Prevention System was granted Breakthrough Device designation on September 2, 2021 for spinal trauma surgery; spinal reconstructive surgery; spinal degenerative surgery; and intended for use at the non-fused level(s) adjacent to a posterior spinal instrumentation construct when ligament augmentation is considered appropriate to mitigate the risk of post-operative PJK and PJF. The applicant has submitted a 510(k) to FDA for the same indication as the Breakthrough Device designation. The LigaPASS 2.0 PJK Prevention System includes components from two predicate devices: the LigaPASS 2.0 connector and the LigaPASS 2.0 band. The applicant stated there are no technical differences between the LigaPASS 2.0 PJK Prevention System and its predicates; the only difference would be the added PJK/PJF indication covered by the Breakthrough Device designation. The applicant is only seeking new technology add-on payment for the proposed new PJK and PJF indication. The applicant has submitted a request for a unique ICD-10-CM diagnosis code and a unique ICD-10-PCS code that can be used together to identify cases using this technology for the Breakthrough Device designation.

CMS agrees with the applicant that the LigaPASS 2.0 PJK Prevention System meets the cost criterion.

Subject to the LigaPASS 2.0 PJK Prevention System receiving FDA marketing authorization by July 1, 2022, CMS proposes to approve this technology for the indication corresponding to the Breakthrough Device designation for new technology add-on payment for FY 2023. Based on preliminary information from the applicant, the cost of the LigaPASS 2.0 PJK Prevention System is $17,392. CMS proposes that the maximum new technology add-on payment for a case involving the use of this technology would be $11,305 for FY 2023.

(5) Magnus Neuromodulation System with Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) Technology

Magnus Medical submitted an application for Magnus Neuromodulation System (MNS) with SAINT Technology, a transcranial magnetic stimulation (TMS) device with intermittent theta burst (iTBS) capability and includes a target identification software that identifies individualized

targets in the brain for stimulation using structural and functional MRI outputs. The MNS with SAINT technology utilizes magnetic pulses delivered to the prefrontal cortex to treat major depressive disorder (MDD). On July 2, 2021, the FDA designated the Magnus Transcranial Magnetic Stimulation (TMS) System with Magnus Intelligent Neuromodulation Therapy (MINT) for the treatment of MDD in adult patients who failed to receive satisfactory improvement from prior antidepressant medication in the current episode. The applicant states the MNS with SAINT technology is the same system that received Breakthrough Device designation but with a revised name. The applicant anticipates 510(k) clearance for the Breakthrough Device indication by June 1, 2022. The applicant submitted an application for a unique ICD-10-PCS procedure code.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS is concerned that the costs of the MNS with SAINT technology only includes capital equipment: the neurostimulation hardware, the neuronavigation hardware, and the target identification software. Because section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services or technology under the payment system which establishes payment for operating costs of inpatient hospital systems, CMS does not include capital costs in the add-on payments for a new medical service or make new technology add-on payments under the IPPS for capital related costs (86 FR 45145). CMS believes that even if the technology meets the cost criterion, the MNS with SAINT technology is not eligible for new technology add-on payment, because new technology add-on payments are only made for operating costs.[44] **CMS invites comments on whether the MNS with SAINT technology has operating costs and if the operating costs meet the cost criterion**.
If the MNS with SAINT technology meets the cost criterion, CMS proposes to approve new technology add-on payments for only the operating costs of the technology, subject to receiving FDA marketing authorization for the Breakthrough Designation indication by July 1, 2022.

(6) Nelli® Seizure Monitoring System

Neuro Event Labs submitted an application for the Nelli Seizure Monitoring System designed to be used as an adjunct to seizure monitoring in adults and children. Nelli's software automates the analysis of audio and video data to identify seizure events with a positive motor component. Data is collected using the Nelli Seizure Monitoring System hardware, which temporarily stores and pre-processes raw media data to extract periods likely to contain clinically relevant activity. The data is transmitted to the Nelli Seizure Monitoring System software running on a remote server where it is processed using analysis algorithms (pretrain artificial intelligence (AI)) which enables the detection and classification of epileptic events. The technology received Breakthrough Device designation from FDA on October 9, 2020 for the automated analysis of the data to identify seizure events with a positive motor component in children and adults as well as to characterize seizures and peri-ictal events. The applicant anticipates 510(k) clearance from the FDA for the same indication. The applicant stated that the inpatient population would undergo standard video EEG monitoring (ICD -10-PCS code 4A10X4Z) and the applicant has submitted a request for a unique code to identify the technology.

CMS agrees that the Nelli Seizure Monitoring System meets the cost criterion.

[44] 72 FR 47307 through 47308

Subject to the Nelli Seizure Monitoring System receiving FDA marketing authorization by July 1, 2020, CMS proposes to approve technology for the Breakthrough Designation indication for new technology add-on payment for FY 2023. Based on preliminary information from the applicant, the anticipated non-capital costs of the technology to the hospital would be $1,000 per patient for the semiological report and seizure detection notification produced following assessment. The applicant based the cost per case of its technology on two pricing models currently used in Europe; one based on a daily charge and the other based on a single per patient charge. CMS proposes that the maximum new technology add-on payment for a case involving the use of the Nelli Seizure Monitoring System would be $650 for FY 2023.

(7) Phagenyx® System.

Phagenesis Ltd. Submitted an application for the Phagenyx System, a neurostimulation device for the treatment of neurogenic dysphagia.[45] The Phagenyx System received Breakthrough Device designation on December 4, 2019 for use in treating neurogenic dysphagia in adult tracheotomized patients weaned from ventilation. The Breakthrough Device designation was revised on January 29, 2021 to include the treatment of nonprogressive dysphagia in adult patients. The applicant anticipated FDA approval in the second quarter of calendar year 2022. Phagenyx administration can be identified by ICD-10-PCS procedure code (XWHD7Q7).

CMS agrees with the applicant that Phagenyx System meets the cost criterion.

Subject to the Phagenyx System receiving FDA marketing authorization by July 1, 20202, CMS proposes to approve the Phagenyx System for use in treating neurogenic dysphagia (the 2021 revised Breakthrough Designation) for new technology add-on payment for FY 2023. Based on preliminary information from the applicant, the cost of the Phagenyx System is $5,000. CMS proposes that the maximum new technology add-on payment for a case involving the use of the Phagenyx System would be $3,250 for FY 2023.

(8) Precision TAVI™ Coronary Obstruction Module

DASI Simulations submitted an application for the Precision TAVI Coronary Obstruction Module, an added feature of the Precision TAVI Software System, intended to provide decision support powered by AI and machine learning to help physicians accurately predict potential coronary artery obstructions in TAVR procedures. The Precision TAVI Coronary Obstruction Module has not yet received FDA Breakthrough Device designation, but it expects to receive this for the following indication: Precision TAVI Coronary Obstruction Model utilizes an additional proprietary software to analyze the results of the simulation model and output coronary obstruction risk biomarkers corresponding to each implantation simulation scenario. For scenarios involving TAVR in a failed surgical valve or a failed transcatheter valve, the computational test will also include anatomic characteristics to prevent iatrogenic coronary

[45] Phagenesis previously submitted an application for new technology add-on payments for the Phagenyx System for FY 2022 (86 FR 253682 through 25384), 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.

obstruction (BASILICA) procedure. The applicant anticipates receiving 510(k) clearance for the same indication by July 1, 2022. CMS notes that the proposed indication does not describe a disease or population to be treated and it wonders if this is the expected indication or some other description of the technology. The applicant submitted an ICD-10-PCS procedure code to identify the technology.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes the applicant stated the software can identify cases where TAVR should be and should not be performed. The cost analysis only used the ICD-10-PCS codes for TAVR to identify cases where the technology may be used and CMS questions whether the cases where the technology identified that TAVR should not be performed (potentially lower costs) are reflected in the cost analysis.

Subject to the applicant addressing this concern, CMS would agree that the technology meets the cost criterion. If the Precision TAVI Coronary Obstruction Module receives Breakthrough Device designation and FDA marketing authorization by July 1, 2022, CMS proposes to approve the technology for new technology add-on payments for FY 2023. Based on preliminary information from the applicant, the cost of the Precision TAVI Coronary Obstruction Module is $1,995. CMS proposes that the maximum new technology add-on payment for a case involving the use of the technology would be $1,296.75 for FY 2023.

(9) 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.[46] 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.

Subject to the Thoraflex Hybrid Device receiving FDA marketing authorization by July 1, 2022, CMS proposes to approve the Thoraflex for new technology add-on payments for FY 2023. Based on preliminary information from the applicant, the cost of the Thoraflex Hybrid Device is $35,000. CMS proposes that the maximum new technology add-on payment for a case involving the use of the technology would be $22,750 for FY 2023.

(10) TOPS™ System

Premia Spine submitted an application for the TOPS System, a motion preserving device that is

[46] 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.

inserted into the lumbar vertebral joint and anchored using pedicle screws after posterior spinal decompression surgery. The TOPS System replaces anatomical structures removed during spinal decompression treatment to alleviate pain. The TOPS System received Breakthrough Device designation form FDA on October 26, 2020 for patients between 35 and 80 years of age with neurogenic claudication resulting from degenerative spondylolisthesis with specified characteristics. The applicant expects to receive FDA PMA by the second quarter of 2022 for the same indication. The applicant submitted a request for an ICD-10-PCS to identify the TOPS System.

CMS agrees that the TOPS System meets the cost criterion.

Subject to the TOPS System receiving both FDA Breakthrough Device designation and marketing authorization by July 1, 2022, CMS proposes to approve the TOPS System for new technology add-on payments for FY 2023. Based on preliminary information from the applicant, the cost of the TOPS System is $15,000. CMS proposes that the maximum new technology add-on payment for a case involving the use of the technology would be $9,750 for FY 2023.

(11) VITARIA® System

LivaNova submitted an application for the VITARI System, an active implantable neuromodulation system that uses vagus nerve stimulation to deliver autonomic regulation therapy. The VITARI System includes a pulse generator and an electrical lead. After the device is implanted, a hand-held wand position on the skin and a computer tablet are used together to externally adjust the intensity of the electrical impulses delivered from the pulse generator through the electrical led to simulate the vagus nerve. The VITARIA System received designation under the EAP (part of the FDA Breakthrough Devices Program) on October 24, 2016 for patients with moderate to severe heart failure (NYHA ClassII/III), with left ventricular dysfunction who remain symptomatic despite drug therapy and are not candidates for cardiac resynchronization therapy (CRT). The FDA approved an amendment to the IDE trial on November 16, 2018 to include CRT or CRT-D recipients who have been receiving CRT according to guideline directed medical therapy (GDMT)and meet all the other indications for use. The applicant expects FDA premarket approval of the VITARI System by June 30, 2022 for the proposed indication for the symptomatic improvement of heart failure patients who have reduced left ventricular ejection fraction and chronic heart failure despite GDMT. The applicant is only seeking new technology add-on payments for the EAP indication. The applicant submitted a request for an ICD-10-PCS procedure code to identify the VITARIA System.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. Based on the MS-DRGs used in the analysis, CMS is concerned that the analysis may represent a population broader than those cases which are eligible for treatment by the VITARIA System. CMS questions whether this cost analysis is sufficiently representative of cases eligible to treatment with this technology.

Subject to the applicant addressing this concern, CMS would agree that the technology meets the cost criterion. If the VITARIA System receives FDA marketing authorization by July 1, 2022, CMS proposes to approve the technology for new technology add-on payments for FY 2023 for

patients who have moderate to severe heart failure (NYHA Class II/III), with left ventricular dysfunction (EF equal to or less than 40%), who remain symptomatic despite stable, optimal heart failure drug therapy and are not candidates for CRT. The applicant stated that the cost for the VITARIA System will not be available until the device receives FDA approval. CMS notes that the applicant has not indicated which components of the system would comprise the costs; CMS believes the computer tablet and hand-held wand that are used externally are capital costs. As previously noted, capital related costs are not included in the add-on payments. CMS expects the applicant to submit cost information prior to the final rule.

(12) 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 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.

CMS proposes to approve the ViviStim Paired VNS System for new technology add-on payments for FY 2023. 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 applicant has not included charges associated with the external paired stimulation controller and the patient programmer; these components are capital equipment. CMS proposes that the maximum new technology add-on payment for a case involving the use of the technology would be $23,400 for FY 2023.

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

(1) 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.

CMS notes that DefenCath is 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 has not provided an estimate for the cost of DefenCath and expects to provide this information before the final rule.

8. Proposed 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.[47] CMS reviews 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 discusses 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.

The majority of commenters supported using NDCs to identify therapeutic agents for the administration of the new technology add-on payment policy. Some commenters suggested using the 3E0 Administration Table, but another commenter stated the use of the 3E0 Administration Table would be unsustainable due to the potentially large number of new products. A few commenters suggested using different drug terminologies, such as RxNorm.

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.

[47] 80 FR 49434 through 49435

CMS proposes the following policies for the use of NDCs:

- Beginning with discharges on or after October 1, 2022 (FY 2023), CMS proposes 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 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 proposes 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.

    - For technologies newly approved for new technology add-on payments for FY 2023 and remain eligible for the new technology add-on payment for FY 2024 or a subsequent FU, CMS would continue to allow the use of either the existing ICD-10-PCS procedure codes or NDCs.
    - For technologies newly approved for new technology add-on payments prior to FY 2023 and remain eligible for the new technology add-on payment for FY 2024 or a subsequent FU, CMS would continue use the existing ICD-10-PCS procedure codes to identify the administration of those therapeutic agents.

This proposal would 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 need 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. Beginning with FY 2024 new technology add-on payment applications submitted for a therapeutic agent, CMS would review the application and inform the applicant, in advance of the deadline for submitting an ICD-10-PCS procedure code request for the March meeting of the ICD-10 Coordination and Maintenance Committee, whether or not it would be necessary to submit a request for purposes of identifying the administration of the therapeutic agent for a potential new technology add-on payment.

CMS invites comments on its proposal to utilize NDCs to identify claims involving the use of therapeutic agents approved for new technology add-on payments. Including any potential concerns regarding adoption of this code set for purposes of new technology add-on payments.

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

CMS discusses 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 notes 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**.[48]

Beginning with the FY 2024 application cycle, CMS proposes to post online the completed application forms and certain related materials (e.g., attachments and uploaded supportive materials) it receives from applicants. CMS also proposes 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 proposes it would not post cost and volume information or any material that the applicant indicates is not releasable to the public because the applicant does not own the copyright or the applicant does not have the appropriate license to make the material available to the public.

For copyrighted material, CMS proposes 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 proposes 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 plans 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

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

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 notes this proposal would not change the timeline or evaluation process for new technology add-on payments. CMS also does not expect added burdens on prospective applicants since it is not proposing to fundamentally change the information collected in the application.
CMS does expect to make changes in the summaries that appear in the annual proposed and final rule. CMS will 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 expects 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; background on the disease; FDA approval/clearance status; and a summary of the applicant's assertions. CMS also expects 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 seeks public comments on the proposal to post online the completed application forms and certain related materials and updated application submitted subsequent to the initial application submission, beginning with applications for FY 2024.

Regulatory Impact Analysis
For FY 2023, CMS proposes to continue the new technology add-on payment for 15 technologies. Based on the applicant's estimates at the time they submitted their original application, CMS estimates the aggregated total FY 2023 payments for these new technology add-on payments would be approximately $613 billion dollars.

CMS is proposing to approve 13 alternative pathway applications for FY 2023 new technology add-on payments. Based on preliminary information from the applicants, CMS estimates that the total payment for these technologies, if approved, would be in excess of approximately $82 million for FY 2023. This estimate does not include the new technology add-on payments for the two technologies that did not have cost estimates in their applications. CMS has not determined the potential payment impact of the 13 technologies that applied under the traditional pathway as it has not yet determined if they meet the criteria for new technology add-on payments for FY 2023.

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 proposed rule wage index values are based on data from FY 2019 submitted cost reports. CMS is not proposing any changes to the categories of included and excluded costs for FY 2023 relative to prior years. CMS' proposed rule calculations of the FY 2023 wage index are based on wage data of 3,112 hospitals. The data file used to construct the proposed wage index includes FY 2019 data submitted to CMS as of February 5, 2022. Hospitals with later cost report begin dates 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 proposed rule wage index.

General wage index policies are unchanged from prior years. CMS notes that it proposes to exclude 86 providers due to aberrant wage data that failed edits for accuracy. However, if data aberrancies for these providers are resolved timely, CMS will include data from these providers to set the final rule FY 2023 wage indexes.

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 proposed rule includes a detailed listing of these steps. CMS calculates an unadjusted national average hourly wage of $47.77.

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 (3,010 of 3,112) used to determine the FY 2023 proposed rule wage index. Consistent with the statute, CMS will apply

the 2019 occupational mix survey data to the FY 2023 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:

Comparison of Occupational Mix Adjusted to Unadjusted Wage Index	
Number of Urban Areas Wage Index Increasing	230 (55.8%)
Number of Rural Areas Wage Index Increasing	27 (57.4%)
Number of Urban Areas Wage Index Increasing 1%<= and <5%	122 (29.6%)
Number of Urban Areas Wage Index Increasing >5%	4 (1.0%)
Number of Rural Areas Wage Index Increasing 1%<= and <5%	13 (27.7%)
Number of Rural Areas Wage Index Increasing >5%	0 (0%)
Number of Urban Areas Wage Index Decreasing	181 (43.9%)
Number of Rural Areas Wage Index Decreasing	20 (42.6%)
Number of Urban Areas Wage Index Decreasing 1%<= and <5%	78 (18.9%)
Number of Urban Areas Wage Index Decreasing >5%	3 (0.7%)
Number of Rural Areas Wage Index Decreasing 1%<= and <5%	8 (17.0%)
Number of Rural Areas Wage Index Decreasing >5%	0 (0%)
Largest Positive Impact for an Urban Area	7.23%
Largest Positive Impact for a Rural Area	4.19%
Largest Negative Impact for an Urban Area	-5.48%
Largest Negative Impact for a Rural Area	-2.52%
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1 (0.2%)
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0 (0%)

F. 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 proposed rule FY 2023 wage index for 192 urban hospitals requiring a budget neutrality adjustment factor of 0.993656 (-0.63 percent) applied to hospital wage indexes.

