Fiscal Year 2024 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule Summary

On April 10, 2023, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule describing federal fiscal year (FY) 2024 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 1, 2023. **The public comment period will end at 5:00 PM ET on June 9, 2023.**

The payment rates and policies described in the IPPS/LTCH proposed rule (CMS-1785-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, finalized policies will be effective October 1, 2023.

CMS is using the FY 2024 IPPS proposed rule to request information on the challenges faced by safety-net hospitals. It is also proposing to make three ICD-10-CM diagnosis codes describing homelessness as a complication or comorbidity based on the higher average resource costs of cases with these diagnosis codes compared to similar cases without these codes. The rule also makes clarifying changes to the self-referral provisions that apply to physician-owned hospitals.

CMS makes many data files available to support analysis of the proposed rule. These data files are generally available at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-proposed-rule-home-page. Numbered tables that were historically included in the IPPS/LTCH rule are now only available on the CMS website at the above hyperlink.

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

CMS estimates that the IPPS proposed rule will increase FY 2024 combined operating and capital payments to approximately 3,130 acute care hospitals by an estimated $2.7 billion. This net impact results from a combined $3.2 billion increase in FY 2024 operating payments, including uncompensated care payments, low volume hospitals payments, and a decrease of $0.466 million from changes in new technology add-on payments.

A. Inpatient Hospital Operating Update

The above are changes to IPPS payments. The estimated percentage increase in IPPS *payment per service* is estimated at 2.8 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 2.8 percent rate increase is the net result of a market basket update of 3.0 percent less 0.2 percentage points for total factor productivity. 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 SCHs and MDHs are paid.

Factor	Percent Change
FY 2024 Market Basket	3.0%
Total Factor Productivity	-0.2
Net increase before application of budget neutrality factors	2.8%

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 for these hospitals. 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 Total Factor Productivity	Reduction (Percentage Points)	Update	Hospitals
No IQR	25% of the MB	3.0%	2.8%	-0.75	2.05%	63
No EHR	75% of the MB	3.0%	2.8%	-2.25	0.55%	132
No IQR/EHR	100% of the MB	3.0%	2.8%	-3.00	-0.20%	32

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2024 payments increasing 2.8 percent. Not all policy changes are reflected in this total. For example, the total does not include estimated changes in UCP and NTAPs. The factors that are included in this total are shown in the following table.

Contributing Factor	National Percentage Change
FY 2024 increase in payment rates	2.8
Outliers	-0.16[1]
Residual	0.16
Total	2.8

[1]CMS targets 5.1 percent of IPPS payments as outliers but estimates that it will pay 0.16 percentage points more than the amount targeted in FY 2023. As a result, CMS estimates total payments will decline by 0.16 percentage points for FY 2024.
[2]Non-budget neutral wage index changes will increase payments 0.13 percent. There are also "interactive effects among the various factors…which may contribute to…the proposed changes in payments per discharge from FY 2023 and FY 2024."

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	2.8%
Urban	2.8%
Rural	3.3%
Major Teaching	2.5%

To the extent the impact on a given hospital category deviates from the national average of 2.8 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 relatively 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 although even these provisions would be expected to have a modest impact from year-to-year. Imputed floor is not budget neutral while rural floor is made budget neutral through an adjustment to hospital wage indexes.

The total increase for rural hospitals is higher than for other hospitals due to changes in how CMS is calculating the rural wage index when hospitals reclassify from urban to rural.

Other provisions having an impact include:

Rural Floor. The proposed rural floor raises the wage index of 596 urban hospitals. CMS calculates a proposed national rural floor budget neutrality adjustment factor of 0.981145 (-1.88 percent) applied to hospital wage indexes. CMS projects that rural hospitals in the aggregate will experience a 0.5 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 Pacific region can expect a 3.2 percent increase in payments relative to the rural floor not being applied.

Imputed Floor. The imputed floor was established by section 9831 of the American Rescue Plan Act enacted on March 11, 2021. Under section 9831, CMS is required to use a formula to establish a statewide wage index floor in all urban states, Washington, DC, and Puerto Rico. The imputed floor provision is not subject IPPS budget neutrality. CMS estimates the imputed floor will increase payment to 81 hospitals by $249 million in Connecticut, Delaware, Washington, DC, New Jersey, Rhode Island and Puerto Rico.

Frontier Wage Index and Outmigration. The frontier wage index increases payments about $58 million to 43 hospitals in Montana, North Dakota, South Dakota and Wyoming. The outmigration adjustment increases payments about $46 million to 159 hospitals.

NTAP. NTAP payments are not subject to budget neutrality. CMS is proposing to continue NTAP payments for 11 technologies that will remain eligible in FY 2024. CMS estimates that these 11 technologies will receive $131 million in FY 2024.

CMS received another 54 applications for NTAP for FY 2024. Of these 54 applications, 15 were withdrawn. Of the remaining 39 applications, 20 applied under an alternative pathway that only requires CMS to evaluate whether the technology meets cost criterion (not the substantial clinical improvement or the substantial similarity criteria). Of these, one did not submit information that would allow CMS to determine whether it meets the cost criterion. CMS is proposing to approve the remaining 19 applications for NTAP. It has volume information for 13 of these applications for which CMS estimates it will pay in excess of $263 million for FY 2024.

CMS estimates that its expenditures for NTAP will decline by $466 million. However, these estimates do not account for the 19 FY 2024 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 2.4 percent or about $167 million. This includes supplemental payments to Puerto Rico, Indian Health Service and Tribal Hospitals that CMS began making in FY 2023 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.

Reasonable Cost Payments for Nursing and Allied Health Education (NAHE). This provision is explained in more detail in section V.H. In summary, Medicare inadvertently overpaid NAHE reasonable cost payments associated with Medicare Advantage (MA) beneficiaries from FY 2012 through FY 2019. The Consolidated Appropriations Act (CAA), 2023 prohibited CMS from recouping those overpayments. CMS estimates the FY 2024 cost of the provision to be approximately $1.8 billion.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2024 payments to an estimated 2,910 hospitals or 84.1 percent of all hospitals eligible to receive a readmissions penalty. The proposed readmissions penalty is estimated to affect 0.53 percent of payments to the hospitals that are being penalized for excess readmissions. Table I.G.-01 illustrates the average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural, etc.) in FY 2024.

Hospital Value-Based Purchasing (HVBP) Program. The HVBP program is budget neutral but will redistribute 2 percent of base operating MS-DRG payments (approximately $1.7 billion) based on hospitals' performance scores. Table V.G.-05 (although the table is labeled I.G.-01) illustrates the proposed average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural, etc.) in FY 2024.

The estimated effects of the proposed Health Equity Adjustment (HEA) bonus points include larger mean changes in payments for both hospitals that receive bonus payments and for those that incur penalties. In a simulated analysis of the impacts of HEA bonus points in the Hospital VBP Program using FY 2023 program year data, the average bonus payment with the HEA bonus points would be $3,724 and the average penalty would be -$4,246.

Hospital Acquired Conditions (HAC) Reduction Program. An unnumbered table in the impact section of the proposed rule shows the number of hospitals participating the program (2,946) and the number (736) and percent of hospitals (25) on a national level and by category that would be in the worst performing quartile.

Rural Community Hospital Demonstration Program. CMS estimates costs for the Rural Community Hospital Demonstration Program at $37.7 million for FY 2024 and proposes applying a budget neutrality adjustment to the IPPS standardized amounts of -0.04 percent based on these total costs.

C. IPPS Standardized Amounts

The following four rate categories continue in FY 2024 (before adjustments):

	Update
Full Update	2.8%
No IQR	2.05%
No EHR	0.55%
No EHR/IQR	-0.2%

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

- MS-DRG recalibration, 1.001376 (an increase of 0.14 percent);
- MS-DRG recalibration cap, 0.999925 (a decrease of 0.01 percent)
- Wage index, 1.000943 (an increase of 0.09 percent);
- Geographic reclassification, 0.980959 (a reduction of 1.90 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.997371 or -0.26 percent;
- 5 percent cap on wage index reductions, 0.996562 or -0.34 percent;
- The outlier offset factor is 0.949 or -5.1 percent; and
- The rural community hospital demonstration program adjustment is 0.999619 or -0.04 percent.

Of the adjustments above, MS-DRG recalibration and wage index are maintained on the standardized amount from year-to-year. The prior year adjustments for geographic reclassification, wage indexes below the 25th percentile, transitioning reductions to the wage index, the outlier adjustment, and rural community hospital demonstration project are removed from the FY 2023 standardized amount before the FY 2024 adjustments are applied. The net increase in the standardized amount results as follows:

Factor	Net Change
Update	2.8%
DRG Recalibration	0.14%
DRG Recalibration Cap	-0.01%
Wage Index	0.09%
Geographic Reclassification	-0.35%
25th Percentile	-0.08%
5% Cap on Wage Index Reductions	-0.31%
Outlier	0.00%
Rural Community Hospital	0.07%
Net Change*	2.34%

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

The proposed increase in the capital rate is 4.5 percent from $483.79 to $505.54. The combined increase in the proposed operating standardized amount and the capital rate will be 2.49 percent for FY 2024.

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 2024

	Full Update=2.8%	Reduced Update Failed IQR = 2.05%	Reduced Update Failed EHR =0.55%	Reduced Update Failed IQR and EHR = -0.2%
Wage Index >1.0				
Labor (67.6%)	$4,410.86	$4,378.68	$4,134,32	$4,282.14
Non-Labor (32.4%)	$2,114.08	$2,098.66	$2,067.81	$2,052.39
WI<=1.0				
Labor (62%)	$4,045.46	$4,015.95	$3,956.92	$3,927.41
Non-Labor (38%)	$2,479.48	$2,461.39	$2,425.21	$2,407.12
National Capital Rate (All Hospitals)	$505.54			

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 $38,788 for FY 2023. 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 2024 outlier threshold. CMS proposes to adopt an outlier threshold for FY 2024 of $40,732, an increase of 5.0 percent and $1,944 from the FY 2023 amount. CMS projects that the proposed outlier threshold for FY 2024 will result in outlier payments equal to 5.1 percent of operating DRG payments and 4.16 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.958 to the capital federal rate to fund operating and capital outlier payments respectively.

FY 2024 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 (with exceptions during the COVID-19 public health emergency). For FY 2024, the latest year of claims data is the December 2022 update to the FY 2022 Medicare Provider

Analysis and Review File (MedPAR). The latest cost report data is the December 2022 update of the Provider-Specific File (PSF).

Charge Inflation. CMS is proposing to use the latest MedPAR files to compute the charge inflation factor for FYs 2021 and 2022 that it will apply to FY 2022 charges to simulate the FY 2024 outlier threshold. For this purpose, CMS will use the December 2021 MedPAR to determine FY 2021 charges and charges per case and the December 2022 MedPAR to determine the FY 2022 charges and charges per case. The rate of increase is the ratio of the FY 2022 charge per case to the FY 2021 charge per case.

These data are shown in the table below.

	Charges	Cases	Average Charge Per Case
FY 2021	$579,065,304,520	7,415,406	$78,089.49
FY 2022	$574,783,177,187	6,959,997	$82,583.83
Annual Rate of Increase			5.755%
Squared for 2 Years of Inflation			11.8412%

CCRs. CMS is proposing to adjust the CCRs from the December 2022 update of the PSF by comparing the percentage change in the national average case-weighted operating and capital CCRs between the December 2022 and December 2021 updates to the PSF.

	Operating	Capital
December 2021 PSF	0.253006	0.020200
December 2022 PSF	0.247389	0.018054
% Change	-2.22%	-10.62%
Factor	0.977990	0.893762

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 proposing to reflect reconciliation in the determination of the FY 2024 outlier threshold.

For the FY 2024 outlier threshold, CMS will use the historical outlier reconciliation amounts from the FY 2018 cost reports (cost reports with a beginning date on or after October 1, 2017, and on or before September 30, 2018). 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 2024 proposed rule, CMS is using the December 2022 extract of the Hospital Cost Report Information System (HCRIS) to determine the reconciliation amounts.

CMS determines reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2018 for FY 2024). 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 2018 resulted in 5 hospitals being owed $6,925,967 million or -0.0070806 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 $40,808 to $40,732) 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 rounded to the 2nd digit is 0.00 percent based on $383,169 in reconciled capital outlier payments owed to 5 hospitals.

FY 2022 Outlier Payments. CMS' current estimate, using available FY 2022 claims data, is that actual outlier payments for FY 2022 were approximately 6.73 percent of actual total MS-DRG payments or 1.63 percentage points more than the target of 5.1 percent—the amount the standardized amount was reduced to fund outliers. Following long-standing policy, the agency will not make retroactive adjustments to ensure that total outlier payments for FY 2022 are equal to the projected 5.1 percent of total MS-DRG payments and the amount of the reduction in the standardized amounts.

FY 2023 Outlier Payments. CMS says that FY 2023 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 2022 data, outlier payments will be 0.2 percentage points higher (or 5.3 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

CMS refers readers to prior rulemaking for history on the MS-DRGs going back to FY 2008. For the first time in many years, there is no discussion of the documentation and coding adjustment. 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.

Taken together, CMS reduced rates by 3.9 percent to recoup excess spending for documentation and coding changes subsequent to implementation of the MS-DRGs. Statutory changes

prescribed returning 2.9588 percentage points to the rate for a net permanent reduction to IPPS rates of 0.9412 percentage points.

At issue with hospitals is 0.7 percentage points of the 3.9 percent reduction. CMS determined that an additional -0.7 percentage point recoupment adjustment was necessary for FY 2017 after the Medicare Access and CHIP Reauthorization Act (MACRA) was enacted. MACRA prescribed returning 3.0 percentage of points of CMS' estimated (at that time) 3.2 percent in recoupment adjustments. Subsequent legislation reduced the first-year adjustment from 0.5 to 0.4588 percentage points. Hospitals believe the statute requires CMS to restore the additional 0.7 percentage point adjustment made to IPPS rates for FY 2017.

It now clear that CMS will not be restoring this 0.7 percentage point adjustment to the rates. Further litigation on this issue appears highly likely. Past litigation on this issue was unsuccessful but could be argued was not ripe for the court to consider as CMS still could have returned the 0.7 percentage point to IPPS rates once all statutory documentation and coding adjustments were completed.

B. Changes to Specific MS–DRG Classifications

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

Beginning with FY 2024 MS-DRG classification change requests, CMS changed the deadline to request changes to the MS-DRGs to October 20 of each year and changed the process for submitting MS-DRG classification change requests. MS-DRG change requests are only accepted submitted through the Medicare Application Request Information System™ (MEARIS). 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 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 2025 by October 20, 2023 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 41 on its website. This test software reflects the proposed GROUPER logic for FY 2024; it includes the new diagnosis and procedure codes effective for FY 2024 and does not include the diagnosis codes that are invalid beginning in FY 2024. CMS is also making available a supplemental file in Table 6P.1a that includes the mapped Version 41 FY 2024 ICD-10-CM codes and the deleted Version 40.1 FY 2023 ICD-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 2024. CMS used claims data from the September 2022 update of the FY 2022 MedPAR file, which contains hospital bills received through October 1, 2021 through September 30, 2022, for discharges occurring through September 30, 2022 (referred to as the "September 2022 update of the FY 2022 MedPAR file"). In the discussion of proposed MS-DRG reclassification, CMS will sometimes use claims data from the December 2022 update of the FY 2022 MedPAR file, which contains hospital bills received through December 31, 2022 for discharges occurring from October 1, 2021 through September 30, 2021 (referred to as the "December 2022 update of the FY 2022 MedPAR file"). As discussed below, CMS used the December 2022 update of the FY 2022 MedPAR file to assess the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split and to simulate any proposed MS-DRGs.

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.

In the FY 2021 IPPS final rule, CMS finalized its proposal to expand the existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) with a base MS-DRG to include the NonCC subgroup for a three-way severity level split.[1] 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. CMS noted that the application of the NonCC subgroup criteria may result in modifications to certain MS-DRGs that are currently split into three severity levels and result in MS-DRGs that are split into two severity levels.

In the FY 2022 IPPS final rule, due to the PHE, CMS delayed applying the NonCC subgroup criterion to existing MS-DRGs until FY 2023 or future rulemaking. Commenters recommended that a complete analysis of the MS-DRG changes in connection with the expanded three-way severity split criteria should be made available to the public for review and comment. In the FY 2023 IPPS final rule, due to the PHE, CMS again delayed application of the NonCC subgroup criterion and to provide the requested analysis.

[1] 85 FR 58448

The table below, reproduced from the rule, illustrates all five criteria and how they are applied to each CC. For FY 2024, CMS applied these criteria to its analysis of MS-DRG classification requests.

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 MedPAR data. CMS uses 2 years of data to reduce 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. The base MS-DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each subgroup is analyzed in relation to the other two subgroups using the volume (Criteria 1 and 2), average cost (Criteria 3 and 5), and reduction in variance (Criteria 5). If the criteria fail, CMS will determine if criteria are satisfied for a two-way split. A base MS-DRG is initially subdivided into two subgroups: "with MCC" and "without MCC" or with "CC/MCC" and "without "CC/MCC and each subgroup is analyzed to the other using the 5 criteria. 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. If the three-way split fails on any one of the five criteria and meets all of the five criteria for both two-way splits, CMS would apply the two-way split with the highest R2 value. CMS notes that if the request is to split an existing base MS-DGR into severity levels and the request is for one of the two-way splits, CMS will not also evaluate the criteria for a three-way split.

Application of the NonCC subgroup criteria. Using the December 2022 update of the FY 2022 MedPAR file, CMS assessed the application of the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels. CMS also determined whether a proposed new base MS-DRG satisfied the criteria to create subgroups. CMS found that approximately 45 base MS-DRGs would be subject to change based on applying the three-way severity criteria. Specifically, CMS found that applying the NonCC subgroup criteria to all MS-DRGs currently split into three severity levels would delete 135 MS-DRGs (45MS-DRGs x 3 severity levels = 135) and create 86 new MS-DRGs. Table 6P.10a contains the list of the 135 MS-DRGs that would be subject to deletion and Table 6P.10b the list of the 86 new MS-DRGs that would be proposed if the NonCC subgroup criteria were applied. In response to prior public comments expressing concern about the historical low volume of the obstetric related MS-DRGs being subject to the application of the NonCC subgroup criteria, CMS proposes to exclude these MS-DRGs from application of the NonCC subgroup criteria. A table in the proposed rule lists these 12 Obstetric MS-DRGs.

CMS also provides additional related analysis. Table 6P.10d lists all 49 base MS-DRGs that would be subject to change based on the application of the three-way severity level split and Table 6P.10e is the corresponding data dictionary. CMS discusses the four base MS-DRGs (MS-DRGs 283, 296, 411 and 799) currently subdivided with a three-way severity split that result in a potential creation of a single, base MS-DRG.

Table 6P.10f lists the alternate cost weight analysis with application of the NonCC subgroup criteria that includes transfer-adjusted cases from the December 2022 update of the FY 2022 MedPAR file. CMS discusses five MS-DRGs (existing MS-DRGs 021, 411, 573, 574 and 799) which appear to have more than a negative 10% change between the relative weight calculated without and with the application of the NonCC subgroup criteria.

CMS reiterates that any potential MS-DRG updates in connection with application of the NonCC subgroup criteria would also involve a redistribution of cases, which would impact the relative weights and thus payment rates for particular types of cases. In addition to the tables within Table 6P, CMS provides additional files reflecting application of the NonCC subgroup criteria in connection with the FY 202 MS-DRG changes, using the December 2022 update of the FY 2022 MedPAR file. These additional files include an alternate Table 5 and an alternate test version of the ICD-10 MS-DRG GROUPER Software, Version 41.1. CMS notes that the alternate test software reflects the proposed GROUPER logic for FY 2024 modified by the application of the NonCC subgroup criteria. These tables are not published in the Addendum to this proposed rule, but are available on the CMS website at https://www.cms.gov/Medicare/Mediicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html. The alternate test version of the GROUPER Software and the supplemental mapping files in Table 6P.1a are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

CMS is making these additional analyses reflecting application of the NonCC subgroup criteria to inform application of the NonCC subgroup criteria for FY 2025 rulemaking. CMS is interested in feedback for consideration for the development of the FY 2025 proposed rule.

2. MDC 01 (Diseases and Disorders of the Nervous System: Epilepsy with Neurostimulator

CMS received a request to again review the MS-DRG assignment for cases involving the use of the RNS© neurostimulator, a cranially implanted neurostimulator used as a treatment option for individuals diagnosed with medically intractable epilepsy. Cases involving the RNS© neurostimulator are captured within four ICD-10-PCS codes (listed in the proposed rule) and are assigned to MS-DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS PDX with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator). The requestor asked CMS to reassign these cases to MS-DRG 021 (Intracranial Vascular Procedures with PDX Hemorrhage) or to create a new MS-DRG for cases involving a craniectomy/craniotomy with a device implant. As another option, the requestor identified procedures involving a craniectomy or craniotomy by searching for ICD-10-PCS codes that describe the root operations "Destruction", "Insertion", and other related words performed related to the brain anatomy with an "Open Approach" in the claims data. The requestor identified claims involving a device implant with an ICD-10-PCS code that describe the root operation "Insertion" and found that these claims had average costs comparable to the average costs of RNS cases. The requestor stated that creating a new MS-DRG for all cases involving a craniectomy/craniotomy with a device implant was a reasonable alternative option.

The requestor submitted a similar request for FY 2021. At that time, CMS concluded that further analysis of claims data would be necessary to support reassignment of cases involving the use of the RNS neurostimulator.

Based on its analysis of MS-DRG 023, CMS determined that the number of cases involving the RNS© neurostimulator (57 cases) is too small to warrant creating a new MS-DRG for these cases. CMS also examined the reassignment of these cases to MS-DRGs 020 -022. CMS also analyzed the cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the RNS neurostimulator) with a principal diagnosis of epilepsy for the presence or absence of a secondary diagnosis designated as a CC or an MCC. These two analyses showed that the average costs and length of stay are not similar to the cases in MS-DRGs 020-022. CMS' clinical advisors also reviewed the claims data and the clinical issues and did not support reassigning these cases because RNS neurostimulators are not used to treat patients with a diagnosis of hemorrhage.

CMS also analyzed how applying the NonCC subgroup criteria to MS-DRGs 020-022 and found that these MS-DRGs would potentially be subject to change based on the three-way split criteria.

CMS does not agree with searching for ICD-10-PCS codes that describe root operations. Instead, CMS explored alternative options, including examination of cases reporting a procedure code combination representing neurostimulator generator and lead code combinations that are listed as "Major Device Implant" in MS-DRGs 023 and 024 (Cases with neurostimulator, Major Device Implant list cases) with and without a principal diagnosis of epilepsy. CMS only identified 57 cases for MS-DRG 023 and zero cases for MS-DRG 024.

CMS again concludes that additional time is needed to evaluate these cases and CMS is not proposing to reassign these cases or create a new MS-DRG. CMS is also not proposing to create a new MS-DRG for cases involving a craniectomy/craniotomy with device implant.

CMS notes that as part of its analysis of cases reporting LITT procedures performed on the brain or brain stem, it has started to examine the logic for case assignment to MS-DRGs 023-027 to determine where refinements could potentially be made to better account for differences in technical complexity and resource utilization among the procedures assigned to these MS-DRGs. CMS believes that further analysis of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain and a principal diagnosis of epilepsy should be included in its analysis of claims data for MS-DRGs 023-027. CMS is examining procedures by their approach, clinical indications, and whether the procedure involves the insertion or implantation of a device. **CMS continues to seek comments and feedback on factors that should be considered in the potential restructuring of these MS-DRGs.** Feedback may be submitted by October 20, 2023 using the MEARIS.

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

CMS received a request to again review the reassignment of cases reporting diagnosis codes describing central retinal artery occlusion (CRAO). The requestor performed an internal analysis of their claims data and found that the average cost of cases reporting a procedure code describing the administration of a thrombolytic agent with a principal diagnosis of CRAO were 2.5 times higher than similar cases without the administration of a thrombolytic agent. The requestor suggested that these cases be reassigned from MS-DRG 123 (Neurologic Eye Disorder) to three new MS-DRGs created for neurologic eye disorders with thrombolytic agent (MCC, CC, and without CC/MCC).

Although the requestor did not include branch retinal artery occlusion (BRAO), it is a closely allied condition that was included in the prior request, CMS used both diseases in its analysis. CMS summarizes its review of this request and again concludes that the small subset of patients (38 cases) with a diagnosis of CRAO or BRAO receiving a thrombolytic agent does not warrant a separate MS-DRG or reassignment.

CMS recognizes that the average costs of a small number of cases reporting a principal diagnosis describing CRAO or BRAO with a procedure code describing administration of a thrombolytic agent are greater when compare to the average costs of all cases in 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. After additional consideration, CMS thought that these cases could be more suitably group to MS-DRGs 124 and 125 (Other Disorder of the Eye with MCC, and without MCC, respectively). CMS examined the average costs and length of stay for cases in MS-DRGs 124 and 125 and concluded that cases reporting a principal diagnosis describing CRAO or BRAO with administration of a thrombolytic agent more aligned with the average costs of MS-DRG 124.

For FY 2024, CMS proposes to reassign the eight ICD-10-CM diagnosis codes that describe CRAO and BRAO (see table in the proposed rule) from MDC 02 MS-DRG 123 to MS-DRGs 124 and 125. CMS also proposes to add the procedure codes describing the administration of a thrombolytic agent to MS-DRG 124; CMS notes these are “non-O.R. procedures”. CMS also proposes to change the titles of MS-DRGs 124 and 125 to “Other Disorders of the Eye with MCC or Thrombolytic Agent, and without MCC, respectively.

4. MDC 04 (Diseases and Disorders of the Respiratory System

a. Ultrasound Accelerated Thrombolysis for Pulmonary Embolism

A requestor asked CMS to reassign cases reporting ultrasound accelerated thrombolysis (USAT) with the administration of thrombolytic(s) for the treatment of pulmonary embolism (PE) from MS-DRGs 166-168 (Other Respiratory System O.R. Procedures with MCC, with CC and without CC/MCC, respectively) to MS-DRGs 163-165 (Major Chest Procedures). According to the requestor (the manufacture of the EKOS™ EkoSonic® Endovascular System (EKOS System), as compared to conventional catheter-directed thrombolysis (CDT), the EKOS System employs ultrasound to assist in thrombolysis (USAT). The requestor stated that USAT utilizes more resources that other procedures assigned to MS-DRGs 166-168 and is not clinically coherent with other procedures assigned to those MS-DRGs. A table in the proposed rule lists the ICD-10-PCS procedure codes for cases reporting USAT for PE. CMS notes that the requestor did not include a list of diagnosis codes describing PE or a list of procedure codes describing the administration of thrombolytic(s).

In the FY 2021 IPPS final rule, CMS summarized and responded to public comments concerning the proposed MS-DRG assignments for the newly created procedure describing USAT of several anatomic site. Commenters recommended that USAT procedures for the treatment of PE be assigned to MS-DRGs 163-165. CMS finalized the assignment of USAT procedures to MS-DRGs 166-168.

CMS summarizes its review of this request. CMS notes that the listed procedure codes describing USAT identified for its claims analysis differs from the procedure codes identifies by the requestor. Based on its review of the data for MS-DRGs 166-168 and analysis of cases reporting a principal diagnosis of PE and USAT procedure with and without administration of thrombolytic(s), CMS thought that the administration of thrombolytic(s) is not a significant factor in the consumption of resources for cases when USAT is performed in the treatment of PE. Because the administration of thrombolytic(s) would be expected to increase resource consumption, the results suggested that the administration of thrombolytic(s) was not consistently reported.

Based on its finding that suggested that the administration of thrombolytic(s) may not have been consistently reported on claims that identified USAT was performed, CMS analyzed claims data in MS-DRGs 163-165 and compared it to cases reporting a principal diagnosis of PE and USAT procedure with or without thrombolytic(s) in MS-DRGs 166-168. Based on this analysis, CMS did not support reassigning cases reporting an USAT procedure with administration of thrombolytic(s) and a principal diagnosis of PE to MS-DRGs 166-168. CMS then examined cases reporting CDT procedures with or without thrombolytic(s) for the treatment of PE in MS-DRGs 166-168 and compared these findings to similar cases reporting USAT.

Based on its review and various claims data analysis for cases in MS-DRGs 163-165 and MS-DRGs 166-168, CMS states the differences in resource consumption warrants reassignment of these cases. CMS does not believe, however, that patients undergoing a thrombolysis (CDT or USAT) procedure for PE are clinically aligned with patients and resources as cases in MS-DRGs 166-168. CMS concludes that a new MS-DRG would reflect more appropriate payment for

USAT and standard CDT procedures in the treatment of PE. Based on evaluation of the new base MS-DRG, CMS concludes that the criteria for a three-way split and a two-way split failed.

For FY 2024, CMS proposes to create new base MS-DRG 173 (USAT and Other Thrombolysis with Principal Diagnosis PE). CMS proposes to define the logic for this MS-DRG using the previously diagnosis codes for USAT and CDT listed in the proposed rule.

b. Respiratory Infections and Inflammations Logic

CMS discusses the logic for case assignments to MS-DRGs 177-179 as displayed in the ICD-10 MS-DRG V40.1 Definitions Manual. For FY 2024, CMS proposes to correct the logic for case assignment to MS-DRG 177 by excluding 15 diagnosis codes from the first logic list "Principal Diagnosis with Secondary Diagnosis" and from acting as an MCC when any one of these codes is reported as a secondary diagnosis with a diagnosis code from the second logic list "or Principal Diagnosis" reported as the principal diagnosis.

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

a. Surgical Ablation

A requestor asked CMS to review the MS-DRG assignments of cases involving open concomitant surgical ablation procedures. The requestor recommended that CMS reassign open concomitant surgical ablation procedures for atrial fibrillation (AF) from MS-DRGs 219 -220 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization) to MS-DRGs 216-218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization). The requestor recommended that if CMS didn't reassign these cases, CMS should create new MS-DRGs for all open mitral or aortic valve repair or replacement procedures with concomitant surgical ablation for AF. The requestor suggested three new MS-DRGs to reflect the number of procedures performed: 2, 3, and 4+ procedures. Based on its own analysis, the requestor stated that the data continues to demonstrate that claims with open surgical ablation procedures for AF are not clinically similar to the remaining cases in MS-DRGs 219-221, and these clinical differences are associated with significant differences in resource utilization.

CMS discusses its review of similar requests for the FY 2022 and FY 2023 IPPS rules. For FY 2022, CMS finalized revision of the surgical hierarchy for the MS-DRGs in MDC 05 to sequence MS-DRGs 231-236 (Coronary Bypass, with or without PTCA, with or without Cardiac Catheterization or Open Ablation) above MS-DRGs 228 and 229 (Other Cardiothoracic Procedures) and assigned cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MD-DRGs 233 and 234. For FY 2023, CMS believed that additional time was necessary to allow further analysis of the claims data to determine to what extent patient's comorbidities or other contributing factors might be contributing to the higher costs for these procedures.

CMS summarizes its review of this request. Consistent with prior analysis, CMS found variation in the volume, length of stay and average costs of these cases for MS-DRGs 216-221. The data continued to show that the increase in average costs appears to directly correlate with the number of procedures performed.

In response to the request to reassign these to MS-DRGs 216-218, CMS continues to be concerned about reporting cases that do not have a cardiac catheterization into these MS-DRGs. CMS also analyzed applying the NonCC subgroup criteria to MS-DRGs 216-218, and found that the number of cases in MS-DRG 218 is below 500 and these MS-DRGs would be subject to change based on the three-way severity level split criteria.

To determine the extent that the number of procedures performed is contributing to higher utilization, CMS analyzed the cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation assigned to MS-DRGs 216-221. This analysis shows that cases reporting aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure plus another concomitant procedure have higher average costs and generally longer lengths of stay compared to all cases in their assigned MS-DRG. CMS concludes that a new MS-DRG for these cases would be appropriate. Based on evaluation of the new base MS-DRG, CMS concludes that the criteria for a three-way split and a two-way split failed because of lack of 500 or more cases in each subgroup.

CMS concludes that it clinically requires greater resources to perform an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure. For FY 2024, CMS proposes to create a new base MS-DRG for these cases. The proposed new MS-DRG is MS-DRG 212 (Concomitant Aortic and Mitral Valve Procedures). Table 6P.41 associated with the proposed rule includes the list of procedure codes proposed to define in the logic for the proposed new MS-DRG.

b. External Heart Assist

CMS received a request to reassign certain cases reporting procedure codes describing the insertion of a short-term external heart assist device using an axillary artery conduit from MS-DRG 215 to MS DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System) and Ms-DRG 003 (ECHMO or Tracheostomy with MV>96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures). According to the requestor, the manufacturer of the Impella® Ventricular Support System, this device is indicated for more complex patients that other femoral artery access percutaneous ventricular assist devices (pVADs) that treat cardiogenic shock. The requestor stated that the Impella 5.5 with SmartAssist is more clinically comparable to implantable heart assist systems, such as left ventricular assist devices (LVADs) and the insertion of the device must be performed by a surgeon in the operating room. The requestor stated that analysis showed a significant variation in the resource utilization for patients treated with the device compared to patients treated with other femoral access pVADs assigned to MS-DRG 215. The requestor also submitted a request for a new ICD-10-PCS procedure code to describe the Impella 5.5 with SmartAssist System.

CMS discusses a similar request received for FY 2022. CMS' clinical advisors reviewed this clinical issue and claims data and finalized assigning ICD-10-PCS codes that describe the insertion of a short-term external heart assist device using an axillary artery conduit (02HA0RJ, 02HA3RJ, or 02HA4RJ) to MS-DRGs 216-221.

CMS summarizes its review of this request. CMS agrees with the requestor that the insertion of a short-term external heart assist device using an axillary artery conduit (such as the Impella 5.5 with SmartAssist System) is not separately identifiable in the claims data. CMS identified cases

reporting the three ICD-10-PCS codes for MS-DRG 215 and found that cases reporting a procedure code describing the open insertion of a short-term external heart assist device are generally more resource intensive and are clinical distinct from other cases reporting procedure codes describing the insertion of short-term external heart devices by other approaches assigned to MS-DRG 215. A simulation of reassigning ICD-10-PCS procedure code 02HA0RZ to MS-DRGs 001 and 002 supports that the resulting MS-DRG assignments would be more clinically homogenous and better reflect resource use.

For FY 2024, CMS proposes to reassign ICD-10-PCS code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) from MDC 05 in MS-DRG 215 to Pre-MDS MS-DRG 001 and 002. If a new procedure code for the Impella 5.5 with SmartAssist System is finalized, this information will be included in the FY 2024 code files made available in May/June.[2] CMS would use its established process for MS-DRG assignment which examines the MS-DRG assignment for the predecessor codes to determine the most appropriate MS-DRG assignment.

c. Ultrasound Accelerated Thrombolysis

A requestor asked CMS to reassign cases reporting ultrasound accelerated thrombolysis (USAT) of peripheral vascular structure procedures with the administration of thrombolytic(s) for the treatment of deep venous thrombosis (DVT) from MS-DRGs 252-254 (Other Vascular Procedures) to MS-DRGs 270-272 (Other Major Cardiovascular Procedures). According to the requestor (the manufacture of the EKOS™ EkoSonic® Endovascular System (EKOS System), as compared to conventional catheter-directed thrombolysis (CDT), the EKOS System employs ultrasound to assist in thrombolysis (USAT). The requestor stated that USAT utilizes more resources that other procedures assigned to MS-DRGs 252-254 and is not clinically coherent with other procedures assigned to those MS-DRGs. A table in the proposed rule lists the ICD-10-PCS procedure codes for cases reporting USAT for PE. CMS notes that the requestor did not include a list of diagnosis codes describing PE or a list of procedure codes describing the administration of thrombolytic(s).

In the FY 2021 IPPS final rule, CMS summarized and responded to public comments concerning the proposed MS-DRG assignments for the newly created procedure describing USAT of several anatomic site. Commenters recommended that USAT procedures for the treatment of DVT be assigned to MS-DRGs 270-272. CMS finalized the assignment of USAT procedures to MS-DRGs 252-254.

CMS summarizes its review of this request. For this analysis, CMS does similar analysis previously described above for a similar request for reassignment of USAT procedures for PE.

Based on its review of the data for MS-DRGs 252-254 and analysis of cases reporting a principal diagnosis of DVT and USAT procedure with and without administration of thrombolytic(s), CMS thought that the administration of thrombolytic(s) may be considered a factor in the consumption of resources when USAT is performed for the treatment of a DVT. Since the request was the reassignment of these cases to MS-DRGs 270-272, CMS analyzed claims data for cases in MS-DRGs 270-272 and compared it to cases reporting a principal diagnosis of DVT.

[2] This information will be available at https://cms/gov/medicare/coding/icd10.

Based on this analysis, CMS did not support reassigning cases reporting an USAT procedure with administration of thrombolytic(s) and a principal diagnosis of PE to MS-DRGs 270-272. CMS conducted additional analyses to determine if there were significant differences in resource utilization for cases reporting standard CDT as compared to USAT procedures done with or without thrombolytic(s) for the treatment of DVT.

Based on the review and various claims data analysis CMS agreed that the differences in resource consumption warrants reassignment of these cases. CMS does not believe, however, that patients undergoing a thrombolysis (CDT or USAT) procedure for DVT are clinically aligned with patients and resources as cases in MS-DRGs 270-272. CMS concludes that a new MS-DRG would be more appropriate for payment for USAT and standard CDT procedures for treatment of DVT. Based on evaluation of the new base MS-DRG, CMS concludes that a two-way split of the base-MSG met all five criteria.

For FY 2024, CMS proposes to create two new MS-DRGs: new MS-DRG 278 (USAT and Other Thrombolysis of Peripheral Vascular Structures with MCC) and MS-DRG 278 (USAT and Other Thrombolysis of Peripheral Vascular Structures without MCC). CMS proposes to define the logic for this MS-DRG using the previously diagnosis codes for USAT and CDT listed in the proposed rule.

d. Coronary Intravascular Lithotripsy

CMS received a request to review the MS-DRG assignment of cases describing percutaneous coronary intravascular lithotripsy (IVL) involving the insertion of a coronary drug-eluting stents. According to the requestor, PCIs involving coronary IVL are clinically more complex and associated with greater resources. The requestor's analysis of claims date for cases reporting procedure codes describing coronary IVL in MS-DRGs 246 and 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+Arteries of Stents and without MCC, respectively) showed a significant disparity in total standardized costs for cases in MS-DRG 247. The requestor recommended reassigning all cases reporting procedure codes describing percutaneous coronary IVL involving the insertion of a drug-eluting intraluminal device from MS-DRG 247 to MS-DRG 246. The requestor also asked CMS to analyze these cases to determine if reassignment from MS-DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent without MCC) to MS-DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug Eluting Stent with MCC or 4+ Arteries or Stents) would be appropriate.

CMS notes that the Shockwave C2 IVL indicated for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting, was approved for new technology add-on payments for FY 2022 and FY 2023. As discussed below in section D, for FY 2024, CMS proposed to discontinue the new technology add-on payments. A table in the proposed rule lists the four ICD-10-PCS procedure codes that describe percutaneous coronary IVL.

CMS summarizes its review of this request. CMS notes that there are instances where an intraluminal device is not able to be inserted after coronary IVL and for its analysis of MS-DRG 246-249, CMS also included cases reporting percutaneous IVL without describing the insertion of an intraluminal device that group to MS-DRGs 250 and 251 (Percutaneous Cardiovascular

Procedures without Coronary Artery Stent). The data analysis shows that the average cost of cases reporting percutaneous coronary IVL, with or without the insertion of an intraluminal device, are higher than for all cases in their respective MS-DRG. The data also shows that average costs are generally similar without regard as to whether a drug-eluting or non-drug-eluting intraluminal device was placed.

CMS agrees that percutaneous coronary IVL contributes to increased resource consumption for these PCI procedures; these cases have higher average costs and generally longer lengths of stay compared to all the cases in their assigned MS-DRG. CMS proposes to create new MS-DRGs for percutaneous coronary IVL involving the insertion of an intraluminal device. Based on its analysis, CMS concludes that a two-way split of the base MSG met all five criteria. In addition, although CMS generally prefer not to create a new MS-DRG unless it includes a substantial number of cases, CMS proposes to create a new MS-DRG for cases describing percutaneous coronary IVL without the insertion of an intraluminal device even through the total number of identified cases was 404. CMS concludes that a new MS-DRG would reflect more appropriate payment for USAT and standard CDT procedures in the treatment of DVT. Based on evaluation of the new base MS-DRG, CMS concludes that a two-way split of the base-MSG met all five criteria.

For FY 2024, CMS proposes to create two new MS-DRGs for cases describing coronary intravascular lithotripsy involving the insertion of an intraluminal device and one new MS-DRG for cases describing coronary intravascular lithotripsy without an intraluminal device:

- MS-DRG 323 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC);
- MS-DRG 324 (Coronary Intravascular Lithotripsy with Intraluminal Device without MCC); and
- MS-DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device).

CMS proposes to define the logic for this MS-DRG using the previously diagnosis codes for USAT and CDT listed in the proposed rule.

MS-DRG assignments for insertion of coronary stents in PCIs. CMS discusses the above analysis that shows that in percutaneous cardiovascular procedures involving the insertion of an intraluminal device, the average costs are generally similar without regard as to whether a drug-eluting or non-drug eluting intraluminal device(s) was inserted. CMS notes that a request for the FY 2022 rulemaking suggested CMS eliminate the distinction between drug-eluting and bare-metal coronary stents in the MS-DRG classification. In response to this request, CMS stated that it needed more extensive analysis and would consider this request in future rulemaking.

CMS discusses why it believes it may no longer be necessary to subdivide the MS-DRGs based on the type of coronary intraluminal device inserted. CMS proposes to delete MS-DRGs 246-249 and create new MS-DRGs. CMS summarizes its analysis of this proposal and concludes it is no longer necessary to subdivide the MS-DRGs for percutaneous cardiovascular procedures based on the type of coronary intraluminal device inserted.

For FY 2024, CMS proposes to delete MS-DRGs 246-249 and create a new base MS-DRG with a two-way severity level split for cases describing percutaneous cardiovascular procedures with intraluminal device in MDC 05:

- MS-DRG 321 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices) and
- MS-DRG 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC)

CMS proposes to add the procedure codes from MS-DRGs 246-249 to the new proposed MS-DRGs 250 and 251.

e. Shock

CMS received a request to add ICD-10-CM diagnosis R57.0 (Cardiogenic shock) to the list of "secondary diagnoses" that group to MS-DRGs 223 and 223 (Cardiac Defibrillator Implant with Cardiac catheterization with Acute Myocardial Infarction (AMI), Heart Failure (HF), or Shock.

CMS summarizes its analysis which include the GROUPER logic and the claims data for MS-DRGs 222 and 223, MS-DRGs 224 and 225 (Cardiac Defibrillator Implant with Cardiac catheterization without AMI, HF or Shock), and MS-DRGs 226 and 227 (Cardiac Defibrillator Implant without Cardiac catheterization).

Based on this data, CMS does not propose modifying the grouper language to allow cases reporting diagnosis code R57.0 as a secondary diagnosis to group to MS-DRGs 222 and 223 when reported with qualifying procedures.