CMS is also proposing 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 will be 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.

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

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).

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 $64 million in IPPS operating payments due to the frontier floor.

Low Wage Index Hospital Policy. CMS is proposing 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, the 25th percentile wage index value across all hospitals is 0.8401. CMS is proposing 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. CMS is continuing to evaluate the court's decision which is subject to appeal. Although CMS proposes to continue this policy for FY 2023, it may take a different approach in the final rule, depending on public comments or developments in the court proceedings.

G. Wage Index Tables

Proposed rule wage index tables 2, 3 and 4 can be found at: FY 2023 IPPS Proposed Rule Home Page | CMS. Select #2 under FY 2023 Proposed Rule Tables.

H. 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 491 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2023. There are 288 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2021 that will continue for FY 2023. There are 304 hospitals approved for wage index reclassification in FY 2022 that may continue for FY 2023. CMS indicates that there will be 1,083 hospitals in MGCRB reclassification status for FY 2023 (with 192 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 45 days from publication of the FY 2023 proposed rule in the *Federal Register* (June 24, 2022). Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process will be incorporated into the final FY 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.

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 is proposing 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.

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 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 be reclassified 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 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).

I. Outmigration Adjustment

CMS proposes to apply the same policies for the FY 2023 outmigration adjustment that it has been using since FY 2012. CMS estimates the outmigration adjustment will increase IPPS payments by $55 million to 245 hospitals in FY 2023. This provision is not budget neutral.

J. 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 is clarifying 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 indicates 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. 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 hospitals 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.

K. Process for Wage Index Data Corrections

CMS has a long-established a 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. The rule indicates that some hospitals in Louisiana and Mississippi were given additional time to meet particular deadlines because of Hurricane Ida. 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: FY 2019 WI Timetable (cms.gov)

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 the 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.

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 is proposing 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 indicates typical year-to-year variation in the wage index has historically been within 5 percent. Therefore, the proposed 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 indicates 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 proposal 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.[49]
- 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 that would also not be found in Table 2 of the prior fiscal year's rule.

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.

[49] 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 proposed rule.

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. Proposed 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) January 2022 Medicare DSH estimates, which were based on the September 2021 update of the HCRIS and the FY 2022 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 January 2022 Medicare estimate of DSH payments for FY 2023 is $13.266 billion. **The proposed Factor 1 amount is seventy-five percent of this amount, or $9.949 billion.** The proposed Factor 1 for 2023 is about $540 million less than the final Factor 1 for FY 2022.

The Factor 1 estimate for FY 2023 began with a baseline of $13.808 billion in Medicare DSH expenditures for FY 2019. The table below shows the factors applied to update this baseline to the current proposed estimate for FY 2023.

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

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2020	1.031	0.862	1.038	0.9890	0.9123	12.598
2021	1.029	0.947	1.029	0.9842	0.9869	12.432
2022	1.025	1.007	0.990	1.0084	1.0304	12.811
2023	1.032	1.010	0.990	1.0035	1.0355	13.266

- 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 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 and the IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in other columns (such as the change in rates for the 2-midnight stay policy and the 20 percent add-on for COVID-19 discharges). The "other" column also includes a factor for Medicaid expansion due to the ACA.[50]

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

FY	Market Basket Percentage	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2020	3.0	-0.4	0.5	3.1
2021	2.4	0	0.5	2.9
2022	2.7	-0.7	0.5	2.5
2023	3.1	-0.4	0.5	3.2

2. Proposed FY 2023 Factor 2

Factor 2 adjusts Factor 1 based on the percent change in the uninsured since implementation of the ACA. For FYs 2014-2017, the statute required CMS to use the Congressional Budget Office's (CBO) estimate of the uninsured rate in the under 65 population from before enactment of the ACA for FY 2013. For FY 2018 and subsequent years, the statute requires Factor 2 to equal the percent

[50] CMS assumes approximately 55 percent of all individuals who were potentially newly eligible Medicaid beneficiaries in 2018, 2019, and 2020 resided in states that elected to expand Medicaid eligibility; assumes 60 percent for 2021-2023 and about 75 percent in 2024 and thereafter. The "Other" column also includes the estimated impacts on Medicaid enrollment; estimated increase of 2.0 percent in FY 2020, 9.5 percent in FY 2021, 4.2 percent in FY 2022, and -5.7 percent in FY 2023.

change in the number of individuals who are uninsured from 2013 until the most recent period for which data are available minus 0.2 percentage points for each of fiscal years 2018 and 2019. In 2018, CMS began using uninsured estimates from the National Health Expenditure Accounts (NHEA) in place of CBO data as the source of change in the uninsured population.[51]

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

Proposed 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 proposed rule to be 0.6571 or 65.71 percent, and the uncompensated care amount for FY 2023 to be $9.949 billion x 0.6571 = $6.538 billion which is about $654 million less than the FY 2022 UCP total of about $7.192 billion; the percentage decrease is 9.1 percent. The table below shows the Factor 1 and Factor 2 estimates for FY 2022 and the proposed factors for FY 2023.

FY 2023 Proposed Change in UCP
($ in billions)

	FY 2022	FY 2023	$ Change	% Change
Factor 1	$10.489	$9.949	-$0.540	-5.1%
Factor 2	0.6857	0.6571	-.0286	-4.2%
UCP	$7.192	$6.538	-$0.654	-9.1%

CMS also proposes 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.

[51]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

3. Proposed 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.[52]

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).[53] 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).[54]

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.

[52] 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.
[53] 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).
[54] Medicaid inpatient days from FY 2013 and SSI days from FY 2016.

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 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. Proposed 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 proposes 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 proposes 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 proposals address concerns from stakeholders regarding year-to-year fluctuations in uncompensated care payments. Consistent with its past methodology, CMS proposes that if a hospital does not have data for all three years, it would determine Factor 3 based on an average of the hospital's available data.

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

CMS proposes 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 proposes to 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 would 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 for these hospitals. It is proposing to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals beginning in FY 2023 to address this concern (this proposal is discussed in detail in section IV.C of this summary).

CMS seeks comment on how to best measure and define the uncompensated care costs associated with these hospitals that might not otherwise be captured in Factor 3 calculations based on Worksheet S-10 data.

Proposed Scaling Factor

To address the effect of calculating Factor 3 using data from multiple fiscal years, CMS proposes 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 1 (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 multiply 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.

New Hospital for Purposes of Factor 3

CMS is modifying its new hospital policy that was initially adopted in FY 2020 to determine Factor 3 for new hospitals. It proposes to define new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. Thus, hospitals with CCNs established on or after October 1, 2019, would be subject to the new hospital policy in FY 2023.

The proposed rule indicates 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, would not receive interim uncompensated care payments during FY 2023 because CMS would have no FY 2018 or FY 2019 uncompensated care data on which to determine those interim payments.

CMS also proposes to modify the methodology it uses to calculate Factor 3 for new hospitals. Under this proposal, 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 proposes to continue 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 proposes that the newly merged hospital's final uncompensated care payment would be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 would 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 would annualize its data for purposes of the Factor 3 calculation. CMS would 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 would 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 would 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 would determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2023 cost report.

Proposed CCR Trim Methodology

Consistent with its process for trimming CCRs in FY 2022, CMS proposes to 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 would calculate a CCR ceiling by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.
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 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 would assign them the statewide average CCR as determined in step 3.

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

Modifications to the Uncompensated Care Data Trim Methodology

CMS proposes to continue the trim methodology for potentially aberrant UCC that it finalized in the FYs 2019-2022 IPPS/LTCH PPS final rules. That is, if the hospital's uncompensated care costs for FY 2018 or FY 2019 are an extremely high ratio (greater than 50 percent) of its total operating

costs, CMS proposes that data from another available cost report would be used for the ratio calculation. For example, to calculate an estimate of the hospital's uncompensated care costs for FY 2018 for purposes of determining Factor 3 for FY 2023, the hospital's uncompensated care costs for FY 2018 would be trimmed by multiplying its FY 2018 total operating costs by the ratio of uncompensated care costs to total operating costs from the hospital's FY 2019 cost report. CMS would 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 proposes 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 proposes 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 uncompensated care costs (line 30) is greater than 60 percent, it would exclude the hospital from the prospective Factor 3 calculation. This proposed trim would 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 would calculate the Factor 3 after reviewing the reported uncompensated care information.

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 proposes to modify 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.

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 have 60 days from the date of public display of each year's proposed rule to review the tables and notify CMS in writing of any inaccuracies.[55]

For FY 2023, CMS is again proposing that after the publication of the FY 2023 IPPS/LTCH PPS final rule, hospitals would 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. CMS states that it currently expects to use data from the March 2022 HCRIS extract for the FY 2023 final rule, which CMS states increases its confidence that hospitals would be able to comment on mergers and report any upload discrepancies during the comment period for this proposed rule.

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.[56] In light of these concerns, CMS proposes to establish a new permanent supplemental payment under the IPPS for IHS/Tribal hospitals and hospitals located in Puerto Rico. CMS believes that this proposed new supplemental payment would also mitigate the anticipated impact on IHS/Tribal hospitals and hospitals located in Puerto Rico from its proposal to discontinue the use of low-income insured days as a proxy for their uncompensated care costs. The additional payment to these hospitals would 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.

CMS proposes to use 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 proposal to discontinue the use of low-income insured days as a proxy for uncompensated care in determining Factor 3 for these hospitals.

CMS proposes to 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 would be calculated as

[55] Comments on the list of mergers can be submitted to the CMS inbox at Section3133DSH@cms.hhs.gov.
[56] 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).

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 proposes to 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 proposed FY 2023 uncompensated care amount and final FY 2022 uncompensated care amount is projected to be negative 9.1 percent. To calculate each hospital's base year amount for FY 2023, CMS would multiply a hospital's FY 2022 uncompensated care amount by 0.909 (1-0.091). The hospital's supplemental payment for a fiscal year would 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 would not receive a supplemental payment.

CMS proposes to align 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 would be based on a projection of DSH eligibility for the applicable fiscal year.
- An average of historical discharges would be used to calculate a per discharge amount for interim supplemental payments. For FY 2023, CMS proposes to use FY 2018, FY 2019, and FY 2021 discharge data (2020 excluded due to the effects of the pandemic).
- Per-discharge supplemental payments would be included in the outlier payment.
- The MAC would 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 would 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 would not be eligible to receive a supplemental payment for that fiscal year.

In addition, CMS proposes 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, would not be eligible to receive the supplemental payment.

CMS seeks comments on its proposal to establish a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals and other alternatives to its proposal to use uncompensated care costs from Worksheet S-10 to determine Factor 3 for these hospitals. It also seeks comments on how to best measure and define the uncompensated care costs

associated with these hospitals that might not otherwise be captured in Factor 3 calculations based on Worksheet S-10 data.

D. Impact

The regulatory impact analysis presented in Appendix A of the proposed 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 2,380 hospitals that are projected to be eligible for DSH in FY 2023.

The proposed total amount of uncompensated care payments ($6.538 billion) combined with proposed supplement payments for IHS/Tribal hospitals and Puerto Rico hospitals ($92 million) is $6.629 billion. This is a 7.82 percent decrease from FY 2022 payments (about $563 million). Changes in FY 2023 payments are driven by a proposed decrease in Factor 1 and Factor 2 and the proposal to establish a 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 proposed new supplemental payment. A percent change in payments lower than negative 7.82 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 7.82 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 proposed uncompensated care payments and supplemental payments.

Hospital Type	Dollar Difference FY 2022-FY 2023 ($ in millions)	Percent Change
All Hospitals	-$563	-7.82%
Urban	-529	-7.79
Large Urban	-269	-6.48
Other Urban	-260	-9.83
Rural	-34	-8.45
Beds: 0-99 (Urban)	-23	-8.32
Beds: 250+ (Urban)	-391	-7.87
New England (Urban)	-19	-10.39
Middle Atlantic (Urban)	-94	-11.42
South Atlantic	-79	-9.87
West North Central (Urban)	-31	-7.05
West South Central (Urban)	-93	-6.5
Pacific (Urban)	-30	-4.98
Puerto Rico	-10	-11.06
Major Teaching	-244	-8.99
Non-Teaching	-130	-6.58
Voluntary	-273	-6.67
Proprietary	-77	-7.58

Hospital Type	Dollar Difference FY 2022-FY 2023 ($ in millions)	Percent Change
Government	-213	-10.19

Under this proposal, rural hospitals are projected to receive a larger percentage decrease in UCP (8.45%) than urban hospitals (7.79%) 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 and West South Central. 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 10.19 percent, whereas voluntary and proprietary hospitals are projected to receive a payment decrease of 6.67 and 7.58 percent, respectively.

E. 1115 Waiver Days in the Medicaid Fraction

Some states extend medical coverage benefits under a section 1115(a) demonstration project (also referred to as a section 1115 waiver) to populations that could not have been made eligible for medical assistance under the Medicaid State plan. CMS reviews its history of when patient days of those expansion groups could be included in Medicaid inpatient days for calculating the Medicare DSH patient percentage. The proposed rule states that CMS' intent has been to include patient days of those populations who, under a demonstration project, receive benefits, including inpatient hospital coverage benefits, that are similar to the benefits provided to traditional Medicaid beneficiaries. This would not include circumstances where states extended coverage only for specific services (such as family planning) and that do not include insurance coverage for hospital care.

CMS also states that it does not believe that the uninsured patients whose costs are partially offset by uncompensated care pools can be "regarded" as being eligible for Medicaid and thus patient days paid from such pools and other similar sources should not be included in the calculation of the Medicare DSH adjustment. Likewise, CMS believes the days of patients who under a section 1115 expansion waiver receive premium assistance (assistance used to purchase health insurance from a private entity) should also be excluded from the calculation of the DSH calculation. CMS explains that because these individuals do not directly receive health insurance for inpatient hospital services and may have higher incomes than traditional Medicaid beneficiaries, it does not believe these days should be included in the numerator of the Medicaid fraction.

Recently, however, CMS notes that courts have decided in a series of cases (Bethesda Health, Inc. v. Azar, 980 F.3d 121 (D.C. Cir. 2020); Forrest General Hospital v. Azar, 926 F.3d 221 (5th Cir. 2019); HealthAlliance Hosps., Inc. v. Azar, 346 F. Supp. 3d 43 (D.D.C. 2018)) that, based on the current language of the regulations, CMS is required to count in the numerator of the Medicaid fraction patient days for which hospitals have received payment from an uncompensated care pool authorized by a section 1115 demonstration and the days of patients who receive premium assistance under a section 1115 demonstration program. These courts have

concluded that if a hospital received payment for otherwise uncompensated inpatient hospital treatment of a patient, that patient is "eligible for inpatient hospital services" within the meaning of the current regulation.

In the FY 2022 IPPS/LTCH PPS proposed rule, CMS proposed to revise the regulation at §412.106(b)(4)(i) to state explicitly that a patient is deemed eligible for Medicaid for the purposes of the DSH calculation on a given day, and the corresponding patient day is included in the numerator of the Medicaid fraction, only if the patient is eligible for inpatient hospital services under an approved state Medicaid plan that includes coverage for inpatient hospital care on that day or the patient directly receives inpatient hospital insurance coverage on that day under a waiver authorized under section 1115(a)(2) of the Act. Commenters disagreed with its proposal arguing that both premium assistance programs and uncompensated/undercompensated care pools are used to provide individuals with inpatient hospital coverage and thus should be included in the DSH calculation. CMS decided not to finalize its proposal and stated that it would revisit the issue.

In this proposed rule, CMS proposes to modify its regulations to explicitly state its view that "regarded as eligible" for Medicaid only includes patients who receive health insurance through a section 1115 demonstration where state expenditures to provide the insurance may be matched with funds from Title XIX (Medicaid). Furthermore, CMS believes that it is appropriate, and therefore proposes, to use its discretion under the Act to include only the days of patients "regarded as" eligible for Medicaid who receive health insurance through a section 1115 demonstration that provides essential health benefits (EHB) as set forth in 42 CFR part 440, subpart C, for an Alternative Benefit Plan, which is a uniform benchmark and a standard that is broadly used. CMS believes that this change from the current regulation will make it easier for providers and CMS contractors to distinguish between section 1115 demonstrations that should be counted in the Medicaid fraction from those demonstrations (like uncompensated care pools) that should not be included.

Consistent with its interpretation of the Medicare DSH statute, CMS proposes to amend its regulation to preclude counting days of patients associated with uncompensated/undercompensated care pools in the numerator of the Medicaid fraction. CMS views these as essentially supplemental Medicaid DSH payments. It believes that because funding pool payments to hospitals do not inure any specific individual, nor do uncompensated/undercompensated care pools provide any health insurance to any patient, it cannot reasonably be argued that patients associated with uncompensated care for which hospitals are reimbursed through section 1115 demonstration-authorized funding pools may be regarded as eligible for Medicaid. CMS argues that if even if the statute could be read to permit patient groups whose uncompensated care is paid for from a section 1115 demonstration-authorized funding pool to be "regarded as" eligible for Medicaid (which the Secretary does not agree the statute permits), CMS proposes to use its discretion under section 1886(d)(5)(F)(vi) of the Act to exclude from the Medicaid fraction the days of patients whose care costs may be reimbursed to the hospitals through uncompensated/undercompensated care pools.

CMS concludes, however, that patients receiving premium assistance through a section 1115 demonstration to purchase health insurance can be "regarded as" eligible for Medicaid under

section 1886(d)(5)(F)(vi). CMS proposes, for purposes of the DSH calculation, to "regard as" eligible for Medicaid those patients who use premium assistance they obtain through a section 1115 demonstration to buy and pay for all or substantially all (as defined below) of the cost of the health insurance. CMS further proposes to include in the Medicaid fraction only those days of patients who have bought health insurance that provides EHB using premium assistance obtained through a section 1115 demonstration that is equal to at least 90 percent of the cost of the health insurance. It chose this threshold because this level of benefit is similar to the benefits received by individuals who are eligible for Title XIX programs, and as such, it would be appropriate to include the days of these individuals in the numerator of the Medicaid fraction, if the individual is also not entitled to benefits under Medicare Part A. Individuals who receive less premium assistance are not receiving benefits similar to the benefits received by individuals eligible for Medicaid under a State plan and would be excluded from the Medicaid fraction.