CMS discusses that the analysis shows that for procedures involving a cardiac defibrillator implant, the average costs and length of stay are generally similar without regard to the presence of diagnosis codes describing AMI, HF or shock. The analysis of MS-DRGs 222-227 demonstrates that the average length of stay and average costs for all cases are similar for each of the "without MCC" subgroups. CMS believes that it is no longer necessary to subdivide these MS-DRGs based on the diagnosis codes reported and supports the removal of the special logic defined as "Principal Diagnosis AMI/HF/Shock" should be removed from the definition for assignment to any proposed modifications to the MS-DRGs.

CMS proposes the deletion of MS-DRGs 222-227 and the creation of three new MS-DRGs. This proposal includes the creation of one base MS-DRG for reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designed as an MCC and another base MS-DRG split by a two-way severity level subgroup for cases reporting a cardiac defibrillator implant without cardiac catheterization. CMS simulation of these proposals showed the proposed MS-DRG assignment of diagnosis codes is more clinically homogeneous, coherent and better reflects hospital resources.

For FY 2024, CMS proposes to delete MS-DRGs 222-227 and create a new MS-DRG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC in MDC 05. CMS is also proposing to create two new MS-DRGS with the two-way severity level split for cases reporting a cardiac defibrillator implant without

additionally reporting both a cardiac catheterization and a secondary diagnosis designated as an MCC. These proposed new MS-DRGs are:

- MS-DRG 275 (Cardiac Defibrillator Implant with Cardiac catheterization and MCC)
- MS-DRG 276 (Cardiac Defibrillator Implant with MCC)
- MS-DRG 277 (Cardiac Defibrillator Implant without MCC)

Tables 6P.7a 6P.7b contains the list of procedure codes CMS is proposing to define the logic for teach of the proposed new MS-DRGs.

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

In the FY 2023 IPPS proposed rule, CMS discussed a request to reconsider the MS-DRG assignment for diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess). CMS noted this topic has been previously discussed in both FY 2019 and FY 2021 rulemakings and summarizes its previous decisions.[3] 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 would consider review of these codes.

Effective for discharges on and after October 1, 2023, there are six new diagnosis codes for describing acute appendicitis with generalized peritonitis, with and without perforation of abscess. A table in the proposed rule assigns these new codes to MS-DRGs 371-373 (Major Gastrointestinal Disorders and Peritoneal Infections).

Based on the revision of the diagnosis codes, CMS believes it is appropriate to address the prior MS-DRG request for diagnosis code K35.20. CMS analysis includes MS-DRGs 371-373, MS-DRGs 338-340 (Appendectomy with Complicated Principal Diagnosis) and MS-DRGs 340-343 (Appendectomy without Complicated Principal Diagnosis). The analysis shows that for both "complicated" and "uncomplicated" diagnosis the groups have comparable average length of stay and similar average costs when compared to the average length of stay and average costs of all the cases in the representative MS-DRG. CMS believes the findings support that clinically, both localized and generalized peritonitis in association with an appendectomy require the same level of patient care and supports eliminating the logic for "complicated" and "uncomplicated" diagnoses and restructuring the six MS-DRGs.

CMS proposes the deletion of MS-DRGs 338-343 and the creation of three new MS-DRGs:

- MS-DRG 397 (Appendix Procedures with MCC);
- MS-DRG 398 (Appendix Procedures with CC); and
- MS-DRG 399 (Appendix Procedures without CC/MCC)

These proposed new MS-DRGs would no longer require a diagnosis in the definition of the logic for case assignment. CMS proposes to include the current list of appendectomy procedures in the logic for case assignment of appendix procedures for the proposed new MS-DRGs.

[3] 83 FR 41230, 85 FR 32500 through 32503, and 85 FR 58484 through 58488.

7. MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas: Alcoholic Hepatitis

CMS received a request to create new MS-DRGs with a two-way slip (with MCC and without MCC) for cases reporting alcoholic hepatitis. Cases with alcoholic hepatitis identified with ICD-10-CM diagnosis codes K70.10 (Alcoholic hepatitis without ascites) and K70.11 (Alcoholic hepatitis with ascites) are assigned to MS-DRGs 432-434 (Cirrhosis with Alcoholic Hepatitis). The requestor (the manufacturer of Larsucosterol) stated that based on two years of claims data it found that patients with alcoholic hepatitis are younger than the typical Medicare beneficiary, represent only a small proportion of cases in these MS-DRGs, and have a higher resource utilization and a longer length of stay when compared to all the cases in MS-DRGs 432-444.

CMS summarizes the analysis of the MS-DRGs 432-444. Based on these results, CMS believes the cases with a principal diagnosis of alcoholic hepatitis without or with ascites demonstrate similar patterns of resource intensity in comparison to the other cases. CMS also believes these diagnoses are clinically coherent with the other diagnoses in these MS-DRGs.

For FY 2024, CMS proposes to maintain the structure of MS-DRGs 432-434. Based on its analysis of the NonCC subgroup criteria to all MS-DRGs, CMS found that these MS-DRGs would be subject to change based on the three-way severity split.

8. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue: Spinal Fusion

The manufacturer of the aprevo™ customized interbody fusion device requested cases reporting spinal fusion procedures utilizing this device be reassigned from the lowest severity to the higher severity level for the following MS-DRG groups: MS-DRG 455 (Combined Anterior and Posterior Spinal Fusion without CC/MCC) to 453 (with MCC); from MS-DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions without CC/MCC) to 456 (with MCC); and from MS-DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively to MS-DRG 456.

CMS notes that the aprevo customized interbody fusion device technology was approved for new technology add-on payments for FY 2022 and FY 2023. As discussed below in section D, for FY 2024, CMS proposes to continue the new technology add-on payments. A table in the proposed rule lists the 12 ICD-10-PCS procedure codes that describe the ICD-10-PCS codes for this technology.

The requestor discussed concerns that its analysis of claims data for the first half of FY 2022 indicate there may be unintentional miscoded claims from providers who are not customers of the aprevo custom-made device. The requestor found that cases utilizing an aprevo custom-made device had higher average costs in comparison to the average costs in the highest severity level MS-DRGs 453 and 456.

CMS summarizes its review of this request. CMS analyzed data for MS-DRGs 453-460 for cases reporting any one of the procedure codes describing utilization of an aprevo customized interbody spinal fusion device. CMS agrees that the findings appear to indicate that cases reporting a procedure utilizing an aprevo custom device reflect a higher consumption of resources. However, due to the concerns expressed by the requestor about the suspected

inaccuracies of the coding, CMS is concerned about the reliability of the claims data and it believes further review is warranted. CMS also note that because of this potential miscoding issue, the requestor proposed revising the ICD-10-PCS procedure codes at the March 2023 ICD-10 Coordination and Maintenance Committee meeting. If finalized, the revised coding may also improve the reporting of procedures using this technology.

For FY 2024, CMS proposes to maintain the current structure of MS-DRGs 453-460.

9. MDC 11 (Diseases and Disorder of the Kidney and Urinary Tract): Complications of Arteriovenous Fistulas and Shunts

CMS received a request to add eight ICD-10-CM diagnosis codes describing complications of arteriovenous fistulas and shunts (see list in the proposed rule) assigned to MS-DRGs 673-675 (Other Kidney and Urinary Tract Procedures) in MDC 11 when reported with procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices. The requestor noted that diagnosis codes that describe complications of dialysis catheters are listed as qualifying principal diagnoses in MS-DRGs 573-675 when reported codes describing the insertion of TIVADs or tunneled vascular access devices.

CMS summarizes its review of this request with including reviewing the GROUPER logic for MS-DRGs 673-675 and the examine the impact of moving eight MDC 05 diagnoses codes to MDC 11. CMS found that if they moved these eight diagnosis codes describing mechanical complications of arteriovenous fistulas and shunts to MDC 11, cases reporting one of the O.R. procedures assigned to MDC 05 (see table in the proposed rule) would inappropriately be assigned to the surgical class referred to as "unrelated operating room procedures". CMS believes these eight diagnosis codes are more clinically aligned with the diagnosis codes assigned to MDC 05.

CMS proposes not to add the requested ICD-10-CM codes to the list of principal diagnosis codes for MS-DRGs 673-675 when reported with a procedure describing the insertion of a TIVAD or a tunneled vascular access device.

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:

- Percutaneous Endoscopic Resection of Colon;
- Open Excision of Muscle;
- Open Replacement of Skull with Synthetic Substitute;

- Endoscopic Dilation of Ureters with Intraluminal Device; and
- Occlusion of Splenic Artery;

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.

Due to the PHE, CMS stated thought it would be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. For FY 2024, CMS continues to believe additional time is necessary to develop the process and methodology. CMS will provide more details in future rulemaking.

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[4], 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.

Overview of Comprehensive CC/MCC Analysis. 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 the 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.[5] 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 analyses using a combination of the prior mathematical analysis of claims data in combination with the guiding principles. CMS has made available on the CMS website updated impact on resource use files for public review of the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2022 MedPAR files.[6] **CMS encourages commenters to provide a detailed explanation of how applying a suggested concept would ensure that the severity designation appropriately reflects resource use for any diagnosis code**. CMS is also interested in how it can improve the reliability and validity of the coding data.

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

[4]72 FR 47152 through 47171
[5]84 FR 42150 through 42152
[6] These files are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

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.

Proposed Changes to Severity Levels for SDOH. In the FY 2023 IPPS proposed rule, CMS requested public comments on how reporting of diagnosis codes in categories Z55-Z65 might improve its ability to recognize severity of illness, complexity of illness, and/or utilization of resources under MS-DRGs. CMS also sought comments on which specific Social Determination of Health Diagnosis (SDOH) codes were most likely to increase hospital resource utilization for inpatient care. CMS noted that homelessness was one of the more frequently reported codes that describe social determinants of health and CMS reviewed the data on the impact on resource use for Z59.0 (Homelessness) when reported as a secondary diagnosis. Effective FY 2022, this subcategory now includes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and code Z59.02 (Unsheltered homelessness).

In this proposed rule, CMS reviewed the data on the impact on resource use for the ICD-10-CM SDOH Z codes that describe homelessness, currently designated as NonCC, when reported as a secondary diagnosis. The data continues to suggest that when the three SDOH Z codes as reported as a secondary diagnosis, the resources involved in caring for a patient experiencing homelessness support increasing the severity level from a NonCC to a CC.

For FY 2024, CMS proposes to change the severity level designation for the three ICD-10-CM diagnosis codes describing homelessness (Z59.00, Z59.01, and Z59.02) from NonCC to CC. CMS may consider changes for other SDOH codes in the future.

CMS continues to be interested in feedback on how it can foster the documentation and reporting of the diagnosis codes describing social and economic circumstances. Feedback and other suggestions may be submitted by October 20,2023 through MEARIS.

Request for Changes to Severity Levels. CMS received several requests to change the severity level designations of specific ICD-10-CMS codes. CMS will consider these individual requests as it continues its comprehensive CC/MCC analysis.

b. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2024
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.

c. Proposed CC Exclusions List for FY 2024

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 ICD-10 MS-DRGs Version 40.1 CC Exclusion List is included as Appendix C in the ICD-10 MS-DRG Definitions Manual with is available on the CMS website link at https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/AcuteInpatientPPS/index.html and includes two list identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. A link is provided to a collection of diagnosis codes, which when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

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.

CMS also identified 668 diagnosis codes listed on various principal diagnosis collection lists that are not able to be reported as a principal diagnosis based on the ICD-10-CM Official Guidelines for Coding and Reporting. In addition, these codes are listed on the MCE code edit lists as not allowed as principal diagnosis. CMS identifies these codes on a supplementary table:

- Table 6H.3 – Principal Diagnosis Codes for Removal from 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 40 (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 received one MCE request related to the Sex Conflict edit related to claims processing for transgender individuals. This request and proposals based on CMS' internal review and analysis are discussed below. 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.
- Manifestation code as principal diagnosis edit.
- Unacceptable principal diagnosis edit.
- Unspecified codes

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 proposed changes for FY 2024, CMS proposes to revise the surgical hierarchy for the MDC 04 (Diseases and Disorders of the Respiratory System); MDC 05 (Diseases and Disorders of the Circulatory System); MD 06 (Diseases and Disorders of the Digestive System); and MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders). These proposals are summarized below in tables reproduced from the proposed rule.

Proposed Surgical Hierarchy: MDC 04	
MS-DRGs 163-165	Major Chest Procedures
Proposed New MS-DRG 173	Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism
MS-DRGs 166-168	Other Respiratory System O.R. Procedures

Proposed Surgical Hierarchy: MDC 05	
MS-DRG 215	Other Heart Assist System Implant
Proposed New MS-DRG 212	Concomitant Aortic and Mitral Valve Procedures
MS-DRGs 216-221	Cardiac Valve and Other Major Cardiothoracic Procedures
MS-DRGs 231-236	Coronary Bypass
Delete MS-DRGs 222-227	Cardiac Defibrillator Implant
Proposed New MS-DRG 275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
Proposed New MS-DRG 276	Cardiac Defibrillator Implant with MCC
Proposed New MS-DRG 277	Cardiac Defibrillator Implant without MCC
MS-DRGs 266-267	Endovascular Cardiac Valve Replacement and Supplement Procedures
MS-DRGs 268-269	Aortic and Heart Assist Procedures
MS-DRGs 228-229	Other Cardiothoracic Procedures
MS-DRGs 319-320	Other Endovascular Cardiac Valve Procedures
MS-DRGs 270-272	Other Major Cardiovascular Procedures
MS-DRGs 239-241	Amputation for Circulatory System Disorders Except Upper Limb and Toe
MS-DRGs 242-244	Permanent Cardiac Pacemaker Implant
MS-DRG 245	AICD Generator Procedures
MS-DRG 265	AICD Lead Procedures
MS-DRGs 273-274	Percutaneous and Other Intracardiac Procedures
Delete MS-DRGs 246-249	Percutaneous Cardiovascular Procedures with Coronary Artery Stent
Proposed New MS-DRGs 323-324	Coronary Intravascular Lithotripsy with Intraluminal Device
Proposed New MS-DRG 325	Coronary Intravascular Lithotripsy without Intraluminal Device
Proposed New MS-DRGs 321-322	Percutaneous Cardiovascular Procedures with Intraluminal Device
MS-DRGs 250-251	Percutaneous Cardiovascular Procedures without Intraluminal Device
Proposed New MS-DRGs 278-279	Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures
MS-DRGs 252-254	Other Vascular Procedures
MS-DRGs 255-257	Upper Limb and Toe Amputation for Circulatory System Disorders
MS-DRGs 258-259	Cardiac Pacemaker Device Replacement
MS-DRGs 260-262	Cardiac Pacemaker Revision Except Device Replacement
MS-DRG 263	Vein Ligation and Stripping
MS-DRG 264	Other Circulatory O.R Procedures

Proposed Surgical Hierarchy: MDC 06	
MS-DRGs 335-337	Peritoneal Adhesiolysis
Delete MS-DRGs 338-343	Appendectomy
Proposed New MS-DRGs 397-399	Appendix Procedures
MS-DRGs 344-346	Minor Small and Large Bowel Procedures

Proposed Surgical Hierarchy: MDC 16	
Proposed New Title MS-DRGs 799-801	Splenic Procedures

Proposed Surgical Hierarchy: MDC 16	
MS-DRGs 802-804	Other O.R. Procedures of the Blood and Blood Forming Organs

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 health-related social needs (HRSNs), defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization. For reporting effective April 1, 2023, the NCHS is implementing 42 HRSN diagnosis codes (see table in the proposed rule).

In addition, CMS implemented 34 procedure codes including laser interstitial thermal therapy (LITT) of various body sites, bone marrow transfusions, and the introduction or infusion of therapeutics into the ICD-10-PCS classification, effective with discharges on and after April 1, 2023 (see table in the proposed rule).

CMS notes that for FY 2023, there are 73,674 diagnosis codes and 78,530 procedure codes. At this time, there are 395 new diagnosis codes and 10 new procedure codes finalized for FY 2024.

17. Replaced Devices Offered without Cost or with a Credit

In the FY 2008 final rule with comment period[7], 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,[8] 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.

[7] 72 FR 47246 through 47251
[8] 76 *FR* 51556 and 51557

CMS notes that it generally maps new MS-DRGs onto the list when they are formed from procedures previously assigned to MS-DRGs that are already on the list. Currently, MS-DRGs 222-227 are on the list. The table below, reproduced from the proposed rule, lists the existing MS-DRGs subject to this policy. CMS proposes that if the applicable proposed MS-DRG changes are finalized, it would also add proposed new MS-DRGs 275-277 to the list.

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without MCC
MDC 01	025	Craniotomy & Endovascular Intracranial Procedures with MCC
MDC 01	026	Craniotomy & Endovascular Intracranial Procedures with CC
MDC 01	027	Craniotomy & Endovascular Intracranial Procedures without CC/MCC
MDC 01	040	Peripheral/Cranial Nerve & Other Nervous System Procedures with MCC
MDC 01	041	Peripheral/Cranial Nerve & Other Nervous System Procedures with CC or Peripheral Neurostimulation
MDC 01	042	Peripheral/Cranial Nerve & Other Nervous System Procedures without CC/MCC
MDC 03	140	Major Head and Neck Procedures with MCC
MDC 03	141	Major Head and Neck Procedures with CC
MDC 03	142	Major Head and Neck Procedures without CC/ MCC
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC
MDC 5	218	Cardiac Valve & Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC
MDC 5	219	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC
MDC 5	220	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC
MDC 5	221	Cardiac Valve & Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC
MDC 5	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock with MCC
MDC 5	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/HF/Shock without MCC
MDC 5	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock with MCC
MDC 5	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/HF/Shock without MCC

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
MDC 5	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC
MDC 5	227	Cardiac Defibrillator Implant without Cardiac Catheterization without MCC
MDC 5	242	Permanent Cardiac Pacemaker Implant with MCC
MDC 5	243	Permanent Cardiac Pacemaker Implant with CC
MDC 5	244	Permanent Cardiac Pacemaker Implant without CC/MCC
MDC 5	245	AICD Generator Procedures
MDC 5	258	Cardiac Pacemaker Device Replacement with MCC
MDC 5	259	Cardiac Pacemaker Device Replacement without MCC
MDC 5	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
MDC 5	261	Cardiac Pacemaker Revision Except Device Replacement with CC
MDC 5	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
MDC 5	265	AICD Lead Procedures
MDC 5	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
MDC 5	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
MDC 5	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
MDC 5	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
MDC 5	270	Other Major Cardiovascular Procedures with MCC
MDC 5	271	Other Major Cardiovascular Procedures with CC
MDC 5	272	Other Major Cardiovascular Procedures without CC/MCC
MDC 5	319	Other Endovascular Cardiac Valve Procedures with MCC
MDC 5	320	Other Endovascular Cardiac Valve Procedures without MCC
MDC 8	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
MDC 8	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
MDC 8	466	Revision of Hip or Knee Replacement with MCC
MDC 8	467	Revision of Hip or Knee Replacement with CC
MDC 8	468	Revision of Hip or Knee Replacement without CC/MCC
MDC 8	469	Major Joint Replacement or Reattachment of Lower Extremity with MCC
MDC 8	470	Major Joint Replacement or Reattachment of Lower Extremity without MCC
MDC 8	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
MDC 8	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

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 uses 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 2022 for FY 2024). It also

uses Medicare cost report data from the 3rd year preceding the ratesetting year (e.g., FY 2021 for FY 2024).

In developing relative weights for FY 2024, CMS proposes to use:

- FY 2022 MedPAR data: Bills received through December 31, 2022 from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). Medicare Advantage (MA) claims and claims from facilities currently classified as CAHs are excluded. CMS used data from approximately 6,959,859 million Medicare discharges regrouped using the FY 2024 proposed MS-DRG classifications.
- FY 2021 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2021 cost reporting periods, using the December 31, 2022 update of the FY 2021 HCRIS.

For FY 2024, 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 2024, available at https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-proposed-rule-home-page. (Select file #4 under FY 2024 Proposed Rule Data files, "FY 2024 Proposed Rule: HCRIS Data File (ZIP)".)

In cases where an MS-DRG with a higher severity level has a lower weight than its base or lower severity level MS-DRG (known as non-monotonicity), CMS will calculate a single weight for both MS-DRGs based on their combined cases. For FY 2024, this will only occur for MS-DRGs 016 and 017 (Autologous Bone Marrow Transplants with and without CC/MCC respectively).

National Average CCRs. The FY 2024 proposed CCRs in comparison to the final FY 2023 CCRs are shown in the following table:

Group	Final FY 2023 CCR	Proposed FY 2024 CCR
Routine Days	0.422	0.415
Intensive Days	0.341	0.352
Drugs	0.184	0.184
Supplies & Equipment	0.311	0.305
Implantable Devices	0.281	0.278
Inhalation Therapy	0.150	0.155
Therapy Services	0.283	0.272
Anesthesia	0.072	0.075
Labor & Delivery	0.366	0.420
Operating Room	0.165	0.162
Cardiology	0.094	0.087
Cardiac Catheterization	0.104	0.103
Laboratory	0.107	0.104
Radiology	0.137	0.129
MRIs	0.071	0.068
CT Scans	0.034	0.034
Emergency Room	0.155	0.153

Group	Final FY 2023 CCR	Proposed FY 2024 CCR
Blood and Blood Products	0.255	0.251
Other Services	0.359	0.344

Relative Weight Calculation for CAR-T cell Therapy (MS-DRG 018). In some cases, patients receiving CAR-T cell therapy 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 continue eliminating clinical trial cases from the standardized amount calculation but no longer using drug costs of less than $373,000 as a proxy for the case being a clinical trial case. The proposed rule indicates that the clinical trial indicator is being used with more frequency obviating the need to use the drug cost proxy to identify clinical trial cases that should be removed from the relative weight calculation. CMS is finding relatively fewer cases in the FY 2022 data (4 percent) than in prior years (18 percent) where there is not a clinical trial indicator on the claim and drug costs of less than $373,000.