CMS proposes that these changes would be effective for discharges occurring on or after October 1, 2022.

V. Other Decisions and Changes to the IPPS

A. Inpatient Hospital Update

The proposed 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) 4th quarter 2021 forecast (with historical data through the 3rd quarter of 2021) for the hospital market basket is 3.1 percent. IGI's 4th quarter 2021 forecast of total factor productivity is 0.4 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	3.1	3.1	3.1	3.1
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.775	-0.775
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.325	0.0	-2.325
Productivity Adjustment	-0.4	-0.4	-0.4	-0.4
Applicable Percentage Increase	**2.7**	**0.375**	**1.925**	**-0.4**

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

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.

Fiscal year 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, CMS proposes that Puerto Rico hospitals that are not meaningful EHR users will be subject to a market basket reduction of 2/3 of 75 percent of 3.1 percent, or 1.55 percentage points. The productivity adjustment further reduces the update by 0.4 percentage points. The update for Puerto Rico hospitals that are not meaningful users of EHR technology will be subject to update of 1.15 percent (3.1 percent less 1.55 less 0.4).

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 proposes to use FY 2021 data to set the CMI criteria. 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 1.8251 (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)	1.49620
2. Middle Atlantic (PA, NJ, NY)	1.60700
3. East North Central (IL, IN, MI, OH, WI	1.70530
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.76720
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.68955
6. East South Central (AL, KY, MS, TN	1.67705
7. West South Central (AR, LA, OK, TX	1.88435
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.89610
9. Pacific (AK, CA, HI, OR, WA)	1.85605

The median regional CMIs in the proposed rule reflect the December update of the FY 2021 MedPAR containing data from bills received through December 2021. 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 is proposing 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.

For FY 2023, CMS indicates that if a hospital that 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 proposes 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 proposes that any approval will be effective prospectively within 30 days of the date of the MAC's determination.

D. Medicare-Dependent Small Rural Hospitals

Section 1886(d)(5)(G) of the Act provides special payments under the IPPS to a Medicare-dependent, small rural hospital (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 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 a sole community hospital (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.

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*. The original rule was adopted on an interim final basis in 1997 with comment but the agency received no public comments and the rule was finalized as originally adopted. In this 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 v. Becerra* 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 example 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 is proposing 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 provides 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 NPRs 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 proposes 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.

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 $60 million 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.[57]

For 2020 and future years, CMS is proposing 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 payment 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.

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

[57] 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.

separately accredited family medicine RTP programs in the "1-2 format"—meaning the resident's first year is at a core family medicine program and the second and third years are at another site. 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.

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 agrees and is proposing 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 proposes 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 explains that precluding RTP Programs not separately accredited in the 1-2 format and that are not in family medicine from entering into affiliation agreements is proposed 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 RTP programs to be exempt from FTE caps for 5 years, CMS believes it is premature to allow these newer programs to participate in affiliated groups. If finalized, CMS may reassess this proposed policy at a future date once FTE caps for these CAA, 2021 RTPs are set.

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.

F. CAR-T and Immunotherapy Cases

In some cases, the 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 of 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 in drug costs—from the relative weight calculation.

CMS is proposing 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 ($61,356) were 20 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($299,460). Accordingly, CMS is proposing 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 indicates 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 also indicated that it is developing a modifier for hospitals that will allow them to exclude these situations from the policy when they occur.

CMS further notes that the policy will apply to expanded access use of immunotherapy—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.

G. Hospital Readmissions Reduction Program (HRRP)

In this rule, CMS announces technical specification updates for all six measures in the HRRP measure set for the FY 2023 program year to incorporate the findings from continued monitoring and analysis of COVID-19 PHE impacts on the measures. CMS proposes modifications to the Program's *Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) following Pneumonia Hospitalization* measure (NQF #0506) (Pneumonia Hospitalization) that would allow use of this measure to resume beginning with program year FY 2024; suppression of this measure for the FY 2023 program year due to COVID-19 PHE effects was finalized during FY 2022 rulemaking. Finally, CMS seeks public comment on promoting health equity through future incorporation of hospital performance for socially at-risk populations into the HRRP. All proposals are open for comment.

CMS does not propose any changes to the Program's payment calculation methodology.[58] Per policy, the FY 2023 applicable period—the 3-year period from which data are collected for HRRP calculations—includes discharges from July 1, 2018 through June 30, 2021. Also per policy, CMS will use claims-paid data for the applicable period from the Medicare Provider Analysis and Review (MedPAR) file for aggregate payment calculations.[59]

In the regulatory impact analysis section of the proposed rule, using the final FY 2022 HRRP payment adjustment factors, CMS estimates that 2,364 hospitals, or 81.6 percent of those eligible (2364/2897), will be penalized under the Program in FY 2023. Aggregate penalties are estimated to represent 0.50 percent of total base operating DRG payments to those hospitals; an estimated dollar total of penalties is not provided. An unnumbered table (see Appendix A section I.H.3. of the rule) shows the variation in these impacts when stratified by hospital characteristics.

1. HRRP Basics

Under the Program, hospitals with disproportionately high numbers of readmissions for selected common conditions and procedures have their adjusted operating base DRG payments reduced by up to 3 percent. The six conditions/procedures to which the HRRP applies in FY 2023 are unchanged from FY 2022: 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 determined by hospitals' proportions of Medicare inpatients who are full-benefit Medicare and Medicaid dual eligible beneficiaries. From the ERR comparisons, an adjustment factor is derived for each hospital that ranges from 1.0 (no payment reduction) to 0.9700 (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 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.

[58] Details of HRRP scoring and payment adjustment calculations can be downloaded at https://qualitynet.cms.gov/inpatient/hrrp/resources.

[59] 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.

2. Current HRRP Measures

No changes are proposed 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),
- 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. Prior Actions

During FY 22 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.[60] 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, listed below. CMS makes no changes to the policy or the factors for FY 2023.

1) Significant deviation in national performance on the measure during the PHE for COVID-19, which could be significantly better or worse compared to historical performance during the immediately preceding program years;
2) Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the COVID-19 PHE;
3) Rapid or unprecedented changes in
    i. Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
    ii. The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin;
4) Significant national shortages or rapid or unprecedented changes in
    i. Healthcare personnel;

[60] 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.

ii. Medical supplies, equipment, or diagnostic tools or materials; or
iii. Patient case volumes or facility-level case mix.

Specifically, for the HRRP, during FY 2022 rulemaking CMS finalized suppression of the Pneumonia Readmission Measure for the FY 2023 program year, citing Factor 2. As a result, this measure will be assigned a weight of zero during program scoring. Further, CMS announced nonsubstantive technical updates to the specifications of all five remaining Program measures, such that patients with principal or secondary diagnoses of COVID-19 are excluded from those measures' numerators and denominators beginning in FY 2023. Nonsubstantive technical updates are not contingent on rulemaking and are disseminated through the Program's established subregulatory guidance mechanisms.[61]

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

CMS announces a plan to end suppression and resume use of the PN Readmission measure beginning with program year FY 2024. Whether or not suppression ends, the measure will undergo a technical update to exclude patients with principal or secondary diagnoses of COVID-19 from the denominator. This update was not made to this measure for FY 2023 since suppression of the measure had been finalized.[62] CMS bases its plan on analyses of claims showing differences between the FY 2023 and FY 2024 measure performance periods: enhanced coding specificity allowing accurate identification of COVID-19 as either a principal or secondary diagnosis; decreasing proportion of readmissions attributable to COVID-19 pneumonia; and sufficient accumulated data on which to base adjustments to properly account for COVID-19 pneumonia patients within the PN Readmission measure.

Analyses performed and an associated data table are presented in section V.H.5.b. of the rule. Below are performance period data for December 2020 through September 2021 excerpted from that table for illustrative purposes.

Principal or Secondary COVID-19 Diagnoses in PN Readmission Measure Cohort (%)										
	Dec	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept
Pneumonia	27.1	9.8	5.6	2.5	1.9	1.2	0.8	0.7	2.1	3.5
Source: Tables V.H.-01 and V.H.-02 in the rule, excerpted by HPA										

c. Proposed Actions: Applicable to All HRRP Measures

CMS announces addition of a covariate adjustment for COVID-19 as a nonsubstantive update to all six Program measures. The update will begin with program year FY 2023 for the five HRRP measures not suppressed and with FY 2024 for the PN Readmission measure. Adjustment will be made for patient history of COVID-19 in the 12 months prior to the admission. CMS believes that the covariate adjustment is appropriate to capture lasting effects of COVID-19 illness (so-

[61] HRRP measure methodology reports are available for download at https://qualitynet.cms.gov/inpatient/measures/readmission/methodology.
[62] The technical specifications for the PN Readmission measure actually will be applied to the FY 2023 performance data that will be confidentially reported to hospitals but will not be applied to publicly reported data until FY 2024.

called "long COVID"), as these may affect readmission risks for all of the conditions and procedures included in the Program's measure set. CMS states that addition of the covariate adjustment to the previously modified measure specifications (excluding patients with COVID-19 diagnoses) further mitigates COVID-19 effects on the measure scores, bringing the observed readmission rates close to those of pre-COVID results.

4. Extraordinary Circumstance Exception (ECE) Policy for the HRRP

CMS reprises the history of the HRRP's ECE policy, including the exceptions granted due to the COVID-19 PHE. The exceptions recognized the variations (e.g., geographic) in COVID-19 PHE impacts and their potential effects on the reported data. CMS does not propose any changes to the ECE policy for FY 2023, but reiterates several clarifications made in response to stakeholder queries received during the COVID-19 PHE:

- An ECE granted under the Program would exclude all claims data from the period for which the ECE is being granted.
- A hospital granted an ECE is not automatically and completely exempted from payment reductions under the Program, even though the hospital's data specified under the terms of the ECE would be excluded from payment reduction calculations.
- While excepted data would be excluded from payment reduction calculations, the hospital receiving an ECE would still be required to submit claims data as usual for services provided during the period covered by the ECE.

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

CMS seeks comment on approaches to updating the HRRP by incorporating hospital performance for socially at-risk populations (e.g., compared to all other hospitals, comparing subpopulations of at-risk beneficiaries within a hospital). CMS states its objective as encouraging providers to improve health equity and reduce health disparities without disincentivizing hospitals to treat socially at-risk beneficiaries or disproportionately penalizing hospitals that treat a large proportion of such beneficiaries.

CMS specifically seeks comment on the following:

- Benefit and potential risks, unintended consequences, and costs of incorporating hospital performance for beneficiaries with social risk factors into the HRRP;
- Preferred approach for linking payment reductions to performance in caring for socially at-risk populations: comparing outcomes for socially at-risk beneficiaries at one hospital versus those of other hospitals, or comparing each hospital's overall performance with its own outcomes for one or more of its (prespecified) socially-at-risk subpopulations;
- 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.

By way of background, CMS notes that hospitals subject to the HRRP currently are scored within one of 5 peer groups based on their proportion of dually eligible beneficiaries. However, CMS also notes that this peer grouping methodology does not directly measure or account for disparities in health equity between beneficiary groups with heightened social risk factors and groups with lesser risk. Also provided is a brief description of the agency's two disparities methods (within- and across-hospital methods). CMS states that any proposals for updating the HRRP to better incorporate hospital performance based on social risk factors of patients treated would be brought forward through rulemaking. Finally, CMS refers readers to section IX.B. of the rule in which a much broader request for information concerning principles for measuring disparities in all of Medicare's quality programs is described.

H. Hospital Value-Based Purchasing Program (HVBP)

CMS proposes to suppress multiple measures and adopt a special scoring rule for HVBP program year FY 2023. Funds withheld from hospitals for that fiscal year (as required by statute) would be returned to hospitals as value-based incentive payments in amounts that match their withholds, yielding a net HVBP percentage payment adjustment of zero. Further proposed are updated baseline and performance periods for certain measures for program year FY 2025. Performance standards are provided for program years FY 2025 through FY 2027 to reflect updated measure specifications and revised baseline and performance periods. CMS additionally announces technical updates to the specifications for measures in the Clinical Outcomes domain beginning with program year FY 2023. All proposals are open to comment.

No changes are proposed to the Program's measures themselves or to the measure set as listed in section V.G.9. of this summary. 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.63 Established approaches to managing measure overlaps among the HVBP, Hospital Inpatient Quality Reporting (HIQR) Program, and the Hospital-Acquired Condition Reduction Program (HAC RP), are not changed.

If the proposed HVBP measure suppression and special scoring proposals are finalized, 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.

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.

[63] Table V.I.-14 in the rule shows the current case minimums by domain.

The HVBP Program measure set is specified by CMS through rulemaking for each program (i.e., payment) year. Each hospital's TPS 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.[64] Finally, CMS converts the hospital TPS into a value-based incentive payment percentage 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.

CMS provides sources for the legislative and regulatory histories of the HVBP and refers readers to the program's requirements at §§412.160 through 412.168. 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. Prior Actions

During FY 22 rulemaking, CMS first finalized the same cross-program measure suppression policy and Measure Suppression Factors for use with the HVBP for the duration of the COVID-19 PHE as was finalized for use with the HRRP (see section V.F.3.a. above). In keeping with the policy, CMS then determined that circumstances related to the PHE had significantly compromised HVBP data reliability for several measures and the associated TPS results. Final actions taken for program year FY 2022 specific to the HVBP comprised suppression of measures in the domains of Patient and Community Engagement (1 measure), Safety (5 measures) and Efficiency and Cost Reduction (1 measure). A special scoring rule was adopted such that no TPS results will be used to make payment adjustments for that year.

CMS also finalized actions for program year FY 2023 as follows:

- 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 nonsubstantive 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 subregulatory 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).

[64] 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.

- Adoption of a special scoring rule under which no TPS results would be calculated and the Program's statutory 2 percent withhold would be fully returned to hospitals as value-based incentive payments.

b. Proposed Actions: Patient and Community Engagement Domain

For program year FY 2023, CMS proposes to suppress the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure (NQF #0166), the only measure in the Patient and Community Engagement domain. CMS cites Measure Suppression Factor 1, providing data about declines in "top box" HCAHPS scores for all eight components of this measure (e.g., Communication with Nurses), to support that highly significant changes in national performance have occurred during the COVID-19 PHE as compared to recent pre-COVID years (see Table V.I.-01 of the rule). CMS also cites Factor 4—national shortages and unprecedented, rapid changes in hospital personnel—noting that staffing shortages, especially of nurses, have been shown to adversely affect patient satisfaction with their experiences of care. 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.

c. Proposed Actions: Safety Domain

The Safety domain contains five Healthcare-Associated Infection (HAI) measures, all of which are reported by hospitals to the Centers for Disease Control and Prevention (CDC) through its National Health Safety Network (NHSN). CDC processes the data and transmits measure results to CMS for use in the HVBP and other Medicare quality programs. The Program's five HAI measures 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).

CMS proposes to suppress all five HAI measures for program year FY 2023. CMS first cites Measure Suppression Factor 1 and describes the significant rate increases from pre-pandemic national performance rates for the CAUTI, CLABSI, and MRSA measures as documented by CDC's data analyses. CDI measure rates actually have significantly declined during the COVID-19 PHE, in part related to hospital infection control practices designed to limit COVID-19 transmission (e.g., wearing personal protective equipment). Therefore, CMS cites Factor 3—rapid changes in care delivery protocols—to support suppressing the CDI measure. The SSI measure rate also has fallen during the COVID-19 PHE, which CMS attributes to rapid and substantial declines in the volume of these procedures performed when compared to pre-pandemic years, declines covered under Factor 4. CMS notes that healthcare personnel staffing shortages, also included under Factor 4, further contribute to the observed HAI rate changes. CMS further notes that COVID-19 impacts on the HAI measures cannot be mitigated through risk adjustment as the HAI data are aggregated for reporting by hospital internal location (e.g., intensive care unit) and as such the data lack COVID-19 diagnoses for attribution at the individual patient level. Table V.I.-02 in the rule provides comparative HAI measure data.

d. Proposed Actions: Technical Specification Updates

CMS announces addition of a covariate adjustment for patient history of COVID-19 within 12 months of an admission for treatment of a condition or performance of a procedure covered by an HVBP measure. The covariate will be added to the risk adjustment models for the MORT-30-AMI, MORT-30-CABG, MORT-30-COPD, MORT-30-HF, and COMP-HIP-KNEE measures effective beginning with program year FY 2023. CMS believes that the covariate adjustment is appropriate to capture lasting effects of COVID-19 illness (so-called "long COVID"), as these may affect mortality and morbidity risks for the conditions and procedures included in the Program's measure set. CMS states that adding the covariate adjustment to the previously modified specifications (i.e., excluding patients with COVID diagnoses) for these clinical outcome measures further mitigates COVID-19 effects on measure scores, bringing the observed clinical outcome measure rates close to pre-COVID values.

Based on a similar rationale, addition of the COVID-19 covariate adjustment also is announced for the 30-MORT-PN measure but beginning with program year FY 2024. This timeline will coincide with the agency's plan to end suppression of this measure and to resume its use a Clinical Outcome domain measure in the HVBP measure set beginning with program year FY 2024. Additionally, CMS announces that beginning with program year FY 2024, patients with either principal or secondary COVID-19 diagnoses will be excluded from the MORT-30-PN measure's denominator. This specification change is being facilitated by enhanced coding specificity that allows accurate identification of COVID-19 as either a principal or secondary diagnosis; decreasing proportion of readmissions attributable to COVID-19 pneumonia; and sufficient accumulated data on which to base adjustments to properly account for COVID-19 pneumonia patients within the MORT-30-PN measure.

e. Proposed Actions: Special Scoring Rule for Program Year FY 2023

Based on prior actions taken during FY 2022 rulemaking and proposals made in this rule, for program year FY 2023 only five Clinical Outcomes domain measures and one Efficiency and Cost Reduction domain measure would remain available for scoring and for determining value-based payment adjustments. Fair and equitable value-based payment adjustments would be challenging to implement using established HVBP methodology. CMS, therefore, proposes a special rule for FY 2023 scoring.

- Rates would be calculated for all HVBP measures, regardless of suppression status.
- Achievement or improvement points would be calculated only for the five unsuppressed measures in the Clinical Outcomes domain and the single unsuppressed measure in the Efficiency and Cost Reduction domain, yielding only two domain scores.
- No TPS would be awarded to any hospital.
- Each hospital's base-operating DRG payment amount would be reduced by 2 percent as required in statute.
- CMS would assign to each hospital a value-based incentive payment amount that matches its 2 percent reduction (i.e., unrelated to any measure scoring results).
- Confidential hospital-specific reports of measure rates for all unsuppressed measures would be provided to hospitals along with their domain scores for Clinical Outcomes and Efficiency and Cost Reduction.

- Rates for unsuppressed measures would be displayed publicly according to established HVBP program policy along with explanations about measure suppression and COVID-19 PHE effects on hospital performances.

CMS states that operational constraints due to the special scoring policy may delay release of confidential hospital-specific reports. CMS notes considerable and intentional overlap between the special scoring rule implemented for program year FY 2022 and the corresponding proposed rule for FY 2023. CMS acknowledges that the special scoring rule, under which no hospital is awarded a TPS, would have ramifications for some clinicians participating in the Merit-Based Incentive Payment System (MIPS) pathway of Medicare's Quality Payment Program (QPP). MIPS permits certain 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 TPSs for their hospitals. If a TPS is not available, a clinician would not be eligible for facility-based measurement and would need to participate in the QPP through another MIPS option. Finally, CMS reiterates a plan to resume the use of measure data for scoring and payment adjustment purposes beginning with program year FY 2024.

4. Suppression-Contingent Payment Details for FY 2023

CMS reiterates that if the proposed HVBP measure suppressions are finalized, a 2 percent payment reduction would be made for each HVBP hospital as required by statute but that each hospital would ultimately receive a value-based incentive payment that matches the payment reduction amount. CMS states that the estimated amount of base operating MS-DRG payment amount reductions for the FY 2023 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2023 discharges is approximately $1.7 billion.

CMS describes the consequences should the proposed measure suppressions, special scoring rule, and net neutral payment adjustments not be finalized. First, CMS estimates that 2,595 hospitals would participate in the HVBP, amongst whom approximately $1.7 billion would be redistributed as value-based incentive payments based on hospital TPS scores. An unnumbered table (*Estimated Adjustments to Base Operating DRG Payment Amounts Resulting from the FY 2023 Hospital VBP Program if Proposals Are Not Finalized)* appears in Appendix A section I.H.4. of the rule. Across all hospitals, the average payment adjustment would be +0.012 percent. When hospitals are categorized by size (i.e., number of beds), geographic region, and urban versus rural status, payment adjustments range from -0.206 percent for rural New England hospitals to +.0.270 percent for those in rural Pacific locations.

Second, CMS notes the established pre-COVID HVBP methodology incorporates a linear exchange function to translate TPS results into value-based incentive payment adjustment factors. For the purpose of modeling program year FY 2023 payment adjustment factors, CMS uses TPS results from FY 2021—the most recent data available, as no hospital received a TPS for FY 2022—to create proxy FY 2023 payment adjustment factors for hospitals. The slope of the associated linear exchange function would be 2.6279472273.

The proxy adjustment factors appear in the rule as HVBP Internet Table 16. Absent suppression and the special scoring rule, Table 16 would be updated to Table 16A in the IPPS final rule, using newer MedPAR data. A second update, performed after the Program's review and

correction period for hospitals, would result in Table 16B, containing the final payment adjustments for hospitals, for posting on the CMS website. Table 16B would be accompanied by a final value for the linear exchange function slope. If the suppressed measures and special scoring rule are finalized, Table 16 will not be updated to Table 16A for the final rule nor will Table 16B be posted.

5. Baseline and Performance Periods

To account for downstream effects of measures suppressed for program year FY 2023, CMS proposes to update baseline and performance periods for certain measures for program year FY 2025. No changes to periods for the Clinical Outcomes domain measures are proposed, as CMS believes their 36-month baseline periods are sufficiently long to buffer any impacts of suppressed measure data. Further, no changes are made to the Efficiency and Cost Reduction domain measure (Medicare Spending Per Beneficiary-Hospital version (MSPB-Hospital)) as this measure for program year FY 2025 will not include COVID-impacted data (baseline period of 2023 and performance period of 2025). Thus, only changes to the Safety and the Person and Community Engagement domains are proposed, shown below. Full details are provided by program year in Tables V.H.-04 through V.H.-08. These tables also reflect changes finalized during FY 2022 rulemaking and related to the exceptions granted for quality data reporting throughout the CMS enterprise during Q1 and Q2 2020.

Proposed Program Year FY 2025 Baseline and Performance Periods Updates by Measure		
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
MRSA	1/1/19 – 12/31/19	1/1/23 – 12/31/23
Source: Tables V.H.-04 through V.H.-08 in the rule, excerpted by HPA		

6. Performance Standards

CMS notes having previously established performance standards for HVBP program years FYs 2025 through 2027 in prior IPPS/LTCH final rules. Several proposals made in this rule, if finalized, would change some of those standards (e.g., changes to measurement baseline periods discussed above). CMS proposes updated standards for the Person and Community Engagement domain measure (HCAHPS) and the Safety domain measures for program year FY 2025.

No changes are proposed to previously determined standards for the remaining program year FY 2025 measures nor to Clinical Outcome domain measure standards for program years FY 2026 and FY 2027. Estimating future standards for other domains will become feasible once their associated baseline periods have been complete. CMS notes that advance standard setting is not

possible for the MSPB-Hospital measure for any program year as that measure is based on concurrent performance year data.

CMS proposes newly calculated performance standards for the Clinical Outcome domain measures for program year FY 2028. Performance standards for program years FY 2025 through FY 2028 are provided as Tables V.I.-09 through V.I.-13 in the rule.

7. Impact of Suppression and Special Scoring on HVBP Measure Overlaps

Overlap of HVBP measures exists by design with some included in the HIQR Program. Per statute, measures available for inclusion in the HVBP are those included in the HIQR Program that also have been displayed on the Hospital Compare and/or its successor Care Compare website for at least one year prior to the start of the relevant HVBP performance period. (Care Compare may be accessed at https://www.medicare.gov/care-compare/.) Once a measure is adopted into the HVBP from the HIQR measure set, that measure can be removed from the HIQR Program but would be retained in the HVBP measure set until formal removal of the measure from the HVBP is proposed through rulemaking. Neither the proposed HVBP measure suppression actions or the program year FY 2023 special scoring rule impact or are impacted by the HVBP-HIQR overlap.

CMS notes that the same data are used to calculate the five CDC NHSN HAI measures that are common to both the HVBP and HAC RP measure sets. The HVBP uses the same processes adopted by the HAC RP for hospitals to review and correct data for the shared measures. The HVBP also relies on validation of the shared measures that is done as part of the HAC RP's process. Neither the proposed HVBP measure suppression actions nor the program year FY 2023 special scoring rule impact or are impacted by the HVBP-HAC RP overlap.

8. Requests for Information (RFIs)

CMS refers readers to section IX.E.9.a. of the rule where input is requested about the potential future adoption of two NHSN HAI digital quality measures—the Healthcare-Associated Clostridioides difficile Infection Outcome Measure and the Hospital-Onset Bacteremia & Fungemia Outcome Measure—into the Hospital IQR Program. This RFI also seeks feedback about the potential future inclusion of these two digital measures in the Hospital VBP Program.

Readers are also referred to section IX.B. of the rule where input is requested on overarching principles for use in measuring healthcare quality disparities in hospital quality and value-based purchasing programs, including the HVBP.

9. HVBP Measure Summary Table

Readers are referred to Tables V.I.-03 of the rule that displays the HVBP measure set for HVBP program years FY 2023 through FY 2026 if the measure proposals in this rule are finalized. The table is reproduced below with modifications.

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
*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 final rule.					

I. Hospital-Acquired Condition (HAC) Reduction Program

CMS proposes to suppress all six HAC RP measures for program year FY 2023 and not to calculate measure scores or Total HAC Scores. Absent Total HAC Scores, no hospitals would be penalized under the HAC RP for the year, and associated changes to results reporting are proposed. CMS also clarifies how removal of the No Mapped Location policy will be implemented for program year FY 2023. Further, CMS 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 proposes to suppress FY 2021 data from all five Hospital-Associated Infections (HAI) measure calculations. Additionally for program year FY 2024, CMS announces risk adjustment technical specifications update for the CMS PSI 90 measure. Changes in the Program's HAI data submission requirements for newly opened hospitals beginning in program year FY 2024 also are proposed.

All proposals are open to comment. CMS also calls attention to two Requests for Information (RFIs) related to potential new digital HAC RP measures and to measuring disparities in healthcare quality across the CMS quality enterprise, including the HAC RP.

No changes are proposed to the Program's measures themselves or to the measure set as listed in section V.G.9. of this summary. No changes are proposed to established policies for measure removal or retention, the scoring calculations review and corrections process, data validation process, or extraordinary circumstances exception process.[65] If the proposed measure suppression and Total HAC Score proposals are finalized, no hospital would receive a payment reduction under the HAC RP. As a result, no penalty funds would be available for return to the Medicare trust fund for program year FY 2023, an estimated loss of at approximately $350 million. No added burden for providers under the HAC RP is projected to be created by the changes proposed in this rule.

1. HAC RP Basics

The HAC Reduction Program was implemented beginning in FY 2015. 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. CMS utilizes the "Winsorized Z-Score Method" for determining individual measure performance scores to mitigate outlier effects. The Total HAC Score is calculated as the equally weighted average of the Winsorized z-scores. 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/.

Requirements of the HAC Program are codified at §§412.170 through 412.172. 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. A table of HAC Program measures by program year is provided in section V.I.8. of this summary.

[65] Table V.I.-14 in the rule shows the current case minimums by domain.

2. Current HAC Program Measure Set

No changes are proposed to the HAC RP measure set for program year FY 2023, shown in an unnumbered table in section V.J.3.a. of the rule. 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).

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

a. Prior Actions

During FY 22 rulemaking, CMS first finalized the same cross-program measure suppression policy and Measure Suppression Factors for use with the HAC RP for the duration of the COVID-19 PHE as was finalized for use with the HRRP (see section V.F.3.a. above). In keeping with the policy, CMS then determined that circumstances related to the PHE had significantly compromised HVBP data reliability for several measures and the associated TPS results. Final actions taken specific to the HAC RP were (1) exclusion of all 2020 data from performance calculations (measure and Total HAC scores) for program years FY 2022 and FY 2023, and (2) adjusted applicable performance periods for all measures for program years FY 2022, FY 2023, and FY 2024 to account for excluded data. Total HAC scores were calculated and penalties applied using the previously established HAC RP methodology.

b. Proposed Actions: Program Year FY 2023

For program year FY 2023, CMS proposes (1) to suppress the CMS PSI 90 measure and the five CDC NHSN HAI measures from the calculation of measure scores and the Total HAC score, and (2) not to report measure results for the CMS PSI 90 measure. If these proposals are finalized, no hospitals will receive payment reductions under the HAC RP for program year FY 2023.

Measure Suppression HAI and CMS PSI 90

In support of its proposal to suppress the HAI measures, CMS first cites Measure Suppression Factor 1 and describes the significant rate increases from pre-pandemic national performance rates for the CAUTI, CLABSI, and MRSA measures as documented by CDC's data analyses. CDI measure rates actually have significantly declined during the COVID-19 PHE, in part related to hospital infection control practices designed to limit COVID-19 transmission (e.g., wearing personal protective equipment). Therefore, CMS cites Factor 3—rapid changes in care delivery protocols—to support suppressing the CDI measure. The SSI measure rate has been affected by drops in case volumes to levels that do not allow CDC to calculate standardized infection rates fir the included procedures, and CMS invokes Factor 4 to support measure suppression. CMS notes that healthcare personnel staffing shortages, also included under Factor

4, further contribute to the observed HAI rate changes. CMS further notes that COVID-19 impacts on the HAI measures cannot be mitigated through risk adjustment as the HAI data are aggregated for reporting by hospital internal location (e.g., intensive care unit) and as such the data lack COVID-19 diagnoses for attribution at the individual patient level. An unnumbered table in section V.J.2.b.(2). of the role provides selected comparative data from the CDC.

In support of its proposal to suppress the CMS PSI 90 measure, CMS states concerns about the comparability of measure data over time. The measure's reference period for HAC RP program year FY 2023 does not include data affected by the COVID-19 PHE, while the applicable period does include affected data. CMS believes the misalignment of reference and applicable periods for the measure would produce distorted and biased results disadvantaging hospitals most impacted by the COVID-19 PHE.

Total HAC Scores and Payment Reduction

CMS believes that concerns described above demonstrating continuing effects of the COVID-19 PHE on all measures in the HAC RP measure set make equitable scoring across hospitals impossible. Total HAC scores would not be equally representative of hospitals' performances and would lead to unfair payment reductions.

Results Reporting

CMS endeavors to balance data transparency and utility across a range of stakeholders including hospitals, researchers, and beneficiaries while meeting statutory requirements for public reporting. CMS will continue to confidentially report results for the five CDC NHSN HAI measures to hospitals and then publicly (Care Compare and Provider Data Catalog) after the usual review and correction period. However, CMS proposes not report CMS PSI 90 results to hospitals or publicly. If the measure suppression proposals are finalized, measure scores of "N/A" and Total HAC Scores of zero would be reported to hospitals and publicly. Further, a payment reduction indicator of "no penalty" would be publicly reported for all hospitals.

Alternatives Considered

CMS considered three alternatives to the proposes measure suppression and its downstream consequences for Total HAC Scores and HAC RP payment reductions:

- 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.

c. Proposed Actions: Program Year FY 2024

HAI Measure Suppression

CMS expresses concern about national comparability of performance data from CY 2021 due to continued effects of the COVID-19 PHE. As a result, the agency proposes to suppress CY 2021 CDC NHSN HAI data from the FY 2024 HAC Reduction Program under Measure Suppression Factors 1 and 4. 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 alternative.

Prior data exclusion and measure suppression related to the COVID-19 PHE necessitated adjustments to certain future applicable measure performance periods that were finalized during FY 2022 rulemaking (see unnumbered table in section V.J.2.b.(1). of the rule). Measure suppression as proposed for program year FY 2024 creates similar issues. CMS responds by proposing changes to certain FY 2024 applicable measure periods. An unnumbered table in section V.J.2.b.(3)., reproduced below, incorporates those changes and provides the proposed applicable periods for program years FY 2023 through FY 2025.

Proposed Applicable Periods for FY 2023, FY 2024, and 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	7/1/2021– 6/30/23
Source: Unnumbered table section V.J.2.b.(3). of the rule		

Technical Specification Update CMS PSI 90

CMS uses a subregulatory process for making nonsubstantive changes to the technical specifications of HAC Program measures. In this rule, CMS announces a nonsubstantive technical specification update for the CS PSI 90 measure to become effective with 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.

Future Years

CMS indicates an intent to resume use of all HAC RP measures and return to measure scoring beginning in program year FY 2024, other than exclusion of CY 2021 HAI data if finalized as proposed. CMS will continue monitoring hospital performances on HAC RP measures to assess the feasibility of resumption of measure scoring and calculating Total HAC Scores at that time.

4. CMS PSI 90 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.[66]

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. The total number of hospitals in the lowest performing HAC RP quartile will decrease slightly. 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.

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.

6. HAI Data Submission Requirements for Newly Opened Hospitals

For purposes of CDC NHSN HAI data submission requirements, "newly opened" hospital status currently is determined by the date a hospital filed its Notice of Participation (NOP) for the Hospital IQR Program. This linkage was associated with routine transfer of HAI measure results 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. To accurately reflect current processes, beginning with program year FY 2023 CMS proposes to update the

[66] There are 10 component measures within the CMS PSI 90 composite measure. More information about the measure and its components are available for download on the AHRQ website at https://qualityindicators.ahrq.gov/measures/psi_resources.

definition of "newly opened" hospital applicable to the HAC RP. A hospital would 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. CMS indicates that less than 0.25 percent of hospitals are impacted by the change.

7. Requests for Information (RFIs)

CMS refers readers to two RFIs appearing later in the rule that seek feedback involving the HAC RP. In section IX.E.9.a., input is requested on the adoption of two digital CHC 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. In section IX.B., input is requested on overarching principles for measuring healthcare quality disparities for future application across the agency's quality programs, including the HAC RP. This RFI is extensive and poses numerous questions.

8. Summary Table Measures and Performance Periods

The table below summarizes the performance periods for the six HAC RP measures through the FY 2023 payment (program) year.

HAC RP Measures and Performance Periods for Program Years FY 2020-2023					
	NQF #	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023***
CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531	X	X	X	X
Applicable (Performance) Period		*7/1/16-6/30/18*	*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*
CDC NHSN HAI Measures					
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	0753	X	X	X	X
Methicillin-resistant staphylococcus aureus (MRSA)	1716	X	X	X	X
Clostridium difficile (CDI)	1717	X	X	X	X
Applicable (Performance) Period CDC NHSN Measures		*1/1/17-12/31/18*	*1/1/18-12/31/19*	*1/1/2019-12/31/19*	*1/1/21-12/31/21*
* Proposed Adjustment to HAI Applicable Periods Due to COVID-19 Impacts					
Source: Excerpted from prior finalized rules and from material in section V.J.2.b.(3). of the proposed rule					

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. Proposed FY 2023 Budget Neutrality Adjustment

CMS proposes to continue to use its general budget neutrality methodology applied in previous years and to specifically follow upon the determinations for the previous extension period. 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 $71,955,710 in FY 2023 which it will incorporate into the budget neutrality offset adjustment for FY 2023.

As of the date of publication of the proposed rule, 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 anticipating that the demonstration would end in 2016; thus, it includes the actual costs for the demonstration in FY 2017 in the budget neutrality offset for FY 2023. The agency proposes that if any of the finalized FY 2017 cost reports change due to revised settlements by MACs, it would adjust the amount for the actual costs of the demonstration for FY 2017 when compiling the total budget neutrality offset amount for the FY 2023 final rule.