In addition, CMS now has an indicator in the claims data to identify "expanded access use"—another situation where the hospital would not have costs for the CAR-T product—that CMS is proposing to eliminate from the relative value calculation for MS-DRG 018. Finally, there is an indicator in the FY 2022 data to identify clinical trial cases where a different product is under investigation but the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner. CMS proposes to use this indicator to retain these types of cases in the relative weight calculation.

For FY 2024, CMS estimated that the average costs of CAR-T clinical trial cases ($89,379) were 28 percent of those where the hospital has a cost for the CAR-T product ($323,903). Accordingly, CMS is proposing to adjust the transfer-adjusted case count for MS-DRG 018 by 0.28 to clinical trial and expanded access use immunotherapy cases. This adjusted case count will be used in calculating the national average cost per case and relative weight for MS-DRG 018. 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 Cap for Relative Weight Reductions. Beginning in FY 2023, CMS adopted a 10 percent cap on reductions to the relative weights in a single year. CMS is proposing to continue that policy for FY 2024.

Other Issues. CMS proposes normalizing the relative weights by an adjustment factor of 1.939934 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.[9]

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. New Technology Add-on Payment (NTAP)

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 Secretary is required to establish criteria used to determining if a medical service of technology is new.[10] 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[11]; 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.[12] Also, beginning with FY 2022, a drug approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway), may also qualify for a new technology add-on payment under an alternative pathway.[13]

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[14]:

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

[9] The normalization factor was inadvertently omitted from the proposed rule but has been provided to the public by CMS outside of the rulemaking process.
[10] Section 1886(d)(5)(K)(vi) of the Act
[11] Section 1886(d)(5)(K)(i) of the Act requires the Secretary establish a mechanism to recognize the costs of new medical services and technologies under the payment system established for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. CMS does not include capital costs 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).
[12] 84 FR 42292 through 42297; regulations at §412.87(c) and (d)
[13] 85 FR 58736
[14] 74 FR 43813 and 43814

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 will 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 2025 are included in the data files associated with the FY 2024 proposed rule on the CMS website.[15]

CMS proposes to use the FY 2022 MedPAR claims data for FY 2024 rate setting. For the FY 2025 threshold values, CMS proposes to use the FY 2022 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2025.

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[16], 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;

[15] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.
[16] 84 FR 42288 through 42292

        - More rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time;
        - Improvement in one or more activities of daily living;
        - Improved quality of life; or
        - Demonstrated greater medication adherence or compliance; or
        - The totality of the circumstances otherwise demonstrates substantially improvements, relative to available technologies, for the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished sources from the US or elsewhere may be sufficient to establish an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries includes the following sources: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated may have a low prevalence among Medicare beneficiaries.
- The service or technology may represent an advance that substantially improves, relative to available options, the diagnosis or treatment of a subpopulation of patients with the medical condition.

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

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

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

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

c. Additional Payment for New Medical Service or Technology

In the FY 2020 IPPS final rule[17], CMS finalized an increase in the new technology add-on payment percentage. Specifically, for a new technology, other than a medical product designated as a QIDP or approved under the LPAD pathway, beginning with discharges on or after October 1, 2019, Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the estimated costs of the new technology (if the estimated costs for the case including the new technology exceed the full DRG payment, including payments for IME and DSH but excluding outlier payments); or (2) 65 percent of the difference between the full DRG payment and the hospital's estimated cost for the case.

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

Unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS-DRG payment plus 65 percent (or 75 percent for a QDIP or LPAD) of the estimated costs of the new technology or medical service. CMS notes that add-on payments for new medical services or technologies are not subject to budget neutrality.[18]

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. When considering eligibility for the new technology add-on payment, CMS considers FDA marketing authorization as representing that a product has received FDA approval or clearance (85 FR 58742).

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.[19] 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

[17] 84 FR 42297 through 42300
[18] 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.
[19] 85 FR 58739 through 58742

FDA marketing authorization is received by July 1 of the year for which the applicant applied for new technology add-on payments.

As discussed below, beginning with new technology add-on payment applications for FY 2025, CMS proposes for technologies that are not already FDA market authorized, to require applicants to have a complete and active FDA market authorization request at the time of the application submission, and to provide documentation of the FDA acceptance or filing to CMS when the application is submitted. CMS also proposes, beginning with FY 2025 applications, an applicant must have received approval or clearance by May 1 instead of July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Applications submitted under the alternative pathway for certain antimicrobial products are excluded from this proposal to change the date from July 1 to May 1.

e. New Technology Liaisons

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

f. Application Information for New Medical Services or Technologies

For FY 2025, 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. Once the application deadline has closed, CMS will also post the tracking forms completed by each applicant. At the time the proposed rule is posted, CMS will also post online the application, including the completed application forms, certain related materials, and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost, and other information identified by the applicant as confidential. This information is posted at https://mearis.cms.gov/public/publications/ntap. Applications that are withdrawn prior to the publication of the proposed rule are not publicly posted.

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.[20] On December 14, 2022, CMS held a town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" relating to pending new technology applications.[21] In their evaluation of individual applications, CMS will consider the presentations made at the town hall meeting and written comments received by December 22, 2022. Where applicable, CMS summarizes comments at the end of each

[20] Section 1886(d)(5)(K0(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108-73.
[21] The recording of the virtual town hall is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.

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.

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

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

CMS states that if the PHE ends in May of 2023, as planned by HHS, discharges involving eligible products would continue to be eligible for the NCTAP through September 30, 2023 (through the end of FY 2023). The NCTAP will expire at the end of FY 2023 and no NCTAP will be made beginning in FY 2024 (that is, for discharges on or after October 1, 2023).

5. Proposed FY 2024 Status of Technologies Approved for FY 2023 New Technology Add-On Payments

CMS discusses the proposed FY 2024 status of 24 technologies approved for FY 2023 new technology add-on payments. A medical service or technology may be considered new within 2 or 3 years after which data becomes available which reflects the inpatient hospital code assigned to the new service or technology. CMS' practice has been to begin and end new technology add-on payments on the basis of a fiscal year and it generally follows a guideline that uses a 6-month

[22] 85 FR 71155

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 (70 FR 47362).

Conditional approval of DefenCath™ (a formulation of taurolidine/heparin). CMS conditionally approved DefenCath for FY 2023 new technology add-on payments under the alternative pathway for certain antimicrobial products, subject to the technology receiving FDA marketing authorization by July 1, 2023. DefenCath has not yet obtained FDA approval and CMS discusses the FY 2023 options for DefenCath:

- If DefenCath receives FDA marketing authorization before July 1, 2023, 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, 2023, no new technology add-on payments would be made for cases involving the use of DefenCath for FY 2023.

For FY 2024, CMS proposes the following options:

- If DefenCath receives FDA marketing authorization prior to July 1, 2023, CMS proposes to continue new technology payments for FY 2024.
- If DefenCath does not receive FDA marketing authorization by July 1, 2023, in addition to not being eligible for new technology add-on payments for FY 2023, it would not be eligible for add-on payments for FY 2024. CMS notes that in the event that FDA market authorization is not received by July 1, 2023, the applicant submitted a new technology add-on payment application for DefenCath (discussed below in alternate pathways for QIDPs as the taurolidine/heparin application).

Proposed Continuation of Technologies. Table II.P.-01 in the proposed rule (see table extract below) lists the 11 technologies CMS proposes to continue new technology add-on payments for FY 2024 because the 3-year anniversary date of entry into the U.S. market occurs on or after April 1, 2024. The complete table in the proposed rule also included the proposed maximum NTAP amount for FY 2023, codes used to identify cases eligible for NTAP, and previous related final rule citations.

Proposed Continuation of Technologies Approved for FY 2023 New Technology Add-On Payments Still Considered New for FY 2024 Because 3-Year Anniversary Date Occurs on or After April 1, 2024*				
Technology		Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US. Market
1	Intercept® (PRCFC)	05/05/2021	10/1/2021	5/05/2024
2	Rybrevant™	05/21/2021	10/1/2021	05/21/2024
3	StrataGraft®	06/15/2021	10/1/2021	06/15/2024
4	aprevo® Intervertebral Body Fusion Device	6/30/2021 (TLIF)	10/1/2021	6/30/2024 (TLIF)
5	Hemolung Respiratory Assist System (RAS)	11/15/2021 (other)	10/1/2022	11/15/2024 (other)

Proposed Continuation of Technologies Approved for FY 2023 New Technology Add-On Payments Still Considered New for FY 2024 Because 3-Year Anniversary Date Occurs on or After April 1, 2024*				
Technology		Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto US. Market
6	Livtencity™	12/2/2021	10/1/2022	12/2/2024
7	Thoraflex Hybrid Device	04/19/2022	10/1/2022	04/19/2025
8	ViviStim	04/29/2022	10/1/2022	04/29/2025
9	GORE TAG Thoracic Branch Endoprosthesis	05/13/2022	10/1/2022	05/13/2025
10	Cerament® G	05/17/2022	10/1/2022	05/17/2025
11	iFuse Bedrock Granite Implant System	05/26/2022	10/1/2022	05/26/2025
*As discussed in the following section, CMS proposes to discontinue new technology add-on payments for COVID-19 Hemolung RAS cases.				

Proposed Discontinuation of Technologies. Table II.P.-02 in the proposed rule (see table extract below) lists the 15 technologies CMS proposes to discontinue new technology add-on payments for FY 2024 because the 3-year anniversary date of entry into the U.S. market occurs prior to April 1, 2024. The complete table in the proposed rule also included the proposed maximum NTAP amount for FY 2023, codes used to identify cases eligible for NTAP, and previous related final rule citations.

Proposed Discontinuation of Technologies Approved for FY 2023 New Technology Add-On Payments No Longer Considered New for FY 2024 Because 3-Year Anniversary Date Occurs Prior to April 1, 2024				
Technology		Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market
1	TECARTUS®*	7/4/2020	10/1/2021	7/4/2023
2	VEKLURY®**	7/1/2020*	10/1/2021	7/1/2023*
3	Zepzelca™	6/15/2020	10/1/2021	6/15/2023
4	aScope® Duodeno	7/17/2020	10/1/2021	7/17/2023
5	Caption Guidance™	9/15/2020	10/1/2021	9/15/2023
6	aprevo® Intervertebral Body Fusion Device	12/3/2020 (ALIF and LLIF)	10/1/2021	12/3/2023 (ALIF and LLIF)
7	Cosela™	2/12/2021	10/1/2021	2/12/2024
8	ShockWave C2 Intravascular Lithotripsy (IVL) System	2/12/2021	10/1/2021	2/12/2024
9	ABECMA®	3/26/2021	10/1/2021	3/26/2024
10	Harmony™ Transcatheter Pulmonary Valve (TPV) System	03/26/2021	10/1/2021	3/26/2024
11	Recarbrio™ (HABP/VABP)	6/4/2020	10/1/2021	6/4/2023
12	Fetroja® (HABP/VABP)	9/25/2020	10/1/2021	9/25/2023
13	DARZALEX FASPRO®	01/15/2021	10/1/2022	01/15/2024
14	CARVYKTI™	03/26/2021**	10/1/2022	03/26/2024

Proposed Discontinuation of Technologies Approved for FY 2023 New Technology Add-On Payments No Longer Considered New for FY 2024 Because 3-Year Anniversary Date Occurs Prior to April 1, 2024				
Technology		Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market
15	Hemolung Respiratory Assist System (RAS)	04/22/2020 (COVID-19)	10/1/2022	04/22/2023 (COVID-19)
*See discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48909 through 48914). ** As discussed in the FY 2023 IPPS/LTCH PPS final rule, because CMS determined that CARVYKTI™ is substantially similar to ABECMA®, it considers the beginning of the newness period for CARVYKTI™ to be March 26, 2021, which is the date that ABECMA® received FDA marketing authorization (87 FR 48925).				

New Technology Add-on Payment for Hemolung Respiratory Assist System (RAS). Hemolung RAS received an emergency use authorization (EUA) on April 22, 2020 when used for patients with COVID-19. In the FY 2023 IPPS proposed rule, CMS discussed whether the newness period for the use of the Hemolung RAS for patients with COVID-19 should begin on the date of the EUA, when the product became available on the market for this indication. In a public comment, the applicant for Hemolung RAS stated the newness period for the device should begin on November 15, 2021, the date of commercial availability of the De Novo classified device. The applicant stated that during the EUA period, hospitals were not seeking payment for Hemolung RAS therapy and cost data collected during this period did not accurately reflect the added cost of Hemolung RAS therapy. The applicant did not respond to CMS' request for additional information regarding whether hospitals charged for use of the Hemolung RAS. As discussed in the FY 2023 IPPS final rule, CMS noted that data reflecting the costs of products that received an EUA could become available as the date of the EUA issuance and prior to receiving FDA approval or clearance. CMS continues to welcome additional information regarding whether hospitals charged for use of the Hemolung RAS therapy between the date of its EUA and the date of commercial availability of the De Novo classified device, and how it impacts whether the use of the technology may be reflected in the data.

CMS proposes to continue the new technology add-on payment in FY 2024 for the use of the Hemolung RAS for patients with other causes of hypercapnic respiratory failure unrelated to COVID-19 (see Table II.P.-01). For these indications, CMS considers the beginning of the newness period to begin on the date of commercial availability of the De Novo classified device (November 15, 2021).

6. FY 2024 Applications for New Technology Add-On Payments: Traditional Pathway

CMS received 27 applications for new technology add-on payments for FY 2023; eight applicants withdrew their applications prior to the issuance of this proposed rule. The summary below provides a high-level discussion of the remaining 19 new technology assessment; readers are advised to review the proposed rule for more detailed information. In addition, the publicly posted FY 2024 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted) for the applications discussed in the proposed rule are available at https://mearis.cms.gov/public/publications/ntap. In addition, separate tables listing the ICD-10-CM codes, ICD-10-PCS codes, and/or MS-DRGs related to the analysis of the

cost criterion for certain applications are available in Table 10 associated with the information posted on the CMS website.[23]

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

a. CYTALUX® (pafolacianine), first indication: ovarian cancer

On Target Laboratories submitted an application for CYTALUX, an intraoperative molecular imaging agent that illuminates ovarian cancer and enables the detection of more cancer for resection. CYTALUX is comprised of a folic acid analog conjugated with a fluorescent dye which binds to folate receptor positive cancer cells and illuminates malignant lesions during surgery. CYTALUX is used with a near-infrared imaging system (NMIR) cleared by the FDA for specific use with CYTALUX. The applicant submitted a separate application for CYTALUX used in lung cancer.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017X8NAN.

Newness. The applicant stated that a new drug application (NDA) for CYTALUX was approved by FDA on November 29, 2021, as an optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions. According to the applicant, because of supply/product availability, CYTALUX had market availability delayed until April 15, 2022. The applicant submitted a request for a unique ICD-10-PCS procedure code for CYTALUX.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that CYTALUX is not substantially similar to other currently available technologies because there are no other optical imaging agents with the same active ingredient or the same mechanism of action of binding to folate receptors to illuminate cancerous lesions. For the second criterion (same or different MS-DRG), the applicant states that are no other drugs marketed under the same ingredient category. For the third criterion (same or similar disease or patient population), the applicant stated that there are no existing drugs/biologicals that are used as an adjunct for intraoperative identification of ovarian cancer.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant did not remove any charges for prior technology because the use of CYTALUX does not completely replace any current technology. The applicant concluded that CYTALUX meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that CYTALUX offers a substantial clinical improvement because it allows the surgeon to identify cancer intraoperatively and allows more complete resection in cytoreductive surgery for ovarian cancer and more complete resection during interval debulking surgery after chemotherapy. The applicant provided eleven background articles and two studies (Phase II and Phase III open-label, randomized multicenter

[23] https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps. Click on the link to "Acute Inpatient-Files for Download" and see section VI of the Addendum for additional information regarding tables associated with the proposed rule.

open-label study) to support these claims. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses several concerns regarding whether CYTALUX meets the substantial clinical improvement criterion. CMS is concerned that in the Phase 3 study, CYTALUX showed a false positive rate of 24.8% and is concerned that taking additional tissues that were false positives can impact patient outcomes. The applicant submitted a separate comment stating that there were no impacts on the safety profile for patients with false positive results. In addition, although background articles supported the assertion that improved cytoreduction of tumor results in improved survival, the Phase 3 study focused on the efficacy of the technology and not clinical outcomes such as survival, recurrence, or rate of additional procedures. CMS is interested in data demonstrating that CYTALUX resulted in improved outcomes.

New Technology Town Hall. In response to a question, the applicant provided evidence that there was no worsening in the safety profile for the false positive group in comparison to the overall rate for this study (additional information in table in the proposed rule). In response to a question about surgical results in patients without CYTALUX, the applicant stated that subjects who did not receive CYTALUX were not included in the Phase 3 study. The applicant does state, however, that the Phase 3 study indicated that compete resection would not have been achieved in any patient without the use of CYTALUX. The applicant also provided information from the literature about achievement of complete resection.

b. CYTALUX® (pafolacianine), second indication: lung cancer

On Target Laboratories also submitted an application for CYTALUX, an intraoperative molecular imaging agent that illuminates lung cancer and enables the detection of more cancer for resection. As discussed above, CYTALUX is used with a near-infrared imaging system (NMIR) cleared by the FDA for specific use with CYTALUX.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017ED6BY.

Newness. The applicant stated that a supplemental new drug application (sNDA) for CYTALUX was approved by FDA on December 16, 2022, for an additional indication used as an intraoperative identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected lung cancer. According to the applicant, because of supply/product availability, CYTALUX will have market availability delayed until approximately the middle of 2023 due to supply/product availability. The applicant submitted a request for a unique ICD-10-PCS procedure code for CYTALUX.

CMS notes that CYTALUX for ovarian cancer became commercially available on April 15, 2022 and requests additional information explaining the longer delay for the market availability for CYTALUX for lung cancer.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that CYTALUX is not substantially similar to other currently available technologies because there are no other optical imaging agents with the same active ingredient or the same mechanism of action of binding to folate receptors to illuminate cancerous lesions. For the second criterion (same or different MS-DRG), the applicant states that are no

other drugs marketed under the same ingredient category. For the third criterion (same or similar disease or patient population), the applicant stated that there are no existing drugs/biologicals that are used as an adjunct for intraoperative identification of ovarian cancer.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant did not remove any charges for prior technology because the use of CYTALUX does not completely replace any current technology. The applicant concluded that CYTALUX meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that CYTALUX offers a substantial clinical improvement because the use of CYTALUX during pulmonary resection for lung cancer enhances the intraoperative localization of pulmonary nodules, improves the ability to remove nodules with clean margins, and reduces the probability of leaving otherwise undetected malignant lesions behind. The applicant provided nine background articles and six studies (including a Phase III study) to support these claims. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses several concerns regarding whether CYTALUX meets the substantial clinical improvement criterion. As with the use of CYTALUX for ovarian cancer, CMS is concerned that in the Phase 3 study, CYTALUX showed a false positive rate of 25.7% and is concerned that taking additional tissues that were false positives can impact patient outcomes. The applicant again submitted a separate comment stating that there were no impacts on the safety profile for patients with false positive results. CMS notes that authors in the phase 3 trial discussed that there was a decreased rate of subsequent diagnostic interventions for all patients enrolled in the sturdy. CMS wonders if the authors are referring to fewer resections or reduced mortality. CMS is interested in data demonstrating that CYTALUX resulted in improved outcomes.

New Technology Town Hall. In response to a question, the applicant provided evidence that there was no worsening in the safety profile for the false positive group in comparison to the overall rate for the study. In addition, the histology on the false positive tissues were mostly benign or normal lung parenchyma.

c. DuraGraft®

Marizyme submitted an application for DuraGraft®, an intraoperative vein-graft preservation solution used for vein graft harvesting and storage during coronary artery bypass graft (CABG) surgery.[24]

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221013TEMTR.

Newness. The applicant submitted a De Novo classification request to FDA with a proposed indication for flushing and storage of vascular grafts during CABG surgery. The applicant indicated that ICD-10-PCS code XY0VX83 would identify procedures using the DuraGraft® technology.

[24] Somahlution submitted applications for DURAGRAFT® for FY 2018, FY 2019 and FY 2020, which were withdrawn. Marizyme Inc, acquired Somahlution in 2020.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated there are no other treatment options available with the same mechanism of action as DuraGraft®. In addition, the applicant noted there are no other commercial solutions approved for treating arteries or veins intended for bypass surgery. According to the applicant, common storage solutions are only salt solutions which have no ability to protect against ischemic injury. For the second criterion (same or different MS-DRG) the applicant stated that cases involving patients receiving treatment involving DuraGraft® would be assigned to the same MS-DRGs as patients receiving treatments involving heparinized blood, saline, and electrolyte solutions. For the third criterion (same or similar disease or patient population) the applicant indicated that heparinized blood, saline and electrolyte solutions involve treatment of the same disease process and the same patient population as DuraGraft®.

As in previous discussions, CMS is concerned that the mechanism of action of DURAGRAFT® may be the same or similar to other vein graft storage solutions such as various saline, blood, and electrolyte solutions.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant did not remove any charges for prior technology because the use of DuraGraft does not completely replace any current technology. The applicant concluded that DuraGraft meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that DuraGraft® significantly reduces clinical complications associated with vein graft following coronary artery bypass grafting (CABG) surgery. The applicant asserted there is no other product or technology that reduces the incidence of peri-operative myocardial infarction. The applicant provided three studies to support its assertions and 44 background articles about reducing adverse cardiac events (MACE). A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. It is concerned that some of the studies (Szalkiewicz and Perrault) used a relatively small sample size (166 and 125 patients respectively) as compared to the number of potentially eligible patients. As provided by the applicant about 400,000 CABG surgeries as performed annually and approximately 60% will be performed on Medicare beneficiaries. CMS is also concerned about the relatively short follow-up periods in these studies (4 days and 12 months respectively). CMS notes that both authors indicated limitations with these studies and that larger cohorts and longer-term evaluation is needed. CMS is interested in whether similar clinical results would have been achieved with a larger patient sample and over a longer follow up period.