The total budget neutrality adjustment would be based on $107,945,638. CMS will update this figure for the final rule.

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 is proposing a national capital Federal rate of $480.29 for FY 2023.

Update Factor:

For FY 2023, CMS will increase the national capital Federal rate by 0.8 percent based on the capital input price index (CIPI) of 1.7 percent and other factors shown in Table 1 below.

CMS is not adopting any change to the capital update for intensity. For FY 2023, CMS projects a 0.5 percent increase in total case-mix index. CMS estimates that the real case-mix increase will equal 0.5 percent for FY 2022. 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.

For purposes of this adjustment, CMS estimates reclassification and recalibration would result in no change in the case mix when compared with the case-mix index that would have resulted if it had not made the reclassification and recalibration changes to the MS-DRGs in FY 2021. Therefore, CMS is are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2023.
There will also be no adjustment forecast error correction.

Table 1

CMS FY 2023 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE		
FY 2018-based CIPI		1.7
Intensity		0.0
Case-Mix Adjustment Factors:		
Projected Case Mix Change	0.5	
Real Across DRG Change	0.5	
Net Case-Mix Adjustment (Projected - Real)		0.0
Effect of FY 2021 Reclassification and Recalibration		0.0
Forecast Error Correction		0.0
Total Update		1.7

Other Adjustments:

For FY 2022, CMS estimated that outlier payments would be 5.29 percent of total capital IPPS payments. For FY 2023, CMS is proposing to take outlier reconciliation into account in determining the outlier adjustment. CMS estimates that capital outlier payments will be 5.56 percent of total capital payments in FY 2023. Taking into account outlier reconciliation, CMS is subtracting 0.01 percentage points for outlier payments refunded to hospitals. This makes the estimate of FY 2023 capital outlier payments 5.55 percent of total capital IPPS payments. Therefore, the FY 2023 outlier adjustment factor is 0.9445 (-5.55 percent), compared to 0.9471 (-5.29 percent) in FY 2022. The net change is percent -0.27 percent (1 - 0.9445/0.9471). Thus, the outlier adjustment decreases the FY 2023 capital federal rate by 0.27 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 certain wage indexes) in the budget neutrality adjustment.

CMS has determined a net GAF budget neutrality adjustment in two steps:

- 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).
- Isolate the impact of the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases.

The first step in the GAF budget neutrality adjustment is retained on the capital rate from year-to-year. As explained in the FY 2022 IPPS final rule, CMS believes it would be technically more appropriate to remove the past year's budget neutrality adjustment determined in step 2 before applying the new payment year adjustment.

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 proposes to divide the capital Federal rate by 0.9974, which was the effect of these policy adjustments in FY 2022.

CMS then proposes to continue 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 1.0019 for this factor.
- 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 0.9971 for FY 2022.

CMS also incorporates an adjustment for FY 2023 MS-DRG changes and recalibration of the relative weights of 1.0003 into the capital rate. This combined adjustment for GAFs due to changes in the wage index in step 1 above and changes for MS-DRGs and recalibration is 1.0023 (1.0019 x 1.0003 or 0.23 percent). The Quartile/Cap adjustment of 0.9971 (-0.029 percent) is then applied.

Proposed Rule Calculation:

The proposed rule includes the following chart to show how each of the factors and adjustments affect 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	1.0170	1.0170	1.7
GAF/DRG Adjustment Factor*	N/A	1.0023	1.0023	0.23
Quartile/Cap Adjustment Factor**	0.9974	0.9971	0.9997	-0.03
Outlier Adjustment Factor**	0.9471	0.9445	0.9973	-0.27
Capital Federal Rate	$472.59	$480.29	1.0122	1.63

* 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 1.0023 (or 0.23 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 0.9445/0.9471, or 0.9973 (or -0.27 percent). The net change to the Quartile/Cap adjustment is 0.9971/0.9974 or 0.9997 (-0.03 percent).

Considering the update factor and the budget neutrality adjustments, CMS is proposing to adopt a national capital Federal rate for FY 2023 of $480.29, a 1.63 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.

The annual update to the TEFRA limit is based on IGI's 2021 4th quarter forecast of the hospital market basket for FY 2023 with historical data through the 3rd quarter of FY 2021 and is 3.1 percent.

B. Critical Access Hospitals (CAHs)

The Frontier Community Health Integration Project (FCHIP) Demonstration[67] 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.

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.

For the extension period, CMS is proposing 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 is proposing 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.

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

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.

CMS proposes updates for LTCHs using a process that is generally consistent with prior regulatory policy and that cross-links to relevant IPPS provisions. For FY 2016 and FY 2017, the site neutral payment rate was a blend of the LTCH PPS standard federal rate and the IPPS comparable amount. Section 51005 of the BBA 2018 extended the transitional blended payment rate (50 percent LTCH standard federal payment and 50 percent IPPS comparable amount) for site neutral payment cases for an additional 2 years. The FY 2019 IPPS 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 proposes to use 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' proposal to modify the ratesetting methodology to account for the ongoing COVID-19 PHE.

Summary of Proposed Changes to LTCH PPS Rates for FY 2023*	
Standard Federal Rate, FY 2021	$44,713.67
Proposed Rule Update factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+2.7%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+2.7% (1.027)
Net update LTCHs not reporting quality data	+0.7% (1.007)
Proposed Rule Adjustments	
Proposed area wage index budget neutrality adjustment	1.000691
Proposed Standard Federal Rate, FY 2023	
LTCHs reporting quality data ($44,713.67 x 1.027 x 1.000691)	$45,952.67
LTCHs not reporting quality data ($44,713.67 x 1.007 x 1.000691)	$45,057.78
Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$44,182
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$43,214

Summary of Proposed Changes to LTCH PPS Rates for FY 2023*	
Impact of Proposed Policy Changes on LTCH Payments in FY 2023	
Total estimated impact	0.8% (≈ $25 million)
LTCH standard federal payment rate cases (72% of LTCH cases)	0.7% (≈ $18 million)
Site neutral payment rate cases (28% of LTCH cases)**	2.3% (≈ $8 million)
*More detail is available in 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". 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

CMS proposes to continue to apply the same MS-DRG classification system used for the IPPS payments to the LTCH PPS in the form of MS-LTC-DRGs. Other MS-DRG system updates also would be incorporated into the MS-LTC-DRG system for FY 2023 since the two systems share an identical base. Proposed MS-DRG changes are described elsewhere in this summary and details can be found in section II.F. of the preamble of the proposed rule. Other proposed changes to the MS-DRG that affect assignments under the proposed GROUPER Version 40 are discussed in section II.E of the proposed rule, including changes to the Medicare Code Editor (MCE) software and the ICD-10-CM/PCS coding system, apply to the LTCH PPS.

3. Proposed Changes for the FY 2023 MS-LTC-DRG Relative Weights Methodology

a. Proposed Averaging of Relative Weights for FY 2023

CMS proposes to make some modifications to its current 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. Thus, it proposes 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 would reduce but 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. Proposed Cap on Relative Weight Decreases

In past rulemaking, comments 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 proposes, 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 proposes to implement the policy in a budget neutral manner. It would apply a budget neutrality adjustment 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.

CMS believes the impact of its proposed cap on relative weight reductions on an LTCH's total LTCH PPS payments for a year would be relatively small because a change in the relative weight would be applied to a single MS-LTC-DRG. It considered both higher and lower caps, but determined a higher cap would apply to fewer MS-LTC-DRGs and a lower cap might result in a larger budget neutrality adjustment. CMS notes its proposed 10-percent cap on reductions to a MS-LTC-DRG's relative weight would apply only to a given MS-LTC-DRG with its current MS-LTC-DRG number; it would 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. **CMS seeks comment on this proposal.**

c. Proposed Conforming Changes to Other Components of the Proposed FY 2023 MS-LTC-DRG Relative Weights Methodology

Generally, CMS proposes to continue 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 proposals to average relative weights and to impose a 10-cap on reductions to relative weights. Because the averaging proposal requires the methodology 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, it proposes to continue to apply 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).

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 proposes to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2023 MS-LTC-DRG relative weights.

a. Proposed Relative Weights Source Data

FY 2023 proposed relative weights are derived from the December 2021 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 proposed relative weights.

Consistent with its current methodology, CMS proposes to remove cases with a length of stay of 7 days or less.

b. Volume-related Adjustments

CMS proposes to continue to account for low-volume MS-LTC-DRG cases using its quintile methodology and to use 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 would be assigned to the quintile that has an MS-LTC-DRG with an average charge closest to that reminder.

CMS then determines a proposed relative weight and (geometric) average length of stay for each quintile; each quintile's weight and length of stay are then assigned to each MS-LTC-DRG within that quintile. The calculations were done separately for claims that included and claims that excluded COVID-19 cases. (See http://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 proposes to remove statistical outlier cases with a length of stay of at least 8 days. It also proposes to continue 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 proposes to continue this policy and to perform it on both set of claims (i.e., those with and those without COVID19 cases).

e. Hospital-Specific Relative-Value Methodology (HSRV)

CMS proposes to continue to use 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 would apply the HSRV methodology when 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 proposes to continue for FY 2023 its approach of combining severity levels within the nonmonotonic MS-LTC-DRG for purposes of computing a relative weight to assure that monotonicity is maintained. Table 11 in the proposed 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

If an MS-LTC-DRG has zero cases after data trims are applied (CMS identifies 427 of these MS-LTC-DRGs), CMS proposes to continue to cross-walk it to another proposed MS-LTC-DRG based on clinical similarities in resource use intensity and relative costliness to assign an appropriate proposed relative weight. If the MS-LTC-DRG that is similar is a low-volume DRG that has been

assigned to one of the five quintiles noted above, then the zero volume MS-LTC-DRG would be assigned to that same quintile.

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 December 2021 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, CMS proposes to assign MS-LTC-DRG 273 the relative weight calculated using all applicable LTCH cases. Thus, there are 399 no-volume MS-LTC-DRGs for which CMS proposes to assign 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 http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these zero-volume MS-LTC-DRGs.)

CMS proposes to assign 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. Normalizing the Two Sets of Relative Weights

CMS proposes to normalize 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 1.33568 for all applicable LTCH cases that include COVID-19 cases and 1.33183 for all applicable LTCH cases that exclude COVID-19 cases. CMSS 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. CMS proposes to continue use its existing two-step methodology to achieve budget neutrality for the FY 2023 MS-LTC-DRG and relative weights update with modifications to account for its proposed new policies to average both sets of relative weights and to apply a 10-percent cap on relative weight decreases. Essentially, CMS would apply 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 proposes to use 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 proposed update of the MS-LTC-DRG classifications and relative weights before applying the ten-percent cap (or the uncapped relative weights), CMS proposes to continue to use its established two-step budget neutrality methodology.

First, it proposes to apply 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 proposed 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 proposed MS-LTC-DRG relative weights for FY 2023, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by the proposed normalization factor of 0.99885 in the first step of the budget neutrality methodology which produces "normalized relative weights."

Next, CMS proposes to determine 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 proposed budget neutrality factor of 0.9932185 which will be applied to each uncapped normalized relative weight.

(2) MS-LTC-DRG Cap Budget Neutrality Factor

Under its proposal to limit reductions in relative weights to 10 percent in a given year, the cap would only be applied to the relative weights for MS-LTC-DRGs with applicable LTCH cases; it would not be applied to no-volume MS-LTC-DRGs. For any MS-LTC-DRG where the FY 2023 relative weight would otherwise have been reduced by more than 10 percent, CMS proposes a capped FY 2023 MS-LTC-DRG relative weight equal to 90 percent of that MS-LTC-DRG's FY 2022 relative weight.

CMS proposes a 3-step methodology to determine the budget neutrality adjustment factor for its 10-percent cap on relative weight reductions. It would:

- Simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2023 and proposed GROUPER Version 40;
- Simulate estimated total FY 2023 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2023 (determined in Step 11) and proposed GROUPER Version 40; and
- Calculate the ratio of the estimated total payments.

The proposed budget neutrality adjustment factor for the 10-percent cap is 0.9966694. To determine the proposed FY 2023 MS-LTC-DRG relative weights, CMS would multiply each capped relative weight by the proposed budget neutrality factor to meet the proposed budget neutrality requirement.
Extensive discussion of the entire 13-step process to determine MS-LTC-DRG relative weights is provided in the proposed rule (pages 981 through 1010 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, so that the LTCH market basket includes both operating and capital cost categories.

2. Proposed Annual Update for LTCH PPS Standard Federal Payment Rate for FY 2023

The proposed annual update to the LTCH PPS standard federal payment rate is equal to 3.1 percent. For FY 2021, CMS rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year. Thus, CMS proposes an update to the 2017-based LTCH market basket of 3.1 percent less 0.4 percentage points (PP) for multifactor productivity meaning an update factor of 1.027 to the FY 2022 LTCH PPS standard Federal payment rate. 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 proposed LTCH update for FY 2023 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	3.1%	3.1%
Multifactor Productivity	-0.4 PP	-0.4 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	2.7%	0.7%

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[68] (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 does not propose any changes to the CBSA-based labor market area delineations for FY 2023.

[68] See https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf

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 proposes to 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

CMS proposes an FY 2023 labor-related share of 68.2 percent based on IGI's fourth quarter 2021 forecast of the 2017-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (64 percent) and capital costs (4.2 percent). Operating costs include the following cost categories: wages and salaries; employee benefits; professional fees; labor-related; administrative and facilities support services; installation, maintenance, and repair services; and all other labor-related services.

c. 5-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 proposes 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 would provide increased predictability in LTCH wage indexes and payments and would 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 cap policy proposed for LTCHs is similar to the proposal in section III.N. for IPPS hospitals. To ensure budget neutrality, it would include this policy in the determination of the area wage level budget neutrality factor.

CMS is proposing that an LTCH's wage index cap adjustment would 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 would 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 proposed rule applies would not be subject to the cap (even when other LTCHs in the same geographic area are receiving a wage cap).

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 nonreclassified hospitals in the same geographic area as the LTCH. CMS proposes, 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 made changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals budget neutral; thus, it proposes that its cap on decreases in an LTCH's applicable IPPS comparable wage index not be applied in a budget neutral manner. CMS proposes that an LTCH's applicable IPPS comparable wage index cap adjustment would 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 would be 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 proposed rule applies would not be subject to the cap.

d. Proposed Budget Neutrality Adjustments

CMS proposes to compute 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, it proposes to apply the proposed 5-percent cap on wage index decreases in a budget neutral manner. CMS determined a proposed FY 2023 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.000691.

4. Cost-of-Living (COLA) Adjustment

CMS proposes to continue updating the COLA factors for Alaska and Hawaii as it has done since FY 2014. To account for higher living costs in Alaska and Hawaii, a COLA is provided to LTCHs in those states 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 the Bureau of Labor Statistics (BLS). The COLA is capped at 25 percent and updated every 4 years.

CMS proposes to use data based on the 2009 OPM COLA factors updated through 2020. The table below shows the proposed COLAs for FY 2023 which are unchanged from the COLAs in effect for FY 2022.

Area	**Proposed 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. Proposed 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 proposes to use its established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2021 update of the PSF. Thus, it proposes an LTCH total CCR ceiling of 1.321 under the LTCH PPS for FY 2023 for HCO cases under either payment rate and for the site neutral payment rate.

CMS also proposes to use 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 December 2021 update of the PSF. They would be effective for discharges occurring on or after October 1, 2022 through September 30, 2023.

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. Proposed 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) Proposed Charge Inflation Factor

Due to a significant difference between estimated and actual charge inflation, 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 calculating a provider's average charge in both fiscal years; dividing the average charge for the more recent fiscal year by the average charge for the prior year; and 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 does 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 proposes to use the 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 proposes 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 proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2023.

(2) Proposed CCRs

Historically, CMS has used CCRs from the most recently available PSF file without any adjustment. It proposes to adjust 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 proposes to continue to use the 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 Med PAR 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 does not propose to use the CCR adjustment factor derived from the most recently available data; instead, it would 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) Proposed Fixed-loss Amount for LTCH PPS Standard Federal Payment Rate Cases

CMS does not propose any changes to its methodology to calculate the applicable fixed-loss amount for standard federal rate cases. It proposes a fixed-loss amount of $44,182 for FY 2023 which CMS estimates will result in 7.975 percent of LTCH standard federal payment rate cases being paid as HCOs. The HCO payment continues to equal 80 percent of the estimated care cost and the outlier threshold (adjusted standard rate payment plus fixed-loss amount). If an HCO case is also an SSO case, the HCO payment will equal 80 percent of the estimated case cost and the outlier threshold (SSO payment plus fixed-loss amount). Consistent with historical practice, CMS would use the most recent available LTCH claims data and CCR data for the final rule.

CMS notes that it is considering an alternative to this proposal under which it would use the FY 2021 data without any of its proposed methodological changes that account for an anticipated decline in COVID-19 cases in FY 2023. Under this alternative, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be $61,842.

(4) Proposed HCO Payments for Site Neutral Payment Rate Cases

MS 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 proposes a fixed-loss amount for site neutral payment rate cases of $43,214. CMS also proposes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2023. Consistent with the policy adopted in FY 2019, CMS proposes that the HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount. CMS estimates that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments.

6. IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS proposes to continue its policy that 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) include an applicable operating Medicare DSH and uncompensated care payment amount. 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 expansion of the insured population under the ACA.

C. Impacts

CMS Impact Analysis for LTCHs

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 proposed 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 proposed payment rates and factors, for all LTCHs from FY 2022 to FY 2023, will result in an increase of 0.8 percent or approximately $25 million in aggregate payments. This impact results from aggregate increases in payment of $8 million for site neutral cases (or 2.3 percent). It also results in aggregate increases in payment of $18 million for LTCH standard federal payment rate cases (or 0.7 percent); this is primarily due to the proposed 2.7 percent annual update and the projected 1.7 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 $2.993 billion, as compared to estimated aggregate proposed FY 2023 LTCH PPS payments of approximately $3.018 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 9.7 percent of estimated total LTCH PPS standard Federal payment rate payments. As it does annually, CMS proposes to set 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 9.7 percent figure for FY 2022 and the estimate of 8.0 percent for FY 2023 accounts for the approximately 1.7 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.