CMS is also concerned the studies do not clearly demonstrate an association between exposure to DuraGraft and improved clinical outcomes. CMS notes that in several studies, including the Haime study, that the risk for all-cause mortality was the same for patients with grafts exposed to DuraGraft and those exposed to saline.

In addition, CMS notes that the studies predominately included white male and CMS questions whether the results from studies could be generalized to other patient groups, CMS notes that male patients account for only two-thirds of Medicare beneficiaries who underwent CABG surgery.

CMS also reiterates its prior concern that some of the studies do not account for other variables that may have confounded the association between exposure to DuraGraft and clinical outcomes. This includes site-specific characteristics in single-center studies, differences in surgical techniques or operating room practices during the study periods (saline from 1996 to 1999 and DuraGraft from 2001 to 2004), and characteristics of the vein grafts. CMS agrees with the observation by Perrault that further studies on the effects of confounding factors, like chronic conditions, graft and anastomosis characteristics, type of graft use, or surgical technique are important.

New Technology Town Hall. In response to a question about GALA, the applicant stated that GALA is a pharmacy-compound product used by hospitals for graft storage. It is similar to DuraGraft but has a short shelf-life and is not suitable for distribution and commercialization. The applicant did not conduct any studies that compared the clinical outcomes from using DuraGraft or GALA.

In response to a question about the Medicare population, the applicant stated that DuraGraft has not been studied in Medicare patients; DuraGraft has been studied in many European patients aged 65 or older. To evaluate outcomes with a U.S. population, the applicant compared isolated CABG patients from the DuraGraft Registry in Europe to a propensity-matched control group form the Society of Thoracic Surgeons (STS) Registry Adult Cardiac Surgery Database. The two groups were matched on 35 prespecified variables reflecting mortality risk in the operative, perioperative, and follow-up periods, out to one year. The applicant states the groups were balanced on demographic, procedural and anatomic characteristics. According to the applicant, no significant difference in all-cause mortality rate was found between the matched cohorts. The applicant discussed additional analysis it plans to do with the STS Registry information to include a cohort matched with data from the Medicare database.

d. Elranatamab

Pfizer submitted an application for elranatamab, a heterodimeric humanized full-length bispecific antibody against B-cell maturation antigen (BCMA) on myeloma cells and cluster of differentiation (CD)3 on T cells. Elranatamab is proposed to act by direct bridging of the BCMA cell-surface antigen and the extracellular CD3 subunit expressed on T cells and activates the T cell to release cytokines that kill multiple myeloma (MM) cells.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221014RF1AA.

Newness. The applicant has submitted a biologics license application (BLA) to FDA with a proposed indication for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least three prior therapies, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-cluster of differentiation 38 (anti-CD38) monoclonal antibody. Elranatamab therapy begins with a priming regimen for the first two injection for the first cycle. Dosing is thereafter weekly and dosing is reassessed after six cycles. The applicant anticipates patients could be admitted to receive the first dose cycle in the inpatient setting. The applicant submitted a request for a unique ICD-10-PCS procedure code for elranatamab.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated there are no other treatment options available with the same mechanism of action as elranatamab. Current treatment options (XPOVIO®, BLENREP, ABECMA®, CARVYKTI™, and traditional chemotherapy agents) are not bispecific antibodies. The other FDA-approved bispecific antibodies do not target BCMA and are not FDA approved for the treatment of RRMM. According to the applicant, for the newness criterion, elranatamab is substantially similar to TECVAYLI™ (the application for TECVAYLI is discussed below in section *o*). The applicant believes that a new technology add-on payment should apply to the BCMA-directed bispecific antibody class for treatment of RRMM.

CMS believes that the mechanism of action for elranatamab may be the same or similar to TECVAYLI, both are bispecific antibodies with distinct binding domains that simultaneously bind the BCMS target on tumor cells and the CD3 T cell receptor. CMS also believes that both biologics treat the same or similar disease (RRMM) in the same or similar patient population (patients who have previously received a PI, an IMiD, and an anti-CD38 antibody) and would be assigned to the same MS-DRG. CMS believes these technologies may be substantially similar to each other and should be considered as a single application for purposes of new technology add-on payments. TECVAYLI received FDA approval on October 25, 2022 but was not commercially available until November 9, 2022; CMS believes the newness period for this technology would be November 9, 2022. **CMS is interested in information on how these two technologies may differ with respect to the newness criterion**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant removed 80% of drug charges from the analysis as elranatamab would replace currently used antineoplastics but some drug charges would remain the same. The applicant concluded that elranatamab meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that elranatamab is a substantial clinical improvement over existing technologies because it is a new treatment option for patients with RRMM who are refractory to or otherwise ineligible or unable to access existing therapies, significantly improves clinical outcomes, and has a manageable safety profile. Based on empirical comparisons of individual trials, the applicant stated that in clinical trials, the overall response rates (ORR) with elranatamab were higher that available therapies. The applicant provided two studies to support its assertions and 13 background articles about RRMM. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS is concerned that the evidence presented that elranatamab is the only treatment option for patients who are ineligible for other treatments because of renal insufficiency is not substantiated by the information provided and notes that the information presented described two patients with end stage renal disease who were successfully treated with CAR T-cell therapy. CMS is also concerned that there is no evidence indicating which patients would benefit from elranatamab due to being ineligible for or unresponsive to other treatment options (XPOVIO with dexamethasone, BLENREP and conventional chemotherapy). In addition, the ORR comparisons did not include CAR T-cell therapies. CMS concludes that a manageable safety profile without a comparison to treatment outcomes does not provide evidence for improved outcome.

e. Epocoritamab

Genmab US submitted an application for epocoritamab, an immunoglobulin G1 (IgG1) bispecific antibody which binds cluster of differentiation (CD)3 expressing T cells and CD20 expressing B-cells to potently induce activation and cytotoxic activity of the T cells against malignant B cells. Epocoritamab may be an effective treatment for patient with R/R Large B-Cell Lymphoma (LBCL).

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221012JQM0G.

Newness. The applicant has submitted a BLA with a proposed indication for the treatment of adult patients with R/R LBCL after two or more lines of systemic therapy. According to the applicant, in the Phase 2 study, all patients were required per protocol to be hospitalized for 24 hours for the third dose, which was the first full dose of epocoritamab. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code for epocoritamab.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action, the applicant stated there are no other treatment options available with the same mechanism of action as epocoritamab. The applicant states there are no approved anti-CD3xCD20 bispecific antibodies for the treatment of RR LBCL. CMS notes that epocoritamab may have a similar mechanism of action as glofitimab (the application for glofitimab is discussed below in section *f)*. Glofitimab's mechanism of action is described as bivalent binding of CD20 on malignant B-cells and CD3 on T cells; a mechanism same or similar to epocoritamab. CMS also believes that these biologics may treat the same or similar disease (LBCL/DLBCL) in the same or similar patient population (RR patients who have received two or more lines of therapy) and would be assigned to the same MS-DRG. **CMS is interested in information on how these two technologies may differ with respect to the newness criterion**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that epocoritamab meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that epocoritamab represents a substantial clinical improvement because it offers a treatment option with improved efficacy and safety for RR LBCL patients unresponsive to currently available treatments (e.g., CAR T-cell therapies and non-CAR T-cell therapies such as POLIVY®, ADCETRIS®, XPOVIO®, and ZYNLONTA®) and it significantly improves clinical outcomes among RR LBCL patients as they progress through lines of therapy. The applicant provided two studies and nine background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS is concerned that the applicant did not provide the complete study of epocoritamab (ENCORE NHL-1) to support its claims of substantial clinical improvement and only provided partial results used for the European Hematology Association meeting in 2022. CMS states this limits its ability to fully evaluate and assess the supporting evidence. In addition, CMS is concerned that the evidence comparing differences between trials does not indicate that epocoritamab has a better safety profile and efficacy than existing therapies. CMS requests additional information to support these assertions.

f. Glofitamab

Genentech submitted an application for glofitamab, a full-length, fully humanized, T-cell engaging bispecific antibody with a novel 2:1 structure (two CD20 binding domains, one CD3 binding domain [2:1 structure]) for the treatment of adults with R/R diffuse large B-cell lymphoma (DLBCL).

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017RK2RD.

Newness. The applicant has submitted a BLA with a proposed indication for the treatment of adult patients with R/R DLBCL after two or more lines of systemic therapy. According to the applicant, the administration of glofitamab will be treated as part of the inpatient stay when a patient is admitted within 72 hours of the outpatient administration to treat cytokine release syndrome (CRS). The applicant submitted a request for a unique ICD-10-PCS procedure code for glofitamab.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action, the applicant stated there are no other treatment options available with the same mechanism of action as glofitamab. As previously discussed, CMS notes that epocoritamab may have a similar mechanism of action as glofitimab. Glofitimab's mechanism of action is described as bivalent binding of CD20 on malignant B-cells and CD3 on T cells; a mechanism same or similar to epocoritamab. CMS also believes that these biologics may treat the same or similar disease (LBCL/DLBCL) in the same or similar patient population (RR patients who have received two or more lines of therapy) and would be assigned to the same MS-DRG. **CMS is interested in information on how these two technologies may differ with respect to the newness criterion**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that glofitimab meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that glofitamab is a substantial clinical improvement over existing technologies because it is a treatment option for patients with RR DLBCL who have progressed after two or more lines of therapy and who are refractory to or otherwise ineligible or unable to access existing therapies, significantly improves clinical outcomes, and has a manageable safety profile. The applicant provided two studies to support its assertions and 41 background articles about current therapies. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS is concerned that the evidence presented does not support that glofitamab is a treatment option for patients who are ineligible for other treatments available for RR DLBCL patients who have progressed after other treatments. CMS is concerned that the statement that glofitamab reduces mortality of patients who have progressed after autologous stem cell transplant (ASCT) or Car T-cell therapies is based on comparison between independent studies. Similarly, CMS is concerned that the evidence does not support a difference in safety or efficacy between glofitamab and other treatments. CMS also questions if glofitamab is the only off-the shelf treatment options. CMS

notes that no information is presented to support the claim that glofitamab is a fixed-treatment duration therapy and improves a patient's quality of life.

g. Lunsumio™ (mosunetuzumab)

Genetech submitted a new technology add-on payment application for Lunsumio, a novel full-length, humanized IgG1 bispecific antibody that concomitantly binds to CD3 on T cells and CD20 on B cells for the treatment of adults with RR follicular lymphoma (FL) who have received at least 2 prior systemic therapies (also referred to as 3L+FL).[25] According to the applicant, target B cell killing occurs when Lunsumio simultaneously binds to both targets.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017LJLDM.

Newness. Lunsumio was granted accelerated approval of its BLS on December 22, 2022 for the treatment of adult patients with RR FL after two or more lines of system therapy. Due to a companywide holiday shutdown and to provide manufacturing time, the sale and first order occurred on January 6, 2023. CMS notes it does not consider the date of first sale as an indicator of a product entry onto the U.S. market. The applicant anticipates that most of the inpatient use of Lunsumio will occur as a result of adverse events, mainly CRS, that develop after the outpatient administration of the drug. The applicant stated there are two procedure codes used to identify administration of Lunsumio (XW03358 and XW04358).

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that Lunsumio's mechanism of action is different from other therapies approved for the treatment of 3L+ RR FL. The applicant states that Lunsumio might be assigned to the same MS-DRG as existing technologies and does not involve the treatment of the same or similar population as existing therapies. 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 Lunsumio would be used for the same disease and same population when compared to other therapies approved to treat 3L+ RR FL.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that Lunsumio meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Lunsumio represents a substantial clinical improvement over existing technologies because it will expand access to patients for whom existing therapies are not adequate and because it offers patients with 3L+ RR FL multiple substantial clinical benefits, including high efficacy with significant tolerability and the opportunity to achieve sustained remission without continuous treatment. The applicant provided 13 studies and 34 background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS is concerned that the primary support comes from a single-arm, Phase II trial of 90 patients, sub-study analysis and another single-arm phase I/II trial of 15 patients. The studies

evaluated complete response rate or indicators of safety, but did not evaluate survival as a primary outcome. CMS is also concerned that comparison to other technologies is based on historical rates found in other clinical trials and no direct comparison of therapies is provided.

h. NexoBrid™ (anacaulase-bcdb)

Vericel Corporation submitted an application for NexoBrid™, a non-surgical, biologic option for removal of nonviable burn tissue, or eschar, in adult patients with deep partial-thickness (DPT) and/or full-thickness thermal (FT) burns.[26] According to the applicant NexoBrid™ has two components, the NexoBrid™ powder that contains the active pharmaceutical ingredient (API) which is a concentrate of proteolytic enzymes enriched in bromelain and a Gel Vehicle.

The online application posting for NexoBrid is available at https://mearis.cms.gov/public/publications/ntap/NTP221017WGWTP.

Newness. NexoBrid was granted BLA approval from FDA on December 28,2022 for eschar removal (debridement) in adult patients with DPT and/or FT thermal burns. The applicant states that manufacturing preparations are currently underway and NexoBrid is expected to be commercially available in Q2 2023 in the U.S. market. The applicant stated there are two procedure codes used to identify the use of NexoBrid (XW00X27 and XW01X27).

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that NexoBrid™ has a unique mechanism of action and is the first enzymatic treatment to achieve rapid, consistent eschar removal. The applicant states that collagenase-based technologies are used for burns and are generally considered inefficient. The applicant stated that NexoBrid does treat the same patient population as existing treatment for eschar removal but NexoBrid would not be assigned to the same MS-DRG as existing technologies because there are no similar existing technologies.

CMS states the applicant did not provide enough information about the composition of the proteolytic enzymes within NexoBrid™, its mechanism of action, and how the ingredients differ from other enzymatic debridement products on the market. Specifically, CMS is concerned that the proteolytic enzyme is a type of collagenase similar to existing collagenase based enzymatic debridement products. CMS also believes that patients using NexoBrid™ would be assigned to the same MS-DRGs as patients treated for burns.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that NexoBrid meets the cost criterion.

Substantial Clinical Improvement. The applicant states that NexoBrid represents a substantial clinical improvement over existing technologies for several reasons including faster eschar removal; improved scar outcomes; depth-of-burn diagnosis of indeterminant depth; reduced adverse events associated with surgical removal of tissue; reduced blood loss related to eschar removal; and reduced the need for autografting. The applicant provided 10 studies and one

background article. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS reiterates it concerns discussed in the FY 2022 IPPS proposed rule. CMS is concerned the applicant's claim of superiority of NexoBrid to standard of care debridement methods are non-specific because the studies were not designed to compare NexoBrid™ to a specific surgical method or an enzymatic debridement product. CMS is also concerned that a comparison to a surgical treatment modality might not be the most appropriate comparator. CMS also notes that the studies did not demonstrate that NexoBrid selectively debrides eschar and does not injure viable skin. In addition, the studies provided variable reports of cosmetic outcome, prolonged wound closure, longer lengths of stay and pain associated with NexoBrid as compared to the standard of care.

New Technology Town Hall. In response to a question, the applicant stated that there is no study comparing NexoBrid to collagenase ointment (Santyl®). Although the clinical trial included collagenase ointment the standard of care treatment arm, the data was not stratified nor powered to conduct this analysis. The applicant also provided an additional study using a porcine burn wound model to compare NexoBrid and collagenase ointment.

i. Omidubicel

Gamida Cell submitted an application for omidubicel, a cryopreserved allogeneic advanced cellular therapy derived from allogeneic umbilical cord hematopoietic (CD34+) progenitor cells that are expanded and enhanced to increase the engraftment efficiency of hematopoietic progenitor cells (HPCs.). The HPCs are expanded and enhanced through a proprietary process in the presence of cytokines and nicotinamide (NAM) technology. According to the applicant, NAM preserves the function and long-term engraftment ability of cord blood-derived stem cells used as a hematopoietic stem cell transplant and may lead to favorable engraftment and patient outcomes.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP2210100TN9R.

Newness. The applicant submitted a BLA to FDA for the treatment of patients with hematologic malignancies is need of a hematopoietic stem cell transplant. The applicant stated there are two procedure codes used to identify transfusion of omidubicel (XW143C8 and XW133C8).

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated omidubicel does not use the same of similar mechanism of action as existing technology and it will be the first and only patient-specific advanced cell therapy for use as allogeneic hematopoietic cell transplantation (HCT). The applicant stated that omidubicel will map to the same MS-DRG as other allogeneic bone marrow transplants and is indicated for the same/similar type of disease and patient population as other allogeneic bone marrow transplants.

CMS is concerned that the mechanism of action for omidubicel is the same as standard HCT and wonders if the difference is related to the development of the technology and not the mechanism of action. CMS requests additional information about how the mechanism of action for omidubicel differs from the standard HCT.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that omidubicel meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that omidubicel represents a substantial clinical improvement over existing technologies for several reasons including providing a treatment need for a diverse group of patients with serious, hematologic malignances and improves clinical outcomes by reducing hospitalization time, and faster recovering of neutrophils with lower incidence of infections resulting in a significant clinical improvement. The applicant submitted 13 data submissions and 16 background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS does not believe that the information provided supports the applicant's claim that omidubicel addresses key barriers to the widespread use of umbilical cord blood (UCB) as a donor source. In addition, the applicant did not provide any data supporting how this treatment will address health disparities. CMS discusses additional concerns with the phase 3 study and the other data sources provided by the applicant. CMS does not believe the information provided supports that omidubicel significantly improves clinical outcomes relative to current treatments. CMS also notes that patients in the omidubicel trials were under 65 and it questions the generalizability of this therapy for the Medicare population.

j. REBYOTA™ (fecal microbiota, live-jslm)

Ferring Pharmaceuticals submitted an application for REBYOTA a broad consortium microbiota-based live biotherapeutic suspension used for the prevention of recurrence of Clostridium difficile infection (CDI).

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017WUDXM.

Newness. The applicant stated that REBYOTA received BLA approval from FDA on November 30, 2022 for the prevention of recurrent CDI (rCDI) in individuals 18 years of age and older, following antibiotic treatment for rCDI. The applicant states that REBYOTA was not commercially available until January 23, 2023 due to the need to develop a packaging process. The applicant stated there is a procedure codes used to identify treatment (XW0H7X8).

As summarized in a table in the proposed rule, the applicant stated that REBYOTA is not substantially similar to other treatments to reduce rCDI because it has a different mechanism of action and is approved to treat a broader patient population. The applicant states that the exact mechanism of action for REBYOTA has not been established but some studies indicate that the treatment may significantly change gut microbiome which is associated with suppression of C. difficile (C.diff.). The applicant provided a comparison with other treatments.

CMS discusses several concerns related to the newness criterion. CMS seeks clarification from the applicant regarding the differences in patient populations that would be treated with ZINPLAVA and REBOYTA. CMS is concerned that REBOYTA and ZINPLAVA™ (a monoclonal antibody that binds C. diff. toxin) treat the same patient population. CMS notes that REBYOTA may have a similar mechanism of action as SER-109, another microbiome therapeutic agent for prevention of rCDI in patients following antibiotic treatment for rCDI (the

application for SER-109 is discussed below in section *m*). Although the exact mechanism of action for each biologic is not known, both appear to act on the cut microbiome to suppress C.diff. and thereby prevent rCDI. In addition, both technologies map to the same MS-DRGs and treat the same or similar disease (rCDI) in the same or similar patient population (patients who previously received antibiotics for CDI or rCDI). CMS believes these technologies may be substantially similar to each other and should be considered as a single application for new technology add-on payments. If both technologies are approved, CMS believes that the beginning of the newness period would be January 23, 2023, the date REBYOTA became commercially available. **CMS is interested in information on how these two technologies may differ with respect to the newness criterion**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that REBOYTA meets the cost criterion.

Substantial Clinical Improvement. The applicant asserts that REBYOTA is a significant clinical improvement over existing technologies because it offers a treatment option for patients unresponsive or ineligible for currently available treatments and because it significantly improves clinical outcomes. The applicant provided 8 studies and background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS believes additional information is needed to support the applicants claim that REBOYTA is an FDA-approved therapeutic option for some patients who may not be eligible for treatment with ZINPLAVA due to patient population restrictions (e.g., high-risk patients) or contraindications (e.g., history of congestive heart failure (CHF)). In addition, although CMS understands there are no head-to-head trials comparing REBYOTA to ZINPLAVA, additional information regarding clinical outcomes comparing the two treatments would be helpful to determine whether REBOYTA demonstrates a substantial clinical improvement over the current standard of treatment.

k. Sabizabulin

Veru submitted an application for sabizabulin, a novel oral microtubule disruptor for treatment of severe SARS-CoV-2 infection in patients with moderate to severe COVID-19 at high risk for Acute Respiratory Distress Syndrome (ARDS) and death. According to the applicant, studies demonstrate that sabizabulin has antiviral and anti-inflammatory activities by disrupting microtubule dynamics.

The online application posting is available at https://mearis.cms.goc/public/publications/ntap/NTP22101FTANY.

Newness. The applicant stated it anticipates Emergency Use Authorization (EUA) and/or NDA approval for sabizabulin for treatment of SARS-COV-2 infection in hospitalized patients with moderate to severe COVID-19 infection who are at high risk for ARDS. CMS notes that a product available only through an EUA would not be eligible for new technology add-on payments. The applicant states there were no ICD-10-PCS procedure codes to identify sabizabulin. CMS notes that effective April 1, 2023, three ICD-10-PCS codes can be used to describe procedures involving sabizabulin (XW0DXK8, XW0G7K8, and XW0H7K8).

As summarized in a table in the proposed rule, the applicant stated that sabizabulin is not substantially similar to other available treatments because it has a unique mechanism of action as a microtubule depolymerization agent which disrupts and suppresses the SARS-CoV-2 virus. The applicant states the technology is assigned to the same MS-DRG as other treatments and treats patients who may receive other COVID-19 treatments.

Costs. CMS summarizes the three analyses provided to demonstrate the technology meets the cost criterion. The applicant concluded that sabizabulin meets the cost criterion.

CMS requests additional information about the third analysis including the inclusion/exclusion used for this analysis and what charges were removed.

Substantial Clinical Improvement. The applicant stated that sabizabulin is a substantial clinical improvement because it improves clinical outcomes relative to other COVID-19 treatments including reduction of at least one clinically significant adverse event (SAE); reduces days in intensive care unit (ICU) on mechanical ventilation; reduced length of stay; and reduced recovery time. The applicant submitted a randomized, multicenter placebo-controlled phase 3 clinical trial. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS is concerned that the applicant cites only one study for all substantial clinical improvement claims that has a sample size of 130 patients treated across five countries (U.S., Brazil, Bulgaria, Argentina, and Mexico) with 204 patients randomly assigned to either treatment or placebo group. CMS questions if these results can be repeated since other studies were not provided. CMS also questions whether the findings from this study are directly applicable to the Medicare population because of the significant differences between standards of care in the study countries and the COVID-19 therapies in the study do not appear to be consistent with US guidelines. CMS also raises questions related to the mortality rates for the placebo group and wonders if this is due to different standards of care, severity of illness and underlying risk, and/or the small number of participants.

l. SeptiCyte® RAPID

Immunoexpress submitted an application for SeptiCyte RAPID, a gene expression assay used in conjunction with clinical assessments and other laboratory findings in patients suspected of sepsis on their first day of ICU care. The applicant states that SeptiCyte RAPID generated a score (SeptiScore) rating from 0 to 15 that falls within one of four discrete interpretation bands based on the increasing likelihood of sepsis.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP2210170WWBT.

Newness. SeptiCyte RAPD received 510(k) clearance on November 29, 2021 as a gene expression assay using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes isolated from whole blood collected in the PAXgene® Blood RNA Tube. The test is used as an aid to differentiate infection-positive (sepsis) from infection-negative systemic inflammatory response syndrome (SIRS) in patients suspected of sepsis on their first day of ICU admission. The applicant stated that SeptiCyte RAPID was cleared based on substantial equivalency to the predicate device SeptiCyte LAB, which was FDA cleared on April 6, 1017. The applicant described differences between the two versions of the

technology. The applicant stated that an ICD-10-PCS may be used to describe the procedure (XXE5X38).

As summarized in a table in the proposed rule, the applicant asserted that SeptiCyte RAPID is not substantially similar to other technologies because it differs in its mechanism of action, performance and turnaround form all current sepsis diagnostic tools. The technology measures the host's immune response to systematic inflammation of infectious origin by measurement of gene expression. The applicant states that SeptiCyte RAPID would likely group into the same MS-DRG for sepsis as existing technologies but it believes the technology is unique and does not involve the treatment of the same/similar type of disease and the same/similar patient population when compared to existing technology.

CMS is concerned that the applicant did not include SeptiCyte LAB, the predicate device for SeptiCyte RAPID, in its discussion of existing technologies. Although the applicant described differences between the two versions, both devices utilize a gene expression assay using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes.[27] CMS notes that the applicant also considers the devices as similar as the applicant submitted studies conducted using the SeptiCyte LAB to demonstrate substantial clinical improvement. If SeptiCyte RAPID is substantially similar to SeptiCyte LAB, CMS believes the newness period for this technology would begin on April 6, 2017 with the 510(k) approval for SeptiCyte LAB and the technology would no longer be considered new and would not be eligible for new technology add-on payments.

CMS also notes that the applicant did not explain how SeptiCyte RAPID targets a different disease or patient population compared to existing sepsis diagnostic testing and it unclear how the patient population tested with SeptiCyte RAPID differs from other patients tested for sepsis, including those tested with SeptiCyte LAB.

Costs. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that SeptiCyte RAPID meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that SeptiCyte RAPID is a substantial clinical improvement over existing technologies because it is the only technology that accurately differentiates sepsis versus non-infectious systemic inflammation in 1 hour which allows appropriate intervention in suspected sepsis patients. The applicant provided eight studies and 12 background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS notes that two of the studies use SeptiCyte LAB, the predicate device, to support why SeptiCyte RAPID represents a substantial clinical improvement. No information is presented to compare these two devices. In addition, the studies show that SeptiCyte RAPID is not a definitive test, the resulting SeptiScores in Bands 2 and 3 are inconclusive. CMS is also concerned that if additional laboratory tests are needed in conjunction with SeptiCyte RAPID to make a diagnosis, then it is not clear whether SeptiCyte RAPID provides an earlier diagnosis that affects the management of the patient. The applicant

[27] https://www.accessdata.fda.gov/cdrh/docs/reviews/K163260.pdf.

did not provide any evidence demonstrating that SeptiCyte RAPID affects the management of the patient or improves clinical outcomes.

m. SER-109

Seres Therapeutics submitted an application for SER-109, an oral microbiome therapeutic administered to reduce CDI recurrence after antibiotic treatment for C.diff. According to the applicant, SER-109, is a consortium of purified Firmicutes bacteria spores collected from health stool donors and Firmicutes bacteria produce metabolites which inhibit C. diff growth.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221016VHL8B.

Newness. The applicant submitted a BLA for the proposed indication to prevent the recurrence of CDI in patients with rCDI. The applicant submitted a request for approval for a unique ICD-10-PCS code for SER-109.

As summarized in a table in the proposed rule, the applicant stated that SER-109 is not substantially similar to other treatments to reduce rCDI and does not involve treatment of the same or similar type of disease or patient population as there are no approved therapies indicated to repair a disrupted microbiome as treatment to prevent recurrence in patients with rCDI. The applicant provided a comparison with other treatments.

CMS discusses several concerns related to the newness criterion. It is concerned that SER-109 and ZINPLAVA™ (a monoclonal antibody that binds C. diff. toxin) treat the same patient population. CMS seeks clarification regarding the differences in patient populations for these treatments. As previously discussed in section *j*, CMS notes that REBYOTA may have a similar mechanism of SER-109, another microbiome therapeutic agent for prevention of rCDI in patients following antibiotic treatment for rCDI. Although the exact mechanism of action for each biologic is not known, both appear to act on the cut microbiome to suppress C.diff. and thereby prevent rCDI. In addition, both technologies map to the same MS-DRGs and treat the same or similar disease (rCDI) in the same or similar patient population (patients who previously received antibiotics for CDI or rCDI). CMS believes these technologies may be substantially similar to each other and should be considered as a single application for new technology add-on payments. If both technologies are approved, CMS believes that the beginning of the newness period would be January 23, 2023, the date REBYOTA became commercially available. **CMS is interested in information on how these two technologies may differ with respect to the newness criterion**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that SER-109 meets the cost criterion.

Substantial Clinical Improvement. The applicant asserts that SER-109 is a substantial clinical improvement over existing technologies because it can be used for patients unresponsive to antibiotic treatment for rCDI and can be used in patient's ineligible for ZINPLAVA due to CHF. The applicant also asserts SER-109 improves clinical outcomes by increasing resolution of the disease by expediting microbiome repair and reduce persistence of antimicrobial resistant genes. The applicant provided 5 studies and 11 background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS is concerned that the phase II and phase III trials excluded patients who received ZINPLAVA in the prior 3 months and there is no data comparing the treatment of rCDI utilizing antibiotics plus ZINPLAVA. CMS believes that without a comparison to currently available therapies, there is insufficient evidence to support the applicant's statements that SER-109 is well-tolerated and mitigates the safety concerns of other alternatives, including use in patient's ineligible for ZINPLAVA. In addition, CMS notes there are no studies comparing SER-109 to other available treatments. It notes that additional information regarding clinical outcomes as a result of treatment with SER-109 compared to other treatments would be helpful to determine whether SER-109 demonstrates a substantial clinical improvement over the current treatment standard.

n. SPEVIGO® (spesolimab)

Boehringer Ingelheim Pharmaceutical submitted an application for SPEVIGO, a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL-36R signaling for the treatment of flares in adult patients with generalized pustular psoriasis (GPP).[28]

The online application posting is available at https://mearis/cms/gpv/public/publications/ntap/NTP2210146275W.

Newness. The applicant stated that SPEVIGO received BLA approval on September 1, 2022 for treatment of generalized pustular psoriasis (GPP) flares in adults. A unique ICD-10-PCS code describes procedures involving the use of SPEVIGO (XW03308).

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that SPEVIGO's inhibition of IL-36R signaling is different from other immune mediated inhibitors. The applicant stated SPEVIGO 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 SPEVIGO but indicated that it 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.

Similar to concerns raised in the FY 2023 IPPS proposed rule, 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 notes that the list of four MS-DRGs identified by the applicant in the cost analysis 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. The applicant concluded that elranatamab 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.

[28]An application was submitted and summarized in the FY 2023 IPPS proposed rule (87 FR 28108-28746) but the technology did not meet the deadline of July 1, 2022 for FDA approval.

Substantial Clinical Improvement. The applicant stated that SPEVIGO represents a substantial clinical improvement because it is the first FDA approved drug for GPP. Based on clinical trials, SPEVIGO was associated with clinically significant improvement in patient-reported psoriasis symptoms, including fatigue and reduced inflammatory markers. The applicant provided one study. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS is concerned that the Effisayil-1 study compares SPEVIGO to placebo instead of current treatment options. In addition, the study primarily assessed clearance of skin manifestations, not systemic symptoms which the applicant stated differentiates GPP from other forms of psoriasis. In addition, complete clearance was not always achieved with SPEVIGO. CMS is concerned that the results of the trial are not generalizable to the Medicare population; the mean age in the study with 43.2 years for the treatment arm and the study population did not have significant comorbidities. CMS also discusses other concerns about the study design including the short duration and lack of comparative data to existing technologies. CMS states additional information would be helpful to support the applicant's assertion of superiority over existing technologies.

o. TECVAYLI™ (teclistamab-cqyv)

Jansen Pharmaceutical submitted an application for TECVAYLI, a bispecific antibody (bsAB) that binds to CD3 on T cells and B cell maturation antigen (BCMA) on myeloma cells.[29] 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.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017MFYGL.

Newness. TECVAYKI was granted BLA approval from FDA on October 25, 2022 for treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a PI, an INiD, and an anti-CD38 monoclonal antibody. The product became commercially available on November 9, 2022. Hospitalized patients will receive three doses subcutaneously for their initial TECVAYLI treatment and due to the risk of cytokine release syndrome (CRS) and neurologic toxicity, patients should be hospitalized for 48 hours after administration of all three does. Cases reporting the use of TECVAYKI may be coded with unique ICD-10-PCS code XW01348.

For the first criterion (same or similar mechanism of action), the applicant stated that TECVAYKI uses a different mechanism of action when compared to existing treatments and compares the mechanism of action for TECVAYKI to these treatments. The applicant also stated that TECVAYKI 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 TECVAYKI 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.

[29] An application was submitted and summarized in the FY 2023 IPPS proposed rule (87 FR 28283-28287) and was withdrawn prior to the issuance of the final rule.

As previously discussed in section *d*, CMS is concerned that TECVAYLI may be substantially similar to elranatamab because they have a similar mechanism of action, have the same MS-DRG assignment, and treat similar patients. If elranatamab receives FDA approval by July 1, 2023, CMS will consider these biologics as a single new technology add-on payments application. TECVAYLI received FDA approval of October 25, 2022 but was not commercially available until November 9, 2022; CMS believes the newness period for this technology would be November 9, 2022. **CMS is interested in information on how these two technologies may differ with respect to the newness criterion**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant removed all charges in the drug cost center. The applicant concluded that TECVAYLI meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that TECVAYLI meets the substantial clinical improvement criterion because it offers a treatment option for patients that cannot receive other therapies since its indication is less restrictive and it may be more immediately accessible than the BCMA CAR T-cell therapies. The applicant also stated that TECVAYLI improves clinical outcomes and has less serious side effects than other off the shelf RRMM therapies. The applicant provided one study and 11 background articles.

CMS discusses concerns with the information provided; these concerns are similar to CMS' concerns for the information provided for elranatamab. CMS is concerned that the evidence supporting the claim that TECVAYLI provides a treatment option for patients that cannot receive other treatment options does not include CAR T-cell therapies. In addition, CMS notes that the evidence that TECVAYLI may be a preferred treatment option for patients unable to access CAR T-cell therapy is based on B-cell lymphoma and questions the applicable of this information to RRMM. CMS is also concerned that the evidence supporting improved safety focuses on only a single metric (CRS grade 3 or higher) and is not based on a comparative study. CMS questions whether there is significant clinical improvement compared to CAR T-cell therapies.

p. TERLIVAZ® (terlipressin)

Mallinckrodt Pharmaceuticals submitted an application for TERLIVAZ, a synthetic, systemic vasoconstrictor with selective activity at vasopressin-1 receptors for use in the treatment of adults with hepatorenal syndrome (HRS).[30] According to the applicant, TERLIVAZ is the first and only FDA-approved treatment indicated to improve kidney function in adults with HRS with rapid reduction in kidney function.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221014UR3R2.

Newness. The applicant stated that TERLIVAZ was granted NDA 505(b) approval on September 14, 2022 for the improvement of kidney function in adults with HRS with rapid reduction in kidney function. According to the applicant, TERLIVAZ became commercially available on

[30] Mallinckrodt Pharmaceuticals previously submitted an application for new technology add-on payments for TERLIVAZ for FY 2022 (86 FR 25339 through 25344) and FY 2023 (87 FR 28287-28296). The applicant withdrew both applications prior to the issuance of the FY 2022 and FY 2023 IPPS final rule.

October 14, 2022; there was a delay in market availability because the company needed additional time to complete market commercialization. There are two unique ICD-10-PCS codes for TERLIVAZ infusion (XW03367 and XW04367).

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated TERLIVAZ is not substantially similar to other technologies because its novel mechanism allows for selective vasoconstrictive effects on the splanchnic vasculature through activation of V1 vasopressin receptors. In addition, TERLIVAZ is the first and only FDA-approved treatment for HRS and offers efficacy among patients who fail previous treatment. For the second criterion (same or different MS-DRG), the applicant stated that the technology would not be assigned to the same MS-DRG as existing technologies because there is no other FDA approved technology for HRS 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.

CMS reiterates it prior concern that although TERLIVAZ might be the first treatment specifically indicated for the treatment of HRS, it does not understand the applicant's assertion that TERLIVAZ does not involve the same/similar type of the disease and the same/similar patient population when compared to existing technology. CMS states that although there might be a subset of patients for whom current treatments are ineffective and for whom TERLIVAZ will offer a new treatment option, this does not necessarily speak to the treatment of a new patient population for HRS.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that TERLIVAZ meets the cost criterion.

Substantial Clinical Improvement. The applicant stated TERLIVAZ offers a substantial clinical improvement over existing technologies because it significantly improves renal function among HRS patients who failed previous therapy with available off-label treatments. The applicant also stated that TERLICAZ remains the preferred treatment for HRS-acute kidney injury (AKI) according to several guidelines. In addition, TERLIVAZ significantly improves clinical outcomes among HRS as compared to placebo as well as currently available treatment. The applicant provided 14 studies. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS has several concerns with the information presented in support of substantial clinical improvement. CMS reiterates it concerns about the CONFIRM study (Phase 3 trial) including the use of verified HRS reversal as the primary endpoint. CMS questions whether this is a clinically significant and appropriate measure of improvement in renal function. CMS again notes that the difference in the proportion of patients with verified HRS reversal without HRS recurrence by Day 30 between the treatment and placebo group was not significantly significant. CMS also notes that several of the applicant's assertions related to improved clinical outcomes, including information about patients 65 years or older, are based on evidence from data on file for the clinical study report of the CONFIRM trial and appear to consist of post-hoc analyses of patient subgroups. CMS is concerned that it is not appropriate to draw conclusions form post-hoc analyses alone without additional outcome data. CMS also reiterates concerns related to the patient populations included in the study by Arora et al.

q. VANFLYTA® (quizartinib)

Daiichi Sankyo submitted an application for VANFLYTA, a kinase inhibitor intended to be indicated for use in combination with standard induction and consolidation chemotherapy, and as continuation monotherapy following consolidation for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is a specific subtype, Feline McDonough Sarcoma (FMS)-like tyrosine kinase 3 internal tandem duplication (FLT3-ITD positive). The applicant states that VANFLYTA is the only treatment to target the FLT3-ITD mutation and blocks the FLT3-ITD-dependent cell proliferation.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017FK1AQ.

Newness. The applicant anticipates NDA approval from FDA for the following proposed indication: a kinase inhibitor indicated in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed AML that is FLT3-ITD positive as detected by an FDA-authorized test. The applicant submitted a request for a unique ICD-10-PCS procedure code for VANFLYTA.

CMS is concerned that the applicant's estimated average inpatient cost per stay is summed instead of being averaged. CMS notes this information is important for determining the new technology add-on payment amount.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that VANFLYTA is the first drug to be expressly developed as a FLT3 inhibitor, not a multi-kinase inhibitor, and specifically optimized to inhibit the FLT3-ITD AML subpopulation. The applicant stated that VANFLYTA would not be assigned to the same DRG as existing technology but identified three MS-DRGs for AML. The applicant also stated that the technology does not treat the same/similar disease and the same/similar patient population when compared to an existing technology. The applicant discusses differences between VANFLYTA and RYDAPT® and XOSPATA®, FDA approved drugs for treatment of AML.

CMS is concerned that the mechanism of action of VANFLYTA is similar to RYDAPT which is indicated for adult patients with newly diagnosed AML who are FLT3 mutation-positive. CMS notes that as indicated by the applicant, VANFLYTA would map to the three existing MS-DRGs for AML. In addition, the patient population for XOSPATA, adult patients with RR AML with the FLT3 mutation, may also be similar to VANFLYTA since both target patient populations with a FLT3 mutation. CMS also notes that the applicant's potential unique patient population for the continuation monotherapy indication would occur on an outpatient basis and does not relate to the technology add-on payment.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that VANFLYTA meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that VANFLYTA represents a substantial clinical improvement for Medicare beneficiaries and offers a treatment option for newly diagnosed patient with FLT3-ITD positive AML. The applicant stated that patients

receiving VANFLYTA had significantly reduced rates of relapse and overall improved survival, regardless of whether patients had a hematopoietic stem cell transplantation (HSCT) when compared to the placebo group. The applicant references multiple sources regarding one study and five background articles about AML and RYDAPT. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS has several concerns with the limited information provided by the applicant which are based only on the results of a single phase 3 trial provided as presentation slides and an abstract. CMS is concerned that the visual abstract does not appear to include all the data that the applicant cited as outcomes to support the claims for a reduced rate of relapse and reduced mortality rate; CMS cannot fully evaluate this supporting evidence. CMS also discusses limitations about the claims related to the Medicare population and notes that age eligibility in a trial is not a clinical outcome. In addition, CMS discusses several concerns related to assertions related to RYDAPT including basing results on the comparison two separate 3 trials.

r. VEST

Vascular Graft Solutions submitted an application for VEST, an external support device fitted over the saphenous vein when used as a bypass conduit in coronary artery bypass grafting (CABG) surgery. According to the applicant, VEST is designed to improve the long-term clinical outcome of CABG surgery by reducing graft failure.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017VRFLQ.

Newness. The applicant is seeking premarket approval from FDA for the indication to prevent vein graft intimal hyperplasia (IH) by providing permanent support to saphenous vein grafts used as conduits in patients undergoing CABG surgery. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code for VEST.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated there is no technology with a similar mechanism of action as VEST. The VEST device will be assigned to MS-DRG for CABG and will be indicated for the patient population undergoing CABG.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that VEST meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that VEST represents a substantial clinical improvement over existing technologies because VEST reduces the incidence of cardiac events and the need for further interventions due to vein graft disease; reduces graft failure rates from kinking; and mitigates vein graft disease. The applicant provided five studies. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS has several concerns with the information presented in support of substantial clinical improvement. First, CMS is concerned that the evidence provided in the studies demonstrates clinical improvement or if some of the outcomes are only inferred from surrogate endpoints. Second, CMS questions whether the impact of VEST on clinical outcomes may have been

confounded by demographic, clinical, or surgical factors. It is also concerned that differences in baseline characteristics of the patients in the treatment and placebo group may have confounded the association between the use of VEST and clinical improvements. CMS is also concerned that surgical decisions could impact VEST on clinical outcomes. Thirdly, CMS questions whether the results can be replicated in the Medicare population undergoing surgery as the study participants were predominately male. CMS notes that female CABG patients tend to have poorer outcomes than men.

New Technology Town Hall. In response to a question, the applicant stated that the surgical technique in the VEST US pivotal trial study did not include patients with "no touch" vein harvesting technique. The applicant stated this technique is rarely used in clinical practice. The applicant also provided information about the analysis used in this study.

s. *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.[31] 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 online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017PBF9L.

Newness. According to the applicant, XENOVIEW was granted NDA approval on December 23, 2022 for use with MRI for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. The applicant stated there is a unique ICD-10-PCS procedure code for XENOVIEW (BB34Z3Z0.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that XENOVIEW is not substantially similar to other technologies because HP^{129}Xe is a new chemical entity and a new lung MRI signaling agent that is created on-site following an FDA approved method, for oral inhalation. 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 stated that lung imaging ICD-10-PCS codes do not determine the MS-DRG assignment upon discharge. For the third criterion (same or similar disease or patient population), the applicant discussed how the use of XENOVIEW would not be for a distinct disease or patient population.

CMS reiterates its prior statement 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.

[31] The applicant submitted an application for new technology add-on payments for XENOVIEW for FY 2023 (87 FR 28307-28317) and withdrew the application prior to the issuance of the FY 2023 IPPS final rule.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that XENOVIEW meets the cost criterion.