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. RFI: Climate Change Impacts on Outcomes, Care, and Health Equity

CMS requests 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 grass emissions. **CMS poses an extensive list of discussion questions and topics for stakeholder feedback, some of which are excerpted below. The full discussion topic list is found in section IX.A.2. of the rule.**

- The availability of information, such as analyses of climate change impacts (whether developed internally or collected from outside sources), that hospitals, nursing homes, hospices, home health agencies, and other providers can access to better understand climate threats to their patients, community, and staff.
- The degree to which facility efforts to prepare for climate impacts overlap with the work they already complete to meet CMS' Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers, and the degree to which related CMS requirements sufficiently (or insufficiently) prepare them for the threats created by climate change and help or hinder these efforts.
- The nature of facility plans for assisting the community and patients to prepare for and recover from climate-related events, as well as the nature of plans for evacuating patients with differing needs, including those with disabilities.
- The degree to which climate change, and climate change linked to health equity, is publicly addressed in strategic plans and objectives in your facility or system, and the degree to which hospital leadership regularly reviews progress on goals related to climate preparedness and mitigation and invests in health professional training on this topic.
- The tools and supports that health systems and facilities most heavily rely on to support their efforts to reduce greenhouse gas emissions.
- How HHS and CMS can support hospitals, nursing homes, hospices, home health agencies, and other providers in their efforts to more fully prepare for climate change's catastrophic and chronic impacts on their operations and the people they serve, as well as what incentives (for example, recognition, payment, reporting) might assist them in taking more action on climate readiness and emissions reduction.

B. RFI: Measuring Healthcare Quality Disparities Across CMS Quality Programs

CMS notes that health inequity, manifested by significant disparities in healthcare outcomes, 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."

In this RFI, CMS describes key principles and approaches the agency will consider when addressing disparities through quality measure development and stratification. Topics for comment and supporting information provided are grouped by CMS around 5 key considerations, listed below. Highlights from the topics for comment and extensive supporting information provided by CMS are reviewed below; topics for comment appear in bold font.

- Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs
    - Within- and between-provider disparity methods to present stratified quality measure results.

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). CMS views the two methods as complementary when reporting data stratified by the presence or absence of a demographic or social risk factor.[69]

- Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting

    Measures to be prioritized could include:
    - Existing, validated, 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.
    - Outcome measures as well as measures of access and appropriateness of care.

- Principles for Social Risk Factor and Demographic Data Selection and Use
    - Patient-reported data are the gold standard.
    - Criteria for appropriate use of administrative data, area-based indicators (e.g., Area Deprivation Index) and imputed variables when patient-reported data are unavailable.
    - Data collection and submission burden (time and costs) imposed on providers.

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

[69] 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.

positive experience using Medicare Bayesian Improved Surname Geocoding (MBISG) to impute missing values for race and ethnicity from administrative data, surname, and residence.[70]

- Identification of Meaningful Performance Differences

  Methods for detecting meaningful differences 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.
  - National or state-level benchmarking (e.g., mean, median).

- Guiding Principles for Reporting Disparity Measures

  - Confidential reporting to providers for new programs and/or new measures.
  - Satisfying statutory requirements for public reporting.
  - Synchronous reporting of overall and stratified results for maximum value and impact.

C. RFI: FHIR in Hospital Quality Programs

CMS seeks broad input on the transition to digital quality measurement. First, CMS 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 seeks feedback on the updated dQM definition and on challenges associated with non-EHR sources of patient data for dQMs.**

CMS also seeks input into the following general categories. Further discussion of each is 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. The agency also plans to develop a unified CMS FHIR receiving system. Identify opportunities for the public to provide input on FHIR-based measure specifications prior to implementation. Identify opportunities for

[70] 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

collaboration with vendors and implementers via systems testing of FHIR-based eCQM reporting.

- **Venues for Continued Feedback on CMS future measurement direction and data aggregation approaches, including engagement with Standards Development Organizations.**

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. **CMS asks 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?

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 proposes changes to the IQR program that would add 10 new measures including two related to health equity and two focused on maternal health and perinatal care. Four are electronic clinical quality measures (eCQMs), one is a Patient-Reported Outcomes Performance

Measure (PRO-PM), and two are claims-based. Further proposed are refinements for two other existing claims-based measures.

CMS also proposes several policy changes related to eCQMs, PRO-PM and hybrid measures. Additionally, the agency is proposing to establish a publicly reported maternity care quality and safety designation for hospitals. All proposals are open to comment. No changes are proposed to policies regarding the retention, removal, addition, or updating of measures.[71] Specifications for most of the proposed measures are found in the CMS List of Measures Under Consideration for December 1, 2021, available for download at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.

CMS seeks input on the potential future addition of two CDC NHSN HAI measures and about future activities to be associated with the proposed maternal care designation. Finally, the agency invites comments on initiatives for continuing to advance towards digital quality measurement and the use of Fast Healthcare Interoperability Resources (FHIR®).

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. CMS further estimates that for FY 2023, 25 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. Under the proposed rule, these hospitals would receive an update factor of 1.925 percent. Another 19 hospitals are estimated to receive an update of -0.4 percent because they failed to meet the requirements of both the IQR Program and the Promoting Interoperability Program.[72]

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

Rationale. CMS proposes adding a 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 and for subsequent years. The measure is intended to assess a hospital's commitment to health equity across five domains (e.g., Data Collection) within each of which are multiple elements (e.g., training staff in culturally sensitive collection of demographic and/or social determinant of health (SDoH) information). A complete list of domains and elements

[71] 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.
[72] The 0.2 percent reduction reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user.

appears as Table IX.E-01 of the rule. Measure specifications are available for download at https://qualitynet.cms.gov/inpatient/iqr/resources.

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 attest affirmatively and receive a point for that domain.
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. Measures Under Consideration (MUC) List December 2021. Measure Applications Partnership (MAP) Review overall outcome ultimately was conditional support for rulemaking. Concerns expressed about undue burden to rural hospitals, actionability, how related improvements in health outcomes will be measured, and measure interpretation by consumers once publicly reported. The measure has not been submitted for NQF endorsement and CMS does not state an intent to do so.

b. Screening for Social Drivers of Health

Rationale. CMS proposes adding a process 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. The measure is intended to promote adoption of screening for health-related social needs (HRSNs) by hospitals across five domains: food security, housing instability, transportation needs, utility difficulties, and interpersonal safety. Screening for these five domains has been widely tested through the CMS Innovation Center's Accountable Health Communities Model; the domains are described further in Table IX.E.-02 of the rule. The measure as proposed does not require use of a standardized screening tool. If finalized, it would be the first patient-level measurement of social drivers of health in the Hospital IQR Program.

Numerator. Number of patients admitted to an inpatient hospital stay who are screened for one or more of the five included 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 screened 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. Measures Under Consideration (MUC) List December 2021. Measure Applications Partnership (MAP) Review overall outcome ultimately was conditional support for rulemaking pending NQF endorsement. Concerns expressed during MAP review included lack of screening tool standardization and unclear link between the measure and better patient health outcomes. CMS states an intent to submit the measure for NQF endorsement in the future.

c. Screen Positive Rate for Social Drivers of Health

Rationale. CMS proposes adding this structural measure as a companion measure to the proposed Screening for Social Drivers of Health measure, intended to enhance standardized data collection for identifying high-risk individuals who could benefit from connection via the hospital to community-based services relevant to their HRSNs. The measure also could allow impact estimates for the effects of the included HRSN domains on hospitalizations and be valuable during discharge planning. CMS notes that the measure is not intended for comparisons among hospitals.

> 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. Measures Under Consideration (MUC) List December 2021. Measure Applications Partnership (MAP) Review overall outcome ultimately was 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

Rationale. CMS proposes 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.

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 reduces 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.[73]
Data Submission and Reporting. This measure would follow established policies for eCQM submission. As proposed, the measure could 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.

Pre-rulemaking. Measures Under Consideration (MUC) List December 2018. Measure Applications Partnership (MAP) Review overall outcome ultimately was conditional support for rulemaking pending NQF endorsement. The MAP suggested further feasibility testing and stakeholder consultation. Additional feasibility, reliability, and validity testing have been done along with stakeholder consultation. The measure has been submitted for NQF endorsement in the Spring 2022 cycle. A chart-abstracted version of this measure PC-02 *Cesarean Birth* has been NQF-endorsed continuously since 2008 (NQF #0471); the most recent re-endorsement occurred in 2020. Both the chart-abstracted and eCQM versions are in use by The Joint Commission.

e. Severe Obstetric Complications eCQM

Rationale. CMS proposes adding an 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 delivery hospitalizations. It 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. Related measures in the Hospital IPR Program measure set are PC-01 *Elective Delivery* and *the Maternal Morbidity Structural Measure*.

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).

[73] EHR = electronic health record. CEHRT = certified Health Information 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.

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 would follow established policies for eCQM submission. As proposed, the measure could 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/FY 2026 payment determination.

Pre-rulemaking. Measures Under Consideration (MUC) List December 2021. Measure Applications Partnership (MAP) Review overall outcome ultimately was conditional support for rulemaking pending NQF endorsement. The MAP expressed concerns related to discouraging necessary blood transfusions, sample size and minimum case volumes, and the risk-adjustment methodology. The measure as proposed supports outcomes separately for cases whose only reason for numerator inclusion is blood transfusion. Validity, feasibility, and reliability testing yielded results acceptable to CMS. The measure has been submitted for NQF endorsement in January 2022 and is under review.

f. Hospital Harm—Opioid-Related Adverse Events eCQM (NQF #3501e)

Rationale. CMS proposes 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 events, most of which are avoidable, triggered by opioid administration to inpatients. The measure is intended to provide information to hospitals to improve their monitoring of and response to inpatients given opioids. 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.

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 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. (Mandatory reporting is not being proposed.)

Pre-rulemaking. Measures Under Consideration (MUC) List December 2021. Measure Applications Partnership (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)

Rationale. CMS proposes adding an 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. This measure would be the only one in the measure set to directly address malnutrition of hospitalized patients. 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. The measure has a lengthy development history beginning with individual measures that did not receive NQF endorsement and were not adopted for use by CMS. Additional testing and refinement led to the proposed composite measure; 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).

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 determined. The average is 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. (Mandatory reporting is not being proposed.)

Pre-rulemaking. Measures Under Consideration (MUC) List December 2020. Measure Applications Partnership (MAP) Review of the composite measure ended in conditional support for rulemaking pending NQF endorsement. Concerns raised by the NQF Prevention and Population Health Standing Committee were resolved by the developer 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 proposes adding an eCQM *Hospital-Level, Risk Standardized Patient-Reported Outcomes Performance Measure Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)* to the Hospital IQR Program measure set beginning with two voluntary periods, followed by mandatory reporting for the reporting period which runs from July 1, 2025 through June 30, 2026 and impacts the FY 2028 payment determination, and subsequent years. 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. 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. Specifications are available for download at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.

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 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 matched, completed 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 would not be publicly reported but

indicators would identify hospitals choosing to voluntarily report. Public release of results and response rates would start with the first mandatory reporting cycle. The somewhat complex 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.					

i. Substantive Measure Refinement and Reintroduction: Medicare Spending Per Beneficiary (MSPB) Hospital (NQF #2158)

Rationale. CMS proposes the addition of 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 Hospital IQR Program, the original version was not simultaneously removed from the HVBP 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.

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. 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. CMS discusses an illustrative example of the refined measure in sections IX.E.5.h.(1).(a). and (b). of the rule. (Also see 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.

CMS states that the costs of the refined measure no longer outweigh its benefits. The agency lays out a plan to propose replacement of the original measure in the HVBP 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).

j. Substantive Measure Refinement and Reintroduction: Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA/TKA (NQF #1550) (THA/TKA Complication Measure)

Rationale. CMS proposes the addition of 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. When removed from the Hospital IQR Program, the original version was not simultaneously removed from the HVBP measure set, where it had been adopted previously into the Clinical Outcomes domain. The original version currently remains actively used in the HVBP.

The agency lays out a plan to propose replacement of the original measure in the HVBP 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.

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.

As is done for the HVBP version of this measure, admissions with principal or secondary COVID-19 diagnoses are excluded from the numerator when assessing the medical complications of acute myocardial infarction within 7 days, pneumonia within 7 days, sepsis within 7 days, or pulmonary embolism within 30 days. A covariate adjustment for a history of COVID-19 also is part of the refined measure (and is being proposed for the HVBP measure).

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).

Public reporting of the refined measure would begin in 2023. Once the statutory requirement for use of the measure and public reporting in the Hospital IQR is satisfied, CMS states a plan to propose replacement of the original measure in the HVBP measure set with the refined measure.

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 above in this summary. These diagnoses were identified during routine measure maintenance review by the measure steward. 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 would 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 from 2.42 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.

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 proposes 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 would receive confidential feedback but their results would not be publicly posted. Public reporting on Care Compare would occur for hospitals meeting or exceeding the threshold, after confidential reporting and a review and corrections period. CMS proposes that the refinement would 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.

3. Quality and Safety of Maternal Care

a. Establishing the Maternal Care Designation

CMS proposes to establish a hospital designation reflecting the quality and safety of maternal care for use that would be publicly reported on a public-facing CMS website beginning in Fall 2023. The designation would be awarded to hospitals that report "Yes" to both questions embedded in the Maternal Morbidity Structural Measure of the Hospital IQR Program. 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?

CMS indicates its intention to expand the requirements for hospitals to be awarded the maternal care quality and safety designation.

b. Solicitation of Comments

Designation Name. CMS solicits names for the proposed designation.

Data Sources. CMS solicits input about additional sources of data other than the Maternal Morbidity Structural Measure. Potential sources include the proposed Cesarean Birth and Severe Obstetric Complications measures proposed earlier in this rule, if finalized. CMS particularly seeks comments about relevant patient experience-of-care measures.

c. RFI: Additional Activities to Advance Maternal Health Equity

In addition to recognizing hospitals for quality and safety of maternal care, CMS requests 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 poses a long and detailed list of questions and topics for comment, from which highlights are excerpted below.** Readers are referred to section IX.E.8.d. of the rule for the complete list.

- Beyond a recent memorandum to state survey agencies,[74] what other additional effective best practices in maternal care or quality improvement initiatives are currently being utilized by hospitals?
- For hospitals that offer inpatient maternity services, including labor and delivery care, how could the CoPs be modified to improve maternity care and address disparities in maternal health outcomes (e.g., establish new requirements)?
- Could modified CoPs have differential effects and unintended consequences (e.g., for low-volume or rural providers)?
- What services and staff training should hospitals without inpatient maternity services have in place in preparation for patients in labor?
- What are best practices hospitals are utilizing to increase access to timely maternity care?
- How can hospitals review and monitor aggregate data on the maternal health risks of the patient population that they serve?
- What challenges are there to collecting maternal health risk data stratified by demographics to be used in quality improvement efforts?
- How are hospital reviews of maternal deaths conducted?
- Do hospitals have reporting relationships with the full range of maternal care providers (e.g., physicians, certified nurse midwives, doulas)?
- Do hospitals have sufficient contacts with community-based support services for optimum post-partum discharge planning?
- How is perinatal patient experience-of-care evaluated by hospitals?
- What best practices exist to avoid perpetuation of systemic racism and biases in maternity care?

4. Hospital IQR Program Measure Set: Potential Future Measures

a. Clostridioides difficile CDC NHSN Health-Associated Infection (HA-CDI) Outcome Measure

Rationale. The HA-CDI dQM would track the development of new *C. difficile* infections among hospital inpatients, using algorithmic determinations based on EHR data.

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. Number of patients admitted to the hospital during the data collection period.
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.
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.

[74] Evidence-based best practices for hospitals in managing obstetric emergencies and other key contributors to maternal health disparities. U.S. Department of Health and Human Services. https://www.cms.gov/files/document/qso-22-05-hospitals.pdf

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 PAC 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.

b. CDC NHSN Hospital-Onset Bacteremia and Fungemia Outcome Measure

Rationale. This measure captures the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in EHRs. It captures a wide range of bloodstream infections, rather than simply organism-specific (e.g., MRSA) or source-specific (CLABSI) infections. CMS is considering use of this measure in the Hospital IQR Program and the PCHQR Program and as a replacement for the CAUTI and CLABSI measures in the HVBP and HAC RP Program.

Numerator. Number of observed hospital-onset bacteremia events.
Denominator. Number of observed 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 evolving, 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.

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

All available eCQMs used in the Hospital IQR Program for CY 2023 reporting/FY 2025 payment and subsequent years must be reported using technology certified to the 2015 Edition Cures Update. CMS proposes to modify the current eCQM reporting and submission requirements by increasing eCQM 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 would be required for each eCQM. The proposed increase of numbers of eCQMs to be reported is consistent with the proposed addition of two new maternal health eCQMs for mandatory reporting: *Cesarean Birth* and *Severe Obstetric Complications*. CMS states the proposed increase is consistent with its policy goal to incrementally expand eCQM reporting requirements.

The current and proposed eCQM reporting parameters are shown in the table below.

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**
CURRENT (PREVIOUSLY FINALIZED)			
CY 2021/FY 2023	Two quarters of data	Four	Four self-selected
CY 2022/FY 2024	Three quarters of data	Four	Four self-selected
CY 2023/FY 2025		Four	Three self-selected and Safe Use of Opioids-Concurrent Prescribing
PROPOSED			
CY 2024/FY 2026		Six	Three self-selected and Safe Use of Opioids-Concurrent Prescribing and Cesarean Birth* and Severe Obstetric Complications*
* Measures proposed in this rule Source: Consolidation by HPA of Tables X.E.-14 and IX.E.-15 in the rule			

b. Reporting and Submission Requirements for Hybrid Measures

CMS is proposing to remove the zero denominator declarations and case threshold exemptions policies for hybrid measures beginning with the FY 2026 payment determination. These 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.