CMS notes that the applicant limited its analysis to eight MS-DRGs and is interested in information as to whether the technology would map to other MS-DRGs, such as MS-DRGs under Major Diagnostic Category 004-Disease & Disorders of the Respiratory System.

Substantial Clinical Improvement. The applicant stated that XENOVIEW is a substantial clinical improvement because it offers an effective option for patients with pulmonary challenges to obtain quantitative information regarding their lung ventilation as it relates to their progression of disease without subjecting patients to ionizing radiation or the half-life of nuclear imaging agents. The applicant asserted that XENOVIEW offers the ability to diagnose a medical condition where the condition is undetectable and the ability to diagnose a medical condition earlier. The applicant provided 10 studies. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS reiterates its concern that the information provided by the applicant supporting its assertion that XENOVIEW is able to diagnose a medical condition that is currently undetectable and a medical condition earlier that standard technology does not provide evidence that the use of XENOVIEW to make a diagnosis affected the treatment planning or disease management of patients. CMS also questions whether the detection of alveolar gas-exchange defects using XENOVIEW results in earlier diagnosis and subsequent changes to clinical decision-making following an earlier diagnosis.

7. Proposed FY 2024 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 not need to meet the requirements that it represent a substantial clinical improvement over the current standard of treatment.

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.[32] 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 27 applications for new technology add-on payments under the alternative pathway. Seven applicants withdrew their applications. Of the remaining 20 applications, 16 of

[32] 85 FR 58737 through 58742

the technologies received a Breakthrough Device designation from FDA and 1 has a pending Breakthrough Device designation from FDA. The remaining three applications were designated as a QIDP; there were no applications for technologies approved through 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 2024 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.

In addition, the publicly posted FY 2024 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted) for the applications discussed in the proposed rule are available at https://mearis.cms.gov/public/publications/ntap. In addition, separate tables listing the ICD-10-CM codes, ICD-10-PCS codes, and/or MS-DRGs related to the analysis of the cost criterion for certain applications are available in Table 10 associated with the information posted on the CMS website.[33]

CMS invites public comment on whether these technologies meet the cost criterion.

a. Alternative Pathway for Breakthrough Devices

(1) 4WEB Medical Ankle Truss System

4WEB Medical submitted an application for 4WEB Medical Ankle Truss System (ATS), a tibiotalocalcaneal (TTC) fusion system with a premarket authorized TTC nail to manage ankle bone defects after a failed ankle arthrodesis or arthroplasty.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221014QPJ43

The applicant indicates the ATS received Breakthrough Device designation on October 4, 2022 for use with a premarket TTC nail as part of a TTC fusion system to manage ankle bone defects that may be associated with failed ankle arthrodesis or failed ankle arthroplasty. The applicant is seeking 510(k) clearance from FDA for the same indication. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS questions whether to identify potentially eligible cases the applicant should have search for the ankle fusion codes in combination with diagnosis complication codes reported to identify

[33] https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps. Click on the link to "Acute Inpatient-Files for Download" and see section VI of the Addendum for additional information regarding tables associated with the proposed rule.

previous failure such as category T84, M97.21, or M97.22. Subject to the applicant adequately address this concern, CMS would agree that the technology meets the cost criterion.

Subject to ATS receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2023, CMS proposes to approve ATS for new technology add-on payments for FY 2024. Based on preliminary information provided by the applicant the estimated cost of ATS is $19,500 per patient. CMS proposes the maximum new technology add-on payment for a case involving the use of ATS would be $12,675 for FY 2024 (65 percent of the average cost of the technology).

Note: Abbott Cardiac Rhythm Management submitted separate new technology add-on payments applications for the Aveir™ AR Leadless Pacemaker and The Aveir™ Dual-Chamber Leadless Pacemaker. To facilitate understanding these applications, the application for the dual-chamber leadless pacemaker is summarized before the application for the AR leadless pacemaker. The numbering below reflects the numbering in the proposed rule.

(3) *Aveir™ Leadless Pacemaker* (dual-chamber)

Abbott Cardiac Rhythm Management submitted an application for the Aveir Leadless Pacemaker (dual-chamber), a modular programmable system comprised of two implanted leadless pacemakers that provide dual-chamber pacing therapy: a ventricular leadless pacemaker intended for direct implantation into the right ventricle, and an atrial leadless pacemaker intended for direct implantation into the right atrium. The applicant stated that the Dual Chamber Leadless Pacemaker enables two separate pacemakers to function as one dual-chamber pacing system.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017AJNQH.

The Aveir Dual-Chamber Leadless Pacemaker was granted Breakthrough Device designation on March 27, 2020 for the following proposed indication: Pacemaker implantation is indicated in one of more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. The proposed indications for use of the Leadless Dual Chamber System include all four of the following: (1) Rate-Modulated Pacing indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity; (2) Dual-Chamber Pacing indicated for those patients exhibiting: sick sinus syndrome; chronic, symptomatic second- and third-degree AV block; recurrent Adams-Stroke syndrome; symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out; (3) Atrial Pacing indicated for patients with: sinus node dysfunction and normal AV and intraventricular systems; (4) Ventricular Pacing indicated for patients with: significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest; chronic atrial fibrillation; and severe physical disability. The applicant is seeking FDA approval for the same indications listed on the Breakthrough Device designation.

The applicant also stated that the Breakthrough Device designation applies to two clinical scenarios:

1. A de novo system where a patient receives a Dual-Chamber Leadless Pacemaker, or

2. An upgrade system where a patient already has a ventricular leadless pacemaker and is upgraded to the Dual-Chamber Leadless Pacemaker by receiving the AR Leadless Pacemaker.

The applicant stated that ICD-10-PCS procedure codes 02H6NZ (Insertion of intracardiac pacemaker into right atrium, percutaneous approach) and 02HK3NZ (Insertion of intracardiac pacemaker into right ventricle, percutaneous approach). The applicant also submitted a request for a unique ICD-10-PCS code for the Dual-Chamber Leadless Pacemaker.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. To identify potential cases representing patients who may be eligible for the Dual-Chamber Leadless Pacemaker, the applicant searched the FY 2021 MedPAR file for cases reporting 1CD-10-PCS 02H6NZ in combination with ICD-10-PCS code 02H3NZ. The applicant identified 991 claims mapping to 38 MS-DRGs. The applicant calculated a final inflated average case-weighted standardized charge and concluded that the Dual-Chamber Leadless Pacemaker meets the cost criterion.

CMS questions why there are cases identified with procedure codes 02H6NZ and 02H3NZ and wonders what technology the cases identified in the MedPAR data represent. Although these procedures codes were approved beginning in FY 2017, the applicant stated there are no technologies on the market eligible to be coded with procedure code 02H63NZ and there are no dual-chamber leadless pacemakers currently available. CMS wonders whether searching for cases utilizing standard pacemakers instead of leadless pacemakers would better reflect the technology the Dual-Chamber Leadless Pacemaker will be replacing. Subject to the applicant adequately address this concern, CMS would agree that the technology meets the cost criterion.

Subject to the Dual-Chamber Leadless Pacemaker receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2023, CMS proposes to approve the technology for new technology add-on payments for FY 2024. The applicant has not provided an estimate for the cost of the Dual-Chamber Leadless Pacemaker and CMS expects the applicant to submit cost information prior to the final rule.

(2) Aveir™ AR Leadless Pacemaker

Abbott Cardiac Rhythm Management submitted an application for the Aveir AR Leadless Pacemaker, a programmable system comprised of a single leadless pacemaker implanted into the right atrium that provides single-chamber pacing therapy without the need for traditional wire leads.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP221017AH7JC.

The applicant stated that the Aveir AR Leadless Pacemaker received Breakthrough Device Designation on March 27, 2020 under the Breakthrough Device designation for the Dual-Chamber Leadless Pacemaker. As discussed above, there are four proposed indications for the Dual-Chamber Leadless Pacemaker, the relevant indications for the AR Leadless Pacemaker are the first and third indications, rate-modulated pacing and atrial pacing. In addition, the Breakthrough Device designation applies to two clinical scenarios: a de novo system where a

patient receives the Dual-Chamber Leadless Pacemaker, or an upgrade system where a patient already has a ventricular leadless pacemaker and is upgraded to the Dual-Chamber Leadless Pacemaker by receiving the AR Leadless Pacemaker. The applicant is seeking FDA approval for both the atrial leadless pacemaker and the dual leadless pacemaker.

CMS notes that the Breakthrough Device designation is for the Leadless Dual Chamber System. Although the AR Leadless Pacemaker may be one component of the system, CMS thinks that on its own it is not the subject of the Breakthrough Device designation, and would not be considered a Breakthrough Device once FDA approved. CMS states that because the AR Leadless Pacemaker would only be eligible under the alternative pathway for procedures involving the full dual-chamber system (this includes patients upgraded to the Dual-Chamber Leadless Pacemaker by receiving the AR Leadless Pacemaker), it believes an eligible use of the AR Leadless Pacemaker would be included under the new technology add-on payment application for the Dual-Chamber Leadless Pacemaker.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. To identify potential cases representing patients who may be eligible for the AR Leadless Pacemaker, the applicant searched the FY 2021 MedPAR file for cases reporting 1CD-10-PCS 02H6NZ. The applicant identified 1,186 claims mapping to 43 MS-DRGs. The applicant calculated a final inflated average case-weighted standardized charge and concluded that the Dual-Chamber Leadless Pacemaker meets the cost criterion.

CMS reiterates its concerns about the cost analysis for the Dual-Chamber Leadless Pacemaker. CMS wonders whether searching for cases utilizing standard pacemakers instead of leadless pacemakers would better reflect the technology that the applicant anticipates the AR Leadless Pacemaker will be replacing. Subject to the applicant adequately address this concern, CMS would agree that the technology meets the cost criterion.

Subject to the AR Leadless Pacemaker receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2023, CMS proposes to approve the technology for new technology add-on payments for FY 2024. The applicant has not provided an estimate for the cost of the AR Leadless Pacemaker and CMS expects the applicant to submit cost information prior to the final rule.

(4) Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System

Zimmer Biomet submitted an application for the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System, a tibial extension implant containing electronics and software, used with the Zimmer Persona Personalized Knee System. The CTE with CHIRP System collects kinematic data pertaining to a patient's gait and activity level following total knee arthroplasty (TKA) surgery using internal motion sensor.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221014KYAL1.

CTE with CHIRP received Breakthrough Device designation on October 24, 2019 for the following proposed indication: use with the Zimmer Persona Personalized Knee System for

TKA. CTE with CHIRP was granted De Novo classification on August 27, 2021 for the following indication: to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. The applicant stated the technology was not commercially available until October 4, 2021 due to production delays related to COVID-19 and the need to negotiate data agreements with customer hospitals. The applicant has submitted a request for approval for a unique ICD-10-PCS procedure code.

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

CMS proposes to approve new technology add-on payments for FY 2024. Based on preliminary information provided by the applicant the cost of CTE with CHIRP System is approximately $1,654 per knee. CMS proposes the maximum new technology add-on payment for a case involving the CTE with CHIRP System would be $850.85 for one knee (or $1,701.70 for two knees) for FY 2024.

(5) Ceribell Delirium Monitor

Ceribell submitted an application for the Ceribell Delirium Monitor, a medical device system comprised of proprietary software and two cleared, proprietary products, a single use signal acquisition headband (the Ceribell EEG Headband) and a recorder (the Ceribell Pocket EEG). The software utilizes a machine learning model to analyze EEG signals to provide more effective diagnosis of delirium.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221014R4HKQ.

The Ceribell Delirium Monitor received Breakthrough Device designation on August 11, 2022 for the following proposed indication: The Ceribell Delirium Monitor software is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor software is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients aged 65 and older in critical settings within hospitals. The applicant is seeking market authorization under the De Novo pathway for the same indication. The applicant submitted a request for a unique ICD-10-PCS procedure code for the Ceribell Delirium Monitor.

CMS notes that the Ceribell EEG Headband and Pocket EEG are not included on the Breakthrough Device designation. CMS states that only the software would be eligible for new technology add-on payments under the alternative pathway.

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

CMS proposes to approve the Ceribell Delirium Monitor for new technology add-on payments for FY 2024. The applicant has not provided an estimate for the cost of the technology and CMS expects the applicant to submit cost information prior to the final rule. The applicant stated that the operating costs of the technology is comprised of the Monitor software and the EEG headband. CMS believes that only the software, which is the subject of the Breakthrough Device designation, is eligible for the new technology add-on payment. In addition, CMS believes the

Ceribell EEG software headband was 510(k) cleared on August 21, 2017 and would no longer be considered new. CMS concludes that any add-on payment for the Ceribell Delirium Monitor would only include the cost of the software.

(6) Ceribell Status Epilepticus Monitor

Ceribell submitted another application for the Ceribell Status Epilepticus Monitor, a medical device system comprised of proprietary software and two cleared, proprietary products, a single use signal acquisition headband (the Ceribell EEG Headband) and a recorder (the Ceribell Pocket EEG). The software utilizes a machine learning model to analyze EEG signals to provide more effective diagnosis of status epilepticus (ESE)

The online application is available at https://mearis.cms/gov/public/publications/ntap/NTP22101439A1J.

The Ceribell Status Epilepticus Monitor received Breakthrough Device designation on October 25, 2022 for the following proposed indication: The Ceribell Status Epilepticus Monitor software is intended for the diagnosis of ESE in adult patients at risk for seizure. The Ceribell Status Epilepticus Monitor software analyzes EEG waveforms and identifies patterns consistent with ESE as defined in the American Clinical Neurophysiology Society's Guideline 14. The applicant is seeking market authorization under the De Novo pathway for the same indication. The applicant submitted a request for a unique ICD-10-PCS procedure code for the Ceribell Status Epilepticus Monitor.

CMS notes that the Ceribell EEG Headband and Pocket EEG are not included on the Breakthrough Device designation. CMS states that only the software would be eligible for new technology add-on payments under the alternative pathway.

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

CMS proposes to approve the Ceribell Status Epilepticus Monitor for new technology add-on payments for FY 2024. Based on preliminary information provided by the applicant the total cost of the Ceribell Status Epilepticus Monitor to the hospital is anticipated to be $2,600 per patient ($1,800 for the software and $800 for the required headband). As previously discussed, only the software would be eligible for the new technology add-on payment. Therefore, the add-on payment for the Ceribell Status Epilepticus Monitor would include only the cost of the software and the proposed maximum new technology add-on payment would be $1,170 for FY 2024.

(7) EchoGo Heart Failure 1.0

Ultromics Limited submitted an application for EchoGo Heart Failure 1.0, an automated machine learning-based decision support system indicated as a diagnostic aid for cardiovascular assessment using echocardiography.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2210172L1HN.

EchoGo Heart Failure 1.0 received Breakthrough Device designation on February 24, 2022, as an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilized by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction. Echo Heart Failure 1.0 is indicated in adults over 25 years of age. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis. The applicant received FDA 510(k) clearance for the same indication on November 23, 2022. The applicant submitted a request for a unique ICD-10-PCS procedure code to identify the technology.

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

CMS proposes to approve new technology add-on payments for FY 2024. Based on preliminary information provided by the applicant the cost of EchoGo Heart Failure 1.0 is approximately $1,575. CMS proposes the maximum new technology add-on payment for a case involving the EchoGo Heart Failure 1.0 would be $1,023.75 for FY 2024.

(8) LimFlow System

LimFlow submitted an application for the LimFlow System, a single-use medical device intended for patients with no-option chronic limb-threatening ischemia (CLTI) of the lower extremities who are at risk of major amputation.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221012C5JB7.

The LimFlow system received Breakthrough Device designation on October 3, 2017 for use in patient with CLTI with no suitable endovascular or surgical revascularization options and are at risk of major amputation. The applicant is seeking premarket authorization from FDA for the same indication. The applicant provides a list of ICD-10-PCS codes that describe procedures involving the use of the LimFlow System

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

Subject to the LimFlow System receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2023, CMS proposes to approve the technology for new technology add-on payments for FY 2024. Based on preliminary information provided by the applicant the total cost of the LimFlow System to be $25,000 per patient. The proposed maximum new technology add-on payment would be $16,250 for FY 2024.

(9) Nelli® Seizure Monitoring System

Neuro Event Labs submitted an application for the Nelli Seizure Monitoring System, a prescription-only device designed to be used as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age or over.[34]

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2210147LTUM.

The Nelli Seizure Monitoring System received Breakthrough Device designation from FDA on October 9, 2020 for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults. The applicant stated it is seeking 510(k) clearance with a proposed indication for use as an adjunct to seizure monitoring of adults in healthcare facilities during periods of rest. CMS states that the anticipated FDA indication is included in the scope of the Breakthrough Device designation and it appears the proposed indication is appropriate under the alternative pathway criteria. The applicant stated that an ICD-10-PCS code may be used to uniquely describe procedures with the Nelli Seizure Monitoring System (XXE0X48).

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

Subject to the Nelli Seizure Monitoring System receiving FDA marketing authorization by July 1, 2023, CMS proposes to approve the technology for the Breakthrough Designation indication for new technology add-on payment for FY 2024. 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 2024.

(10) NUsurface® Meniscus Implant

Active Implants submitted an application for NUsurface Meniscus Implant, a flexible, discoid medial meniscus replacement implant intended for patients with persistent knee compartment pain following medical meniscus surgery.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221014466YN.

The NUsurface Meniscus Implant received Breakthrough Device Designation on September 13, 2019 for middle-aged patients for whom nonsurgical care and partial medial meniscectomy surgery failed to relieve knee pain that impacted day-to-day functioning, especially in patients with more than one meniscectomy. The applicant is seeking De Novo classification from FDA

[34] Neuro Event Lab submitted an application for new technology add-on payments for this technology in the FY 2023 IPPS proposed rule (87 FR 28341-28342) but the technology did not meet the FDA approval deadline.

for the same indication. The applicant stated that two ICD-10-PCS codes uniquely describe procedures with this technology (XRRG0M8 and XRRH0M8).

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion and concludes the applicant did not provide a complete cost analysis. Because the cost calculation did not present an analysis based on the average charge per case, CMS is unable to assess whether the average charge per case exceeds the threshold for MS-DRG 489. CMS also believes cases eligible for this technology may map to additional MS-DRGs for consideration in the cost analysis. CMS requested a revised cost analysis to demonstrate that the technology meets the cost criterion but it did not receive a revised analysis in time for consideration of this proposed rule.

Because the applicant has not provided sufficient information to demonstrate that the NUsurface Meniscus Implant meets the cost criterion, CMS is proposing to disapprove new technology add-on payments for FY 2024. If updated information is provided to establish that the technology meets the cost criterion, CMS notes the anticipated total device cost of the NUsurface Meniscus Implant to the hospital will be approximately $9,795 per patient which is the cost of the NUsurface definitive implant ($7,295) and the NUsurface trial implants ($2,500 which are disposable and used to determine the definitive implant size) and the maximum new technology add-on payment for a case involving this technology would be $6,366.75.

The applicant also included $2,026 in related O.R. time and procedure-related costs. CMS notes that payment is based on the cost of the actual technology and not for additional costs related to the use of the device (86 FR 45146.

(11) Phagenyx® System

Phagenesis Ltd. Submitted an application for the Phagenyx System, a neurostimulation device for the treatment of neurogenic dysphagia.[35]

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221013D2MDC.

The Phagenyx System received Breakthrough Device designation on January 29, 2021 for the treatment of non-progressive neurogenic dysphagia in adult patients. The Phagenyx System was granted De Novo Classification on September 16, 2022 as a neurostimulation device delivering electrical stimulation to the oropharynx, to be used in addition to standard dysphagia care, as an aid to improve swallowing in patients with severe dysphagia stroke. CMS states that the FDA indication is included in the scope of the Breakthrough Device designation and the indication is appropriate under the alternative pathway criteria. The applicant indicated that the administration of Phagenyx can be identified by ICD-10-PCS procedure code (XWHD7Q7).

[35] Phagenesis previously submitted an application for new technology add-on payments for the Phagenyx System for FY 2022 IPPS proposed rule (86 FR 253682 through 25384) and FY 2023 IPPS proposed rule (87 FR 28342-28344), but the technology did not meet the July 1deadline for FDA approval or clearance and was not eligible for new technology add-on payments for FY 2022 and FY 2023.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that Phagenyx System meets the cost criterion.

CMS proposes to approve the Phagenyx System for new technology add-on payment for FY 2024. 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 2024.

(12) SAINT Neuromodulation System

Magnus Medical submitted an application for the SAINT Neuromodulation System, a non-invasive repetitive transcranial magnetic stimulation (TMS) device that identifies an individual target and delivers magnetic pulses delivered to the target within the prefrontal cortex to treat major depressive disorder (MDD).[36]

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2210157HBCW.

The SAINT Neuromodulation System received Breakthrough Device designation from FDA on July 1, 2021 for the treatment of MDD in adult patients who failed to receive satisfactory improvement from prior antidepressant medication in the current episode. The Magnus Neuromodulation System (SAINT Neuromodulation System) received 510(k) clearance on September 1, 2022 for the same indication. The applicant does not anticipate the technology being available for sale until March 29, 2024 because of manufacturing changes. Several components of the System are currently being integrated into a single unit and the applicant needs to develop scalable manufacturing of the production systems to optimize commercialization of the technology. The applicant stated that there is one ICD-10-PCS code (X0Z0X18) that unique describe procedures using the technology.

CMS notes that the Breakthrough Device designation was for the SAINT Neuromodulation System and that changes to the system to integrate components may require a reassessment by FDA to determine if the single system still meets the current Breakthrough Device designation or if a new application for Breakthrough Device designation and additional 510(K) clearance is required**. CMS is interested in additional information regarding the Breakthrough Device status of the integrated, single unit system as it becomes available.**

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that the SAINT Neuromodulation System meets the cost criterion.