However, CMS now believes that hybrid measure data reporting processes intrinsically preempt measure reporting when no patients meet a measure's denominator criteria. Hybrid measures are based on a combination of claims data and clinical data electronically submitted by hospitals. CMS performs the measure calculations and reports results back to data submitters (hospitals). During the process of merging the agency's claims data with EHR data received from the hospital, CMS will automatically detect whether denominator criteria have been met by the

hospital. Therefore, zero denominator declarations and case threshold exemptions are no longer needed.

c. Reporting and Submission Requirements for Patient-Reported Outcome-Based Performance Measures (PRO-PMs)

CMS proposes 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. 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 proposes submission and reporting requirements specific to the proposed THA/TKA PRO-PM Measure. If finalized for addition to the Hospital IQR Program measure set, this measure would be the Program's first PRO-PM. The measure's timeline was described with the measure addition proposal above in section IX.C.1.h. of this summary but is repeated below. The measure, if finalized, will affect payments beginning with the FY 2028 payment determination year.

THA/TKA PR-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 proposes 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 would be effective beginning with CY 2022 eCQM data affecting the FY 2025 payment determination and subsequent years. CMS notes that all hospitals selected to date for eCQM validation have met the 75 percent threshold and 95 percent of them have voluntarily and successfully submitted 100 percent of requested records.

CMS further notes that 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. Regulation text modifications are also proposed consistent with the increased submission threshold. The validation requirements for chart-

abstracted measures are not affected by this eCQM validation proposal. Current and proposed validation scoring for eCQMs is shown in Table IX.E.-18 of the rule.

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					
ED-2 Time from admit decision to departure for admitted patients (NQF#0495)[a]	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)*	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* AND Severe Obstetric Complications* AND 3 of the following 9* eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-01 HH-02 HH-ORAE GMCS

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure , V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
Hospital Harm-Severe Hyperglycemia (NQF #3533e)* *Hospital Harm Opioid Related Adverse Events HH-ORAE *ePC-02 Cesarean Birth *ePC-07/SMM Sever Obstetric Complications *Global Malnutrition Composite Score GMCS (NQF #3592e)						
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						
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						

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure , V= Voluntary Reporting						
	2021	**2022**	**2023**	**2024**	**2025**	**2026**
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*
Process Measures						
SDOH-1 Screening for social Drivers of Health*					V*	X*
SDOH-2 Screen Positive Rate for Social Drivers of Health*					V*	X*
*Proposed Change FY 2023 IPPS Proposed Rule						

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

The PCHQR Program applies to hospitals meeting the description of *PPS-exempt cancer hospital* as defined at section 1886(d)(1)(B)(v) of the Act. The Program has 11 participants who 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 proposes to revise the program's measure removal policy, proposes timelines for public display of two measures, and requests 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 proposes 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 would be 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. The proposed exception would be 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/). CMS proposes to begin public display of data from four end-of-life (EOL) measures beginning with program year FY 2024 data. These measures were added to the Program's measure set beginning with program

year FY 2020. Likewise, CMS proposes 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. The specific refresh cycles during which public reporting of these 5 measures will begin will be announced by CMS through routine channels (e.g., CMS website).

3. Request for Information (RFI): Potential Future HAI Measure Adoption

CMS notes that cancer patients are often immunosuppressed and therefore at increased risk for healthcare-associated infections (HAIs). CMS refers readers to the RFI at section IX.E.9.a. of the rule requesting feedback about two CDC NHSN HAI measures—Healthcare-associated *Clostridioides difficile* Infection Outcome and Hospital-Onset Bacteremia & Fungemia Outcome. The measures are under consideration for future adoption into multiple CMS quality programs, including the PCHQR Program.

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.

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)	Proposed for 2024
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215)	Proposed 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)	Proposed 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)	Proposed 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)	Not Displayed

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.[75] 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 seeks input on three concept areas in which one or more measures would be developed for future use in the LTCH QRP.

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.
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.
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.

CMS indicates that it will not respond directly in the FY 2023 IPPS/LTCH final rule to comments received on this RFI but states an intent to use the input during measure development.

[75] Post-acute care providers required to report SPADEs are long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.

2. RFI: LTCH QRP Digital Quality Measures and *Clostridioides difficile* Infection Outcome Measure

CMS invites input into requiring electronic submission of quality data from LTCHs via their electronic health records (EHRs) as part of the LTCH QRP. Specifically, CMS poses questions related to the future inclusion of the *NHSN Healthcare-Associated Clostridioides difficile Infection Outcome Measure (HA-CDI)*[76] as the LTCH QRP's first digital quality measure (dQM).

- Would you support using EHRs to collect and submit data for LTCH QRP measures?
- Would your EHR support exposing data via HL7 FHIR to locally installed software from CDC? For LTCHs using certified EHR technology (CEHRT), how can existing certification criteria from the Office of the National Coordinator (ONC) for Health Information Technology (HIT) support reporting of dQM data? What updates, if any, to ONC's Certification Program would be needed to better support data capture and submission?
- Is a transition period between the current data submission method and an electronic submission method necessary? If so, how long; further, what specific factors are relevant in determining the length of any transition?
- Would vendors, including those that service LTCHs, be interested in or willing to participate in pilots or voluntary electronic submission of quality data?
- Do LTCHs anticipate challenges, other than the adoption of EHRs, to implementing the HA-CDI; if so, what are potential solutions for those challenges?

a. Background

In prior rulemaking, CMS expressed a commitment to transitioning its quality enterprise to dQMs by 2025. Data collection, submission, and other health information exchange related to the measures would occur primarily using application programming interfaces (APIs) that are based on the Health Level 7 Fast Healthcare Interoperability Resources standards (HL7 FHIR®).

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.[77] 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.

[76] 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.
[77] CDC processes the data then transmits the output to CMS.

CMS notes that the HA-CDI measure better distinguishes *C. difficile* infection from colonization and allows easier identification of new *C. difficile* infections in patients already admitted to a facility when compared to the current CDI measure.

b. Measure Details

The HA-CDI dQM would track the development of new *C. difficile* infections among patients already admitted to an LTCH, using algorithmic determinations based on EHR data.

Numerator. Patients with (1) a qualifying *C. difficile*-positive assay on an inpatient encounter on day 4 or later of an LTCH admission and with no previously positive event in ≤ 14 days before the LTCH encounter; and (2) qualifying antimicrobial therapy newly started within the appropriate window (i.e., based on timing of stool specimen collection).
Denominator. Number of patients admitted to the LTCH during the data collection period.
Exclusions. None (the measure's exclusion of patients from well-baby nurseries and neonatal intensive care units when the measure is used in other settings—e.g., acute care hospital—is not applicable to LTCHs).
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.

CMS states that the CDC would maintain both the CDI and HA-CDI measures concurrently for sufficient time until facilities gain enough experience with the HA-CDI measure to remove the CDI measure from the LTCH QRP measure set.

c. Pre-rulemaking Process

In accordance with the CMS pre-rulemaking process, the HA-CDI measure was included on the 2021 Measures Under Consideration (MUC) list as MUC2021-098. CDC is the measure's steward. The measure was suggested for potential use in multiple CMS quality reporting programs for PAC providers, including the LTCH QRP.

Also, as part of pre-rulemaking, the HA-CDI measure was reviewed by the PAC-Long-Term Care workgroup of the Measure Applications Partnership (MAP). The MAP conditionally supported the measure for rulemaking, contingent on NQF endorsement.

3. RFI: Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs

CMS notes that health inequity, manifested by significant disparities in healthcare outcomes, 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."

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. Already underway are confidential reporting to acute care hospitals about readmissions stratified by dual eligibility status and reporting of stratified Health Effectiveness Data Information Set (HEDIS) measure performance results to Medicare Advantage (MA) plans using several demographic and social risk factor variables.

In this RFI, CMS describes key principles and approaches the agency will consider when addressing disparities through quality measure development and stratification. Topics for comment and supporting information provided are grouped by CMS around 5 key considerations and 2 potential measures. Highlights from the topics for comment and extensive supporting information provided by CMS are reviewed below; topics for comment appear in bold font. (See section V.A. of the preamble for the full set of topics and complete background material.)

- **Identification of Goals and Approaches for Measuring Healthcare Disparities and Using Measure Stratification Across CMS Quality Reporting Programs**
    - **Within- and between-provider disparity methods to present stratified LTCH quality measure results.**
    - **Decomposition approaches to explain possible causes of measure performance disparities.**
    - **Alternative methods to identify disparities and the drivers of disparities.**

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). CMS views the two methods as complementary when reporting data stratified by the presence or absence of a demographic or social risk factor.[78]

Another approach, regression decomposition, can facilitate analysis when an identified performance disparity may have multiple contributing factors, allowing estimation of the relative contributions of the factors.[79] CMS walks through a decomposition analysis of hypothetical LTCH data for the Medicare Spending Per Beneficiary Measure stratified by dual eligible status, for the factors of health literacy level and Emergency Department service utilization (see section V.A.2.a. of the rule).

[78] 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.

[79] Rahimi E, Hashemi Nazari S. A detailed explanation and graphical representation of the Blinder-Oaxaca decomposition method with its application in health inequalities. Emerg Themes Epidemiol. (2021)18:12. https://doi.org/10.1186/s12982-021-00100-9.

- **Guiding Principles for Selecting and Prioritizing Measures for Disparity Reporting**

  Measures to be prioritized could include:
  - **Existing, validated, 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.**
  - **Measures that offer meaningful, actionable, and valid feedback to providers.**

- **Principles for Social Risk Factor and Demographic Data Selection and Use**
  - **Patient-reported data are the gold standard.**
  - **Criteria for appropriate use of administrative data, area-based indicators (e.g., Area Deprivation Index), and imputed variables when patient-reported data are unavailable.**
  - **Data collection and submission burden (time and costs) imposed on providers.**

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.[80]

- **Identification of Meaningful Performance Differences**

  Methods for detecting meaningful differences could include:
  - **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;**
  - **National or state-level benchmarking (e.g., mean, median); and**
  - **Criteria for when ranking performances is inappropriate (i.e., when only measure results can or should be reported without making comparisons).**

CMS states an intention to standardize its analytic approaches wherever possible. However, the agency also states that approaches must be tailored to contextual variations at the program level. Input on the benefits and limitations of the above list of methods is sought.

- **Guiding Principles for Reporting Disparity Measures**
  - **Confidential reporting to providers for new programs and/or new measures;**
  - **Satisfying statutory requirements for public reporting;**

[80] 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

- **Special considerations for resource-limited settings (e.g., rural, underserved) to avoid unintended disadvantaging of critical-access providers; and**
- **Synchronous reporting of overall and stratified results for maximum value and impact.**

CMS believes that varying approaches to results reporting may be useful for driving quality improvement in different contexts and settings. CMS emphasizes that overall improvement without resolution of disparities would be undesirable.

- **Potential Health Equity Measures for the LTCH QRP: Desirable Characteristics**
  - **Actionable for providers.**
  - **Assist beneficiary decision making.**
  - **Adhere to high scientific acceptability standards (e.g., reliability).**
  - **Avoid creating incentives to lower the quality of care.**

Health Equity Summary Score[81]

CMS seeks input about adapting the Health Equity Summary Score (HESS) for use in the LTCH QRP. 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[82]—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.

Hospital Commitment to Health Equity

CMS seeks input about adopting a structural measure for the LTCH QRP to assess engagement of hospital leadership in collecting health equity performance data. The measure—*Hospital Commitment to Health Equity*—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 began the pre-rulemaking process by including this measure on the 2021 MUC List. CMS also solicits comments on additional domains and facility-level information collection to facilitate health equity measure scoring, and input on other potential LTCH QRP equity measures. Finally, CMS notes that it is proposing to add this measure to the Hospital IQR Program beginning with program year (payment determination year) FY 2025 as described in section IX.D.5.a. of this rule.

[81] 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.

[82] 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).

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 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: Proposed 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.

In this rule, CMS proposes the following changes to the Query of PDMP measure for 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.
- If the proposal to require reporting of the Query of PDMP measure is finalized, to remove the phrase "except where prohibited and in accordance with applicable law" from the measure description because it would be provided as an exclusion under the proposal above.
- To expand the Query of PDMP measure to include Schedule III and IV drugs.

The proposed measure description would read 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. CMS further proposes to maintain the associated points at 10 points, and the maximum total points for this objective would remain at 20 points for 2023.

The agency also notes that all states collect data on schedules II, III, and IV drugs. It believes its proposal to expand the measure to include additional Scheduled drugs would facilitate more informed prescribing practices and improve patient outcomes. The query of the PDMP for prescription drug history would have to 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 would be included no matter how small the amount prescribed during an encounter and that only one query would have to 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.

CMS only proposed two exclusions. It did not include 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 believes 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, CMS welcomes comment on any barriers (e.g., technology solutions, cost, and workflow) that should be considered as well as any other exclusions that should be considered for the measure**.

b. Proposed 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 proposes the following technical revisions:

- In the measure description: "For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT"; and

- In the numerator "[t]he number of prescriptions in the denominator generated and transmitted electronically".

3. Health Information Exchange (HIE) Objective: Proposed 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. Later in the proposed rule, CMS proposes to reduce the total amount of points available for the HIE Objective to 30. The change to the scoring methodology is a result of the proposal to make the Query of PDMP measure required and worth 10 points.

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. In this proposed rule, 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[83], 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.

b. Proposed 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 would mean stakeholders would be: 1) 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) in good standing (that is not suspended) under that agreement, and 3) 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 proposes 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. It would call this new measure the "Enabling Exchange Under TEFCA measure."

[83] 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

For 2023, CMS proposes 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 proposed Enabling Exchange Under TEFCA measure.

As noted above, CMS is proposing to reduce the total amount of points for the HIE Objective to 30. Under its proposal, the Enabling Exchange Under TEFCA measure would be worth 30 points. However, should CMS not finalize its proposal to make the Query of PDMP measure required and worth 10 points, then the Enabling Exchange Under TEFCA measure would be worth 40 points. No more than 40 points could be earned for this objective.

The Enabling Exchange Under TEFCA measure would be reported by attestation, and the measure would require a "yes/no" response. CMS proposes that the measure may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT. Eligible hospitals and CAHs would 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 would have to 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).

CMS seeks comment on the proposals.

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 measures.[84] 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.

[84] The four measures are Syndromic Surveillance Reporting; Immunization Registry Reporting; Electronic Case Reporting; and Electronic Reportable Laboratory Result Reporting.

b. Proposed 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.

Beginning with the EHR reporting period in 2023, CMS proposes to require reporting on a fifth measure under the Public Health and Clinical Data Exchange Objective:

- 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 would result in no credit for the measure and thus failure to meet the Objective. There would be no additional points for reporting this measure.

To report this measure, eligible hospitals and CAHs would have to use technology certified to the criterion at 45 CFR 170.315(f)(6), "Transmission to public health agencies – antimicrobial use and resistance reporting."

There would be 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 believes it will likely review the second and third exclusions for future EHR reporting periods.

Finally, the measure would be calculated by reviewing all patient records, not just those whose records are maintained using CEHRT. **CMS invites comment on its proposals, including on the feasibility of the timeline and any additional exclusions that we should consider for this measure.**

c. Proposed 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 proposes to consolidate current options 1 and 2 into one option beginning with the EHR reporting period in CY 2023. It does not propose any substantive changes to the individual options or requirements for selecting individual options. The two options would be as follows:

- Proposed Option 1. Pre-production and Validation (a combination of current option 1, completed registration to submit data, and current option 2, testing and validation);
- Proposed Option 2. Validated Data Production (current option 3, production).

(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 proposes to require eligible hospitals and CAHs to submit their level of active engagement using the options for active engagement (as proposed to be modified above i.e., either Pre-production and Validation or Validated Data Production) for each measure they report. If the proposal to reduce the number of options used to report active engagement is not finalized, one of the three current options would have to be submitted for each measure reported.

(3) Changes to the Duration of Active Engagement Options

As noted above, currently eligible hospitals and CAHs need not report their level of active engagement, or advance from one option to the next option within a certain period of time. CMS proposes, 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 proposes 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.

CMS invites comments on all its proposals for active engagement.

(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.[85] 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.[86]

5. Proposed 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

[85] See https://www.healthit.gov/curesrule/faq/would-not-complying-another-law-implicate-information-blockingregulations.

[86] See https://www.healthit.gov/curesrule/faq/how-would-any-claim-or-report-information-blocking-be-evaluated.

Objective	Measures	Maximum 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 would retain the 10 points associated with it, which are currently allocated as bonus points in 2022. If the change is finalized, CMS proposes 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.

Currently, 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 proposes to increase the points for this objective to 25. CMS would 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 (reproduced below) shows the proposed performance-based scoring methodology for EHR reporting periods in 2023.

TABLE IX.H.-04: PROPOSED 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
	Report the following 5 measures: *	25 points*	Required

Objective	Measures	Maximum Points	Required/Optional
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Electronic Reportable Laboratory Result Reporting AUR Surveillance Reporting*		
	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 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.

6. Proposed 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 proposes 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 HER 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 would 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 does not propose to publish individual measure scores at this time on this website, it will continue to evaluate that possibility for future rulemaking. If the proposal is finalized, 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 seeks comment on the proposal.**

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 the regulatory text. It proposes 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 establish a new paragraph (f) of that section as described in Table IX.H.-06.

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 made in the proposed 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 proposed 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. Proposed 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 proposes to adopt four new eCQMs for the Medicare PIP eCQM measure set.

Beginning with the 2023 reporting period, CMS proposes to add the following:

- Severe Obstetric Complications eCQM (NQF NA); and
- Cesarean Birth eCQM (NQF NA).

CMS proposes to require mandatory reporting of these two eCQMs for the 2024 reporting period and for subsequent years.

Beginning with the 2024 reporting period, CMS proposes to adopt the following two measures 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 proposed and previously finalized eCQMs for the 2023 and 2024 reporting periods respectively.

c. Proposed 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 the 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 does not propose any changes the data reporting and submission requirements for the 2023 reporting period.

For the 2024 reporting period and subsequent years, CMS proposes to increase the number of eCQMs that must be reported to six. Eligible hospitals and CAHs would have to 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.

If the proposals to adopt the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM are finalized, those measures would be 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 would be required to report these two eCQMs. **Comments are solicited on these proposals.**

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 seeks comments on how to promote equitable patient access and use of their health information without adding unnecessary burden on providers. **It seeks information on a number of questions, including the following**:

- Moving beyond providing the information and technical capabilities to access their data, are there additional approaches to promote patient access and use of their health information? Are there examples of successful approaches or initiatives that have enhanced patient access and use of their health information?
- Recent studies have raised concerns about the presence of racial bias and stigmatizing language within EHRs that could lead to unintended consequences if patients were to obtain disparaging notes regarding their medical care. What policy, implementation strategies, or other considerations are necessary to address existing racial bias or other biases and prevent use of stigmatizing language?

- What are the most common barriers to patient access and use of their health information that have been observed? Are there differences by populations or individual characteristics?

- Patients' health information may be found in multiple patient portals. How could CMS or HHS facilitate individuals' ability to access all their health information in one place?

- What policy, governance and implementation strategies or other considerations for HIT, EHRs and other health-related communication technologies are necessary to ensure equal access to patient portals, equitable portal implementation, appropriate design and encouragement of use?

- What challenges do eligible hospitals and CAHs face when addressing patient questions and requests resulting from patient access of patient portals or access of data through use of a mobile app? What can be done to mitigate potential burden?

- For patients who access their health information, how could CMS, HHS, and health care providers help patients manage their health through the use of their personal health information?

- Do you believe the API and app ecosystem is at the point where it would be beneficial to revisit adding a measure of patient access to their health information which assesses providers on the degree to which their patients actively access their health information? What should be considered when designing a measure of patient access of their health information through portals or apps?

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).

CMS proposing to codify and clarify additional policies relating to deferred compensation plans in a new CFR section in part 413, subpart F. The rule indicates that CMS is not proposing change to current 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 or other CFR sections.

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 or services. 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).

5. Documentation Requirements (§413.99(e))

CMS is proposing to codify at §413.99(e) that a provider of services must maintain and make available upon request documentation to substantiate the costs incurred for the plans included in its Medicare cost report. These proposed 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 proposes to codify in proposed §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 proposed regulations outlined in this section of this proposed 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 proposes to include these provisions on the treatment of costs associated with the PBGC in paragraph (g) of proposed §413.99.

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 is proposing 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 is proposing 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 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 end of the influenza season.

To more effectively respond to future crises, CMS is proposing to require hospitals and CAHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, CMS proposes 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 proposes 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. Further, CMS is particularly interested in comments on whether there is duplication of reporting of these items with those that may be required elsewhere. CMS acknowledges the uncertainties in planning for future emergencies and is interested in public comment on how to best align and incent preparedness, while also reducing burden and costs on regulated entities, and ensuring flexibility.

The rule indicates that CMS considered requiring the data elements that proved most informative and actionable over the course of the COVID-19 PHE. CMS is including 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 indicates 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 explains that hospitals are already reporting quality data to NHSN. Access to NHSN data is restricted. The provided 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 distinguishes the health care facility reporting requirements proposed in this rule from those conducted by state and local health departments. This proposed rule aims 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.

C. RFI: Payment Adjustments for Domestically Made N95 Respirator Masks

1. Introduction and Overview

Executive Order (E.O.) 13987 launched a whole-of-government approach to combat COVID-19 and prepare for future biological and pandemic threats. Pursuant to E.O. 13987, CMS is interested in public comments on how to ensure availability of domestically manufactured National Institute for Occupational Safety and Health (NIOSH) approved N95 surgical masks. The rule indicates that these masks are critical to controlling the spread of respiratory diseases like COVID-19.

The COVID-19 pandemic has illustrated how overseas production shutdowns, foreign export restrictions, or ocean shipping delays can jeopardize availability of raw materials and components needed to make critical public health supplies. In a future pandemic or COVID-19-driven surge, hospitals need to be able to count on PPE manufacturers to deliver the equipment they need on a timely basis in order to protect health care workers and their patients. Sustaining a level of wholly domestic production of surgical N95 respirators is integral to maintaining that assurance according to CMS. However, wholly domestically made NIOSH-approved surgical N95 respirators are generally more expensive than foreign-made ones. CMS is considering IPPS and OPPS adjustments consistent with the policy goal of making sufficient supplies of NIOSH approved domestically manufactured N95 masks.

For the IPPS, the Secretary could potentially make such a payment adjustment under section 1886(d)(5)(I) of the Act, which specifically authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate. For the OPPS, the Secretary could potentially make such a payment adjustment under section 1833(t)(2)(E) of the Social Security Act, which authorizes the Secretary to establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments.

2. Potential Payment Adjustments under the IPPS and OPPS

CMS is considering payment adjustments under the IPPS and OPPS beginning in 2023 as follows:

- Biweekly interim lump-sum payments to hospitals that would be reconciled at cost report settlement that account for the marginal difference in costs between NIOSH-approved surgical N95 respirators that were wholly domestically made and those that were not; or
- A claims-based approach where Medicare could establish a MS-DRG add-on payment when hospitals meet or exceed a threshold of purchasing 50 percent or more wholly domestically sourced surgical N95 respirators.

For the latter approach, CMS would establish a unique billing code that hospitals would use to attest that they met or exceeded the domestic sourcing threshold for the year. A similar approach would apply under the OPPS for each non-telehealth OPPS service. CMS seeks comment on the following:

- Which of the potential frameworks would be a more appropriate approach to provide payment adjustments for purchased wholly domestically made NIOSH-approved surgical N95 respirators? Please explain why.
- How can hospitals determine if the surgical N95 respirators they purchase are wholly domestically made NIOSH-approved surgical N95 respirators and eligible for these payment adjustments?
- For the lump-sum payment framework, what would be the most appropriate methodology to determine Medicare's share of costs for purchased wholly domestically made NIOSH-approved surgical N95 respirators? One potential methodology could use the ratio of Medicare inpatient cases to total inpatient hospital cases for all payers reported on the Medicare cost report.
- For the lump-sum payment framework, a hospital might use only wholly domestically made NIOSH-approved surgical N95 respirators. Such a hospital would not have any cost information to report for NIOSH-approved surgical N95 respirators that were not wholly domestically made. Strictly for purposes of calculating a cost differential in such situations, should a national minimum cost be established for a NIOSH-approved surgical N95 respirator that is not wholly domestically made?
- For the claims-based payment framework, how should Medicare calculate the per claim add-on amount prospectively given the varying costs of NIOSH-approved surgical N95 respirators, and how should it be updated given year-by-year cost changes for NIOSH-approved surgical N95 respirators?
- For the claims-based payment framework, what are reasonable usage assumptions upon which to base the payment adjustments? For example, for OPPS, should the payment adjustments be based on assumption of one wholly domestically made NIOSH-approved surgical N95 respirator worn per face-to-face, in-person encounter? What assumptions should be made for IPPS? Should the claims-based payment adjustment be a percent add-on or a fixed add-on?
- Given that the OPPS authority that would potentially be used for an OPPS payment

adjustment is required by law to be budget neutral, should the IPPS payment adjustment also be budget neutral or should it be applied in a non-budget neutral manner?

- What program integrity safeguards should Medicare institute in effectuating this policy? What documentation should hospitals be required to maintain? How can the policy mitigate price increases for wholly domestically made NIOSH-approved surgical N95 respirators and preserve incentives for hospitals to negotiate fair prices with N95 mask suppliers?
- For hospitals that meet the domestic sourcing threshold, should the submission of the claim be deemed sufficient for attestation of compliance with meeting or exceeding the domestic sourcing threshold or is a separate attestation process necessary? For what time period should a hospital be attesting that it met the domestic sourcing threshold?
- Do special considerations for certain hospitals exist, such as hospitals with low-volume of Medicare patients or those in a rural or urban safety net setting?
- For Group Purchasing Organizations that purchase wholly domestically made NIOSH-approved surgical N95 respirators on behalf of health systems, what considerations, if any, are needed to inform a payment adjustment policy?
- Other than information obtained from hospital cost reports or claims, what additional data sources should CMS consider to inform future adjustments?
- What data or circumstances should be taken into consideration to determine continuation of these payments beyond 2023?
- Are there other types of respiratory devices and PPE that should be considered for payment adjustments?
- Should CMS consider payment adjustments other than on the cost report or a claims-based approach?

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 proposing an applicable percentage increase for FY 2023 of 2.7 percent (before application of the documentation and coding and other adjustments), provided the hospital submits quality data and is a meaningful EHR.

TABLE I
CHANGES TO IPPS OPERATING COSTS FOR FY 2023

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All Proposed FY 2023 Changes (8)[9]
All Hospitals	3,141	3.1	0.0	0.0	0.0	0.0	0.3	-0.2	1.4
By Geographic Location:									
Urban hospitals	2,419	3.2	0.0	0.0	-0.1	0.0	0.3	-0.1	1.4
Rural hospitals	722	2.9	0.1	0.0	1.0	-0.2	0.1	-1.1	1.1
Bed Size (Urban):									
0-99 beds	640	3.1	0.1	0.0	-0.6	0.3	0.6	-1.7	0.2
100-199 beds	709	3.2	0.2	0.0	-0.1	0.2	0.4	-0.4	1.6
200-299 beds	423	3.2	0.1	0.1	0.1	0.0	0.3	0.0	1.8
300-499 beds	409	3.2	0.0	0.0	0.0	0.0	0.3	0.0	1.5
500 or more beds	236	3.1	-0.1	0.0	-0.2	0.0	0.2	0.0	1.2
Bed Size (Rural):									
0-49 beds	348	2.8	-0.1	-0.1	0.5	-0.2	0.2	-2.2	-0.2
50-99 beds	211	2.9	0.1	0.1	0.8	-0.2	0.3	-2.5	-0.1
100-149 beds	86	2.9	0.2	-0.2	1.2	-0.2	0.0	-0.3	2.0
150-199 beds	41	3.0	0.0	-0.2	1.0	-0.2	0.2	0.0	1.8
200 or more beds	36	2.9	0.1	0.1	1.7	-0.2	0.0	0.0	2.3
Urban by Region:									
New England	107	3.2	-0.1	-0.4	2.5	3.3	0.6	-0.2	2.1
Middle Atlantic	295	3.2	0.1	-0.1	0.4	-0.3	0.5	-0.1	1.2
East North Central	373	3.2	-0.1	-0.1	-0.5	-0.3	0.1	-0.4	1.0
West North Central	156	3.1	-0.2	-0.4	-0.6	-0.3	0.8	-0.1	1.1
South Atlantic	402	3.2	0.0	-0.1	-0.6	-0.3	0.3	-0.2	1.3
East South Central	140	3.2	0.1	-0.2	-0.6	-0.3	0.0	-0.1	1.5
West South Central	361	3.2	0.1	0.3	-0.8	-0.3	0.0	-0.1	1.8
Mountain	176	3.1	-0.1	-0.1	-0.2	0.3	0.3	0.0	1.7
Pacific	359	3.1	0.1	0.5	0.3	0.1	0.1	0.0	1.3
Puerto Rico	50	3.2	0.6	-0.5	-1.2	0.5	0.1	0.0	2.7
Rural by Region:									
New England	19	3.0	-0.2	0.7	0.0	-0.3	0.2	-2.2	-1.2
Middle Atlantic	49	3.0	0.0	-0.1	0.9	-0.2	0.0	-0.9	1.1
East North Central	113	2.9	-0.1	-0.2	1.2	-0.2	0.0	-3.1	-1.0
West North Central	86	2.7	0.0	-0.1	0.0	-0.1	0.3	-0.4	1.7
South Atlantic	109	2.9	0.3	0.1	1.8	-0.2	0.1	-0.8	2.2
East South Central	141	3.0	0.4	-0.3	1.2	-0.3	0.1	-0.6	1.8
West South Central	134	3.0	0.2	0.4	1.6	-0.3	0.0	-0.5	1.6

	Number of Hospitals[1]	Proposed Hospital Rate Update and Adjustment under MACRA (1)[2]	Proposed FY 2023 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2023 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2023 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	Expiration of MDH Status (7)[8]	All Proposed FY 2023 Changes (8)[9]
Mountain	47	2.5	-0.2	-0.1	0.3	0.0	1.2	0.0	1.9
Pacific	24	2.8	0.1	-0.1	0.9	-0.1	0.0	0.0	2.3
By Payment Classification:									
Urban hospitals	1,867	3.2	0.0	0.0	-0.7	0.0	0.4	0.0	1.4
Rural areas	1,274	3.1	0.0	0.0	0.8	0.0	0.2	-0.4	1.3
Teaching Status:									
Nonteaching	1,939	3.1	0.1	0.1	0.0	0.1	0.2	-0.5	1.3
Fewer than 100 residents	932	3.2	0.0	0.0	0.0	-0.1	0.4	-0.2	1.4
100 or more residents	270	3.1	0.0	-0.1	0.0	0.0	0.2	0.0	1.3
Urban DSH:									
Non-DSH	374	3.2	-0.2	0.1	-0.3	-0.2	0.6	-0.2	1.3
100 or more beds	1,140	3.2	0.1	0.0	-0.7	0.0	0.3	0.0	1.4
Less than 100 beds	353	3.2	0.2	0.0	-0.6	0.3	0.5	-0.5	1.5
Rural DSH:									
Non-DSH	95	3.1	-0.2	-0.2	0.6	1.1	0.2	-1.7	0.1
SCH	267	2.7	-0.1	0.0	0.1	0.0	0.1	0.0	2.5
RRC	663	3.1	0.0	0.0	0.9	-0.1	0.2	-0.1	1.4
100 or more beds	28	3.2	0.0	0.2	-0.4	0.7	0.0	-3.4	-0.9
Less than 100 beds	221	3.1	0.0	0.0	1.2	-0.4	0.2	-6.1	-4.2
Urban teaching and DSH:									
Both teaching and DSH	663	3.2	0.0	0.0	-0.7	0.0	0.4	0.0	1.4
Teaching and no DSH	62	3.2	-0.4	0.1	0.3	-0.1	0.5	-0.3	1.0
No teaching and DSH	830	3.2	0.1	0.1	-0.7	0.1	0.2	-0.1	1.6
No teaching and no DSH	312	3.2	-0.1	0.1	-0.6	-0.2	0.6	-0.1	1.4
Special Hospital Types:									
RRC	161	3.2	0.0	-0.2	1.5	0.7	0.2	-0.9	0.8
RRC with Section 401 Rural Reclassification	460	3.1	0.0	0.0	0.9	0.0	0.2	-0.1	1.4
SCH	256	2.7	0.0	0.1	0.1	0.0	0.1	0.0	2.5
SCH with Section 401 Rural Reclassification	47	2.7	-0.3	0.0	0.0	0.0	0.0	0.0	2.6
SCH and RRC	120	2.8	0.1	0.0	0.3	-0.1	0.1	0.0	2.3
SCH and RRC with Section 401 Rural Reclassification	37	2.8	-0.1	0.0	0.3	-0.1	0.0	0.0	2.4
Type of Ownership:									
Voluntary	1,907	3.2	0.0	0.0	0.1	0.0	0.3	-0.2	1.2
Proprietary	794	3.2	0.2	0.1	0.0	0.0	0.2	-0.1	2.3
Government	439	3.0	0.1	0.1	-0.3	-0.1	0.1	-0.2	1.3
Medicare Utilization as a Percent of Inpatient Days:									
0-25	683	3.1	0.2	0.1	-0.5	-0.2	0.1	0.0	1.7
25-50	2,072	3.1	0.0	0.0	0.1	0.0	0.3	-0.2	1.3
50-65	300	3.0	0.0	0.0	0.3	0.4	0.5	-1.1	1.0
Over 65	35	2.6	-1.0	-0.5	-1.1	-0.3	0.0	-1.3	-0.5
Medicaid Utilization as a Percent of Inpatient Days:									
0-25	2,073	3.1	-0.1	0.0	0.1	-0.1	0.3	-0.3	1.2

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25-50	953	3.1	0.1	0.0	-0.1	0.1	0.2	-0.1	1.5
50-65	91	3.1	0.8	0.5	-0.6	0.5	0.2	0.0	2.5
Over 65	24	2.9	0.9	1.0	-0.7	-0.1	0.1	0.0	3.4
Hospitals with 5% or more of cases that reported experiencing homelessness	45	3.1	0.8	0.5	-0.7	-0.3	0.2	0.0	2.4
FY 2023 Reclassifications:									
All Reclassified Hospitals	1,071	3.1	0.0	0.0	1.0	0.1	0.2	-0.2	1.4
Non-Reclassified Hospitals	2,070	3.2	0.0	0.0	-1.0	-0.1	0.4	-0.2	1.3
Urban Hospitals Reclassified	893	3.1	0.0	0.0	0.9	0.1	0.2	-0.3	1.3
Urban Non-Reclassified Hospitals	1,539	3.2	0.0	0.0	-1.2	0.0	0.4	0.0	1.4
Rural Hospitals Reclassified Full Year	288	3.0	0.1	-0.1	2.0	-0.2	0.1	-0.9	1.4
Rural Non-Reclassified Hospitals Full Year	421	2.8	0.0	0.2	-0.4	-0.1	0.2	-1.3	0.7
All Section 401 Rural Reclassified Hospitals	608	3.1	-0.1	0.0	0.8	0.0	0.2	-0.3	1.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	3.1	0.1	0.0	3.1	-0.3	0.2	-2.6	-0.5

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2021, and hospital cost report data are from the latest available reporting periods.

[2] This column displays the payment impact of the proposed hospital rate update and other adjustments, including the proposed 2.7 percent update to the national standardized amount and the proposed hospital-specific rate (the proposed 3.1 percent market basket update reduced by 0.4 percentage point for the proposed productivity adjustment), and the proposed 0.5 percentage point adjustment to the national standardized amount required under section 414 of the MACRA.

[3] This column displays the payment impact of the proposed changes to the Version 40 GROUPER, the proposed 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 proposed permanent 10-percent cap where the relative weight for a MS-DRG would decrease by more than ten percent in a given fiscal year. This column displays the application of the proposed recalibration budget neutrality factors of 1.000491 and 0.999765.

[4] This column displays the payment impact of the proposed 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 proposed wage budget neutrality factor, which is calculated separately from the recalibration budget neutrality factor. The proposed wage budget neutrality factor is 1.001303.

[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 proposed geographic budget neutrality factor of 0.985346.

[6] This column displays the effects of the proposed rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index is 0.993656.

[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.