CMS proposes to approve the SAINT Neuromodulation System for new technology add-on payments for FY 2024. Based on preliminary information, the applicant anticipates the total cost of the SAINT Neuromodulation System to be $19,500.00 per patient for 50 sessions over 5 days.

[36] An application for this technology was submitted for a new technology add-on payment for the FY 2023 IPPS proposed rule (87 FR 28339-28341) and withdrawn prior to the issuance of the proposed rule. The application was under the name Magnus Neuromodulation System with SAINT Technology.

CMS proposes that the maximum new technology add-on payment for a case involving this technology would be $12,675.00.

(13) Selux NGP System

Selux Diagnostics submitted an application for the Selux Next-Generation Phenotyping (NGP) System, a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist clinicians in the identification of in vitro susceptibility or resistance to specific antimicrobial agents.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221017CVJ8C.

The Selux NGP System received Breakthrough Device designation form FDA on September 21, 2021 for use with bacteria separated from monomicrobial positive blood cultures and sterile body fluid samples from non-charcoal-containing types of bottles.[37] The applicant is seeking FDA premarket approval for the same indication. CMS notes that the FDA Breakthrough Device designation letter refers to the technology as the "Direct-from-Positive Blood Culture Rapid AST System. CMS requests additional clarification on whether the Selux NGP System is the same as the device granted Breakthrough Device designation. The applicant submitted a request for a unique ICD-10-PCS procedure code.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that the Selux NGP System meets the cost criterion.

CMS proposes to approve the Selux NGP System for new technology add-on payments for FY 2024. As discussed below, CMS calculates the average cost per patient would be $162.05. CMS proposes that the maximum new technology add-on payment for a case involving the Selux NGP System would be $105.33 for FY 2024.

Calculation of the average cost per patient. Based on preliminary information from the applicant, the total cost of the Selux NGP System to the hospital is $149.87; this includes the capital component (Positive Blood Culture Separator, Inoculator and Analyzer ($14.83) and the operating components (Gram Negative and Gram-Positive Kit ($80.00), Positive Blood Culture Kit ($50.00), Analyzer Reagent Kit ($4.79) and Waste Kit ($0.25)). CMS does not include capital costs in the add-on payments and concludes that the total operating cost of the Selux NGP System is $135.04 per patient per test.

In addition, the applicant stated that the total cost per patient will vary depending on the estimated number of tests the hospital expects it will perform. The applicant analyzed the Premier Healthcare Database (PHS-AC) linked to Closed Claims (PHD-CC), microbiology data and found information for over 490,000 patient journals. After applying criteria to optimize the data the applicant determined that on average, each patient with a positive blood culture would receive 1.2 AST tests using the Selux NGP System per stay. Using this information, the average

[37] Non-charcoal-containing types include BACTEC, BacT/ALERT, VIRTUO, and VersaTREK blood culture bottles.

cost per patient would be $162.05 (the cost per test of $135.04 x 1.2 tests on average, per patient).

(14) DETOUR System

Endologix submitted an application for DETOUR System, a fully percutaneous approach to femoral-popliteal bypass.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2210149Y5M6.

The DETOUR System received Breakthrough Device designation from FDA on September 2, 2020 for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease. The applicant is seeking premarket approval from FDA for the same indication. The applicant submitted a request for a unique ICD-10-PCS procedure code for the DETOUR System.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that the DETOUR System meets the cost criterion.

Subject to the DETOUR System receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2023, CMS proposes to approve the technology for new technology add-on payments for FY 2024. The applicant has not provided an estimate for the cost of the technology and CMS expects the applicant to submit cost information prior to the final rule.

(15) TOPS™ System

Premia Spine submitted an application for the TOPS System, a motion preserving device that is inserted into the lumbar vertebral joint and anchored using pedicle screws after posterior spinal decompression surgery to preserve spinal motion and stabilization of the lumbar intervertebral segment.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2210146W0H2.

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 is seeking premarket approval from the FDA for the following indication: for patients between ages 36 and 80 years suffering from degenerative spondylolisthesis with specified characteristics (identical to the Breakthrough Device designation). CMS notes that under the alternative pathway for devices, only the use of the technology for the indication that corresponds to the Breakthrough Device designation would be eligible for new technology add-on payments. The applicant stated there are two ICD-10-PCS procedure codes (XRHB018 and XRHD018) to unique describe procedures using this technology.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that the TOPS System meets the cost criterion.
Subject to the TOPS System receiving marketing authorization by July 1, 2023, CMS proposes to approve the TOPS System for new technology add-on payments for FY 2024. Based on preliminary information from the applicant, the cost of the TOPS System is $17,500. CMS proposes that the maximum new technology add-on payment for a case involving the use of the technology would be $11,375 for FY 2024.

(16) Total Ankle Talar Replacement

4WEB Medical submitted an application for the Total Ankle Talar Replacement, a patient specific, metallic spacer that is a solid, replica of a patient's physiologic talus and intended to articulate to the surrounding native bone anatomy. The device is intended to allow for restoration of function due to losses from talar dysfunction.

The online application is available at https://mearis.cms.gov/public/publication/ntap/NTP221014C88U0.

The applicant is seeking both Breakthrough Device designation and 510(k) clearance from FDA for the Total Ankle Talar Replacement for use with a premarket authorized total ankle arthroplasty system to manage talar dysfunction that may be associated with the following indications: failed ankle arthroplasties, talar trauma, tumors or lesions, ankle arthritis/degenerative joint disease, ankle arthrodesis or malunion, talar osteomyelitis/infection or ankle/foot deformities. The applicant submitted an application for a unique ICD-10-PCS code.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS questions if the tarsal joint replacement procedure codes used for the analysis are appropriate given the technology is a replica of the talus and whether only cases for talar replacement should be used. Subject to the applicant adequately address this concern, CMS would agree that the technology meets the cost criterion.

Subject to the technology receiving both Breakthrough Designation and FDA marketing approval by July 1, 2023, CMS proposes to approve the Total Ankle Talar Replacement for new technology add-on payments for FY 2024. Based on preliminary information provided by the applicant the estimated cost of the technology is $19,500 per implant. CMS proposes the maximum new technology add-on payment for a case involving the use of the Total Ankle Talar Replacement would be $12,675 for FY 2024 (65 percent of the average cost of the technology.

(17) Transdermal GFR Measurement System utilizing Lumitrace

MediBeacon submitted an application for Transdermal Glomerular Filtration Rate (GFR) Measurement System utilizing Lumitrace for measuring GFR in patients with impaired or normal renal function during clinical conditions where the teal time measurement of GFR (versus estimated measures) is clinically useful to patient management.

The online application is available at https://www.mearis.cms.gov/public/publications/ntap/NTP221013VQ6RT.
The Transdermal GFR Measurement System received Breakthrough Device designation from FDA on October 16, 2018 for measuring GFR in patients with impaired or normal renal function. The applicant is seeking premarket approval for the same indication. The applicant stated that one ICD-10-PCS code (XT25XE5) may be used to identify procedures using the technology.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that the Transdermal GFR Measurement System meets the cost criterion.

Subject to the Transdermal GFR Measurement System receiving FDA marketing approval consistent with its Breakthrough Designation by July 1, 2023, CMS proposes to approve the technology for new technology add-on payments for FY 2024. The applicant has not provided an estimate for the cost of the technology and CMS expects the applicant to submit cost information prior to the final rule.

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

(1) taurolidine/heparin

CorMedix submitted an application for 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).

CMS notes that CorMedix submitted an application for new technology add-on payments for taurolidine/heparin for FY 2023 under the name DefenCath and received conditional approval for new technology add-on payments for FY 2023, subject to DefenCath receiving FDA market authorization before July 1, 2023 (87 FR 48978-48982). If the FDA marketing authorization is received on or after July 1, 2023 no new technology add-on payments with be made for cases involving the use of DefenCath for FY 2023. The applicant stated it submitted this second application in the event that it does not obtain FDA approval prior to July 1, 2023.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221014UJ89G.

According to the applicant, taurolidine/heparin received QIDP designation from FDA in 2015 for the prevention of CRBSI in patients with ESRD receiving HD through a CVC, and has been granted FDA Fast Track status. The applicant stated that an ICD-10-PCS code (XY0YX28) may be used to uniquely describe procedures using this technology.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that the taurolidine/heparin meets the cost criterion. **CMS welcomes additional information on additional codes or criteria to better target cases of taurolidine/heparin for the cost criterio**n.

CMS summarizes the following options for this application:

- If taurolidine/heparin receives FDA marketing authorization prior to July 1, 2023, CMS proposes to continue making new technology add-on payments for taurolidine/heparin for FY 2024.
- If taurolidine/heparin does not receive FDA marketing authorization by July 1, 2023 to receive new technology add-on payments beginning with FY 2023, CMS proposes to conditionally approve taurolidine/heparin for new technology add-on payments for FY 2024, subject to the technology receiving FDA market authorization by July 1, 2024.
- If taurolidine/heparin receives FDA marketing authorization by July 1, 2024, the new technology add-on payment for cases involving the use of this technology would be made for discharges beginning in the first quarter after FDA marketing authorization is granted.
- If taurolidine/heparin receives FDA marketing authorization on or after July 1, 2024, no new technology add-on payments would be made for cases involving the use of taurolidine/heparin for FY 2024.

Based on preliminary information form the applicant, the WAC of taurolidine/heparin is $1,170 per three milliliter vial. According to the applicant, on average, patients will receive 9.75 HD treatments per inpatient stay based upon the average length of stay of 13.3 days, which would require 19.5 vials of taurolidine/heparin. CMS is interested in additional information as to how the length of stay for patients on HD and the estimation of daily or every other day dialysis were determined for purposes of estimating the anticipated average cost. The applicant anticipates the cost of taurolidine/heparin to the hospital per patient to be $22,815. CMS proposes that the maximum new technology add-on payment for a case involving the use of taurolidine/heparin would be $17,111.25 for FY 2024 (75% of the average cost of the technology).

(2) REZZAYO™ (rezafungin for injection)

Cidara Therapeutics submitted an application for REZZAYO, an echinocandin antifungal drug for the treatment of candidemia and invasive candidiasis in patients 18 years or older.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221017057WN.

REZZAYO received QIDP designation from FDA on June 27, 2018 for treatment of candidemia and invasive candidiasis. The applicant stated that the NDA for REZZAYO was approved on March 22, 2023 for use in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. CMS notes that approval of this indication is based on limited clinical safety and efficacy data for REZZAYO and it is interested in additional information on whether REZZAYO is considered a QIDP under the NDA. The applicant submitted a request for a unique ICD-10-PCS procedure code for REZZAYO.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that REZZAYO meets the cost criterion.

CMS proposes to approve REZZAYO for the new technology add-on payments for FY 2024 for use in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. The applicant has not provided an estimate for the cost of REZZAYO and CMS expects the applicant to submit cost information prior to the final rule.

(3) SUL-DUR (sulbactam/durlobactam)

Entasis Therapeutics submitted an application for SUL-DUR, a penicillin derivative and classified as a ß-lactamase inhibitor that has antibacterial activity against Acinetobacter baumannii and other members of the Acinetobacter baumannii-calcoaceticus complex (ABC). Sulbactam in combination with durlobactam, will be used for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) and bloodstream infections (BSI) due to Acinetobacter baumannii.

The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP221017F5WKE.

SUL-DUR received QIDP designation for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii. The applicant stated it is seeking a broader NDA from FDA for the treatment of adults with infections due to ABC organisms, including multidrug-resistant and carbapenem-resistant strains. CMS notes that under the alternative pathway, only the FDA QIDP designation, the use of SUL-DUR for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii, is eligible for new technology add-on payments. The applicant submitted an application for a unique ICD-10-PCS procedure code for SUL-DUR.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that REZZAYO meets the cost criterion.

CMS summarizes the following options for this application:

- If SUL-DUR receives FDA marketing authorization prior to July 1, 2023, CMS proposes new technology add-on payments for FY 2024.
- If SUL-DUR does not receive FDA marketing authorization by July 1, 2023, CMS proposes to conditionally approve SUL-DUR for new technology add-on payments for FY 2024, subject to the technology receiving FDA market authorization by July 1, 2024.
- If SUL-DUR receives FDA marketing authorization before July 1, 2024, the new technology add-on payment for cases involving the use of this technology would be made for discharges beginning in the first quarter after FDA marketing authorization is granted.
- If SUL-DUR receives FDA marketing authorization on or after July 1, 2024, no new technology add-on payments would be made for cases involving the use of SUL-DUR for FY 2024.

Based on preliminary information, the anticipated cost of SUL-DUR is $15,000 per stay. The applicant did not provide the cost per vial and did not supply information on the average cost of treatment for 10 days. CMS is interested in this information. CMS proposes that the maximum

new technology add-on payment for a case involving the use of SUL-DUR when used for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii would be $11,250 for FY 2024.

8. Proposal to Modify New Technology Add-On Payment Application Eligibility Requirements Related to FDA Application Status and to Move FDA Marketing Authorization Deadline from July 1 to May 1 for Technologies that Are Not Already FDA Market Authorized

CMS discusses the information submitted and the process CMS uses for determining whether the medical service or technology meets the new technology add-on payment criteria. As part of this process, CMS works to ensure that the public has sufficient information to comment on whether the medical service or technology meets these criteria.

CMS notes that it has not specified how complete an application must be at the time of its submission which has resulted in a significant number of applications that lack critical information to evaluate the eligibility criteria for the proposed rule. Applicants have stated that information is missing because they have not yet submitted a request to the FDA for the necessary marketing authorizations. For the alternative pathway, applications are missing information that provides details about the intended indication and the FDA Breakthrough Device or QIDP designation. CMS believes that requiring applicants to have already submitted a market authorization request to FDA at the time of submission of the new technology add-on payment application would improve the evaluation process and increase transparency.

For FY 2025, CMS proposes that to be eligible for consideration for the new technology add-on payment, an applicant must have already submitted an FDA market authorization request before submitting an application for new technology add-on payments. For this policy, submission of a request for market authorization by the FDA means the applicant has submitted a complete application to FDA, and that the application has an active status with the FDA (such as not in a Hold status or have received a Complete Response Letter).

- An applicant must provide documentation of the market authorization request when the application is submitted to CMS. CMS proposes the documentation would be an FDA acceptance or filing letter.
- The applicant would also indicate on the application whether the FDA request has an active status with FDA.
- Applications for technologies that have already received FDA market authorization would not be required to submit an FDA acceptance of filing letter.

CMS proposes to amend 42 CFR 412.87 by redesignating current paragraph (e) as (f) and add a new provision at 42 CFR 412.87(e) to state that CMS will only consider, for add-on payments for a particular fiscal year, an application for which the medical service or technology is either FDA market authorized for the indication that is the subject of the application or for which the medical service or technology is the subject of a complete and active FDA marketing authorization request and documentation of FDA acceptance or filing is provided at the time of the application submission.

CMS discusses the increased complexity and volume of applications for new technology add-on payments. In the first 20 years of the program, CMS received on average 2-10 applications per year; applications have risen by 200 percent from FY 2020 to FY 2024. As new technology continues to develop, CMS expects both the complexity and number of applications to increase, further increasing the need for additional time to fully evaluate the applications for the final rule. CMS believes additional time is necessary to fully evaluate the applications.

For FY 2025, CMS proposes to move the FDA marketing authorization deadline from July 1 to May 1. CMS notes it would continue not to include in the final rule discussion of new technology add-on payment applications that were withdrawn or ineligible for consideration because they did not meet the proposed May 1 deadline. CMS is not proposing to change the July 1 deadline for certain antimicrobial products submitted under the alternative pathway because they would continue to be eligible for conditional approval.

CMS seeks public comments on these proposals.

Regulatory Impact Analysis
For FY 2024, CMS proposes to continue the new technology add-on payment for 11 technologies. Based on the applicant's estimates at the time they submitted their original application, CMS estimates the aggregated total FY 2024 payments for these new technology add-on payments would be approximately $131 billion dollars.

CMS is proposing to approve 20 technologies under the alternative pathway for FY 2024 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 $263 million for FY 2024. Total estimated FY 2024 payments for QIDP designated new technologies are approximately $213 million and the total estimated FY 2024 payments for Breakthrough Device designated new technologies are approximately $50.5 million. This estimate does not include the new technology add-on payments for six technologies that are part of the Breakthrough Device program and one of the QIDP applicants because cost or volume information was not included in their applications.

CMS has not determined the potential payment impact of the 19 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 2024.

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 2020 submitted cost reports. CMS is not proposing any changes to the categories of included and excluded costs for FY 2024 relative to prior years. CMS' proposed rule calculations of the FY 2024 wage index are based on wage data of 3,103 hospitals. The data file used to construct the proposed wage index includes FY 2020 data submitted to CMS as of January 30, 2023.

CMS notes that the wage index data that it is using for the FY 2024 wage index spans the COVID-19 PHE. The proposed rule presents some summary data showing that a higher proportion of hospitals had an increase in their average hourly wage using the FY 2020 data than in prior years. However, CMS indicates that it is not apparent whether any changes due to the COVID-19 PHE differentially impacted the wages paid by individual hospitals (e.g., only a differential change due to the COVID-19 PHE would affect the wage index). Even if there were differential impacts, it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data.

General wage index policies are unchanged from prior years. CMS proposes to exclude 88 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 2024 wage indexes.

C. Method for Computing the Unadjusted Wage Index

For the FY 2024 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 $50.33.

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 (3,007 of 3,103) used to determine the FY 2024 proposed rule wage index. Consistent with the statute, CMS will apply the 2019 occupational mix survey data to the FY 2024 wage index. The FY 2024 national average hourly wage, adjusted for occupational mix, is $50.27.

A new occupational mix survey will be required for use with the FY 2025 wage index. The FY 2025 occupational mix adjustment will be based on a calendar year 2022 survey. Hospitals are required to submit their completed 2022 surveys to their MACs by June 30, 2023.

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	229 (55.6%)
Number of Rural Areas Wage Index Increasing	26 (55.3%)
Number of Urban Areas Wage Index Increasing 1%<= and <5%	124 (30.1%)
Number of Urban Areas Wage Index Increasing >5%	5 (1.2%)
Number of Rural Areas Wage Index Increasing 1%<= and <5%	12 (25.5%)
Number of Rural Areas Wage Index Increasing >5%	0 (0%)
Number of Urban Areas Wage Index Decreasing	78 (18.9%)
Number of Rural Areas Wage Index Decreasing	21 (44.7%)
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	7.14%
Largest Positive Impact for a Rural Area	4.12%
Largest Negative Impact for an Urban Area	-5.54%
Largest Negative Impact for a Rural Area	-2.56%
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	2 (0.5%)
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 2024 wage index for 596 urban hospitals (compared to 275 in FY 2023) requiring a budget neutrality adjustment factor of 0.981185 (-1.88 percent) applied to hospital wage indexes. This compares to an adjustment of 0.991909 (-0.81 percent) in FY 2023.

From FY 2020 through FY 2022, CMS' policy was to not include hospitals with an urban to rural reclassification in the calculation of the rural floor. CMS adopted this policy to avoid the practice of a high average hourly wage hospital reclassifying from urban to rural in order to set a high rural floor to benefit itself and other hospitals in its state.

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. In response to the Court's decision, CMS did not continue this policy for FY 2023. For FY 2024, CMS proposes to continue its FY 2023 policy—urban to rural reclassified hospitals will be included in the rural floor wage index.

CMS further indicates that after revisiting case law, prior public comments and the relevant statutory language that it will now treat a hospital that reclassifies to a rural area the same as a hospital that is physically located in a rural area. This policy can have significant financial consequences as hospitals can pair an urban to rural reclassification with a Medicare Geographic Classification Review Board (MGCRB) reclassification that would otherwise be unavailable to the hospital under the law. Budget neutrality requirements would allow such hospitals to benefit from this practice at the expense of all other hospitals.

Consistent with the principle of treating an urban to rural reclassified hospital like a hospital physically located in a rural area, CMS also proposes to continue including an urban to rural reclassified hospital in the calculation of the rural wage index of its state even when that hospital has an MGCRB reclassification to another urban area. What follows in the proposed rule is a complex discussion of how CMS' policy is affected by various statutory and regulatory hold harmless provisions.

Statutory provisions provide hold harmless protections for the rural wage index when hospitals reclassify out of the rural area. Under that policy, hospitals are retained in the calculation of the rural wage index if the hospitals (as a group) reclassifying out of the rural area (whether MGCRB or "Lugar" as described below) would reduce the rural area's wage index. By regulation, CMS adopted similar hold harmless provisions for a rural wage index when hospitals reclassify into the rural area. That is, hospitals (as a group) reclassifying into the rural area can only raise the rural area's wage index, not reduce it.

CMS' proposed policy changes how it will treat an urban to rural reclassified hospital for purposes of these calculations. The urban to rural reclassified hospital will be treated like a hospital that is physically located in the rural area. That is, rather than being included in the group that reclassifies into the rural area when determining how to apply the regulatory hold harmless provision, it will be treated as though it was already there.

Similarly, CMS' current policy is to exclude a dually reclassified hospital—an urban hospital that reclassified into the rural area and obtained an MGCRB reclassification out of the rural area—from the calculation of the rural wage index. Under the proposed policy, the urban to rural reclassified hospital with an MGCRB reclassification will be included in the group of hospitals reclassifying out of the rural area to determine whether the hold harmless policy applies with respect to including or excluding these hospitals from the rural wage index.

Another provision of statute provides hold harmless protection to hospitals remaining in an urban county if an MGCRB reclassification or a Lugar reclassification results in the urban county having a wage index below the rural area of its state. In that event, hospitals remaining in that county receive the rural floor wage index of the state in which it is located. CMS is proposing to

continue this policy. CMS also proposes that hospitals that reclassify across state lines to use the rural wage index in a different state would receive the combined wage index that includes the wage data for geographically rural hospitals and all hospitals reclassified into the rural area.

Imputed Floor. The rural floor does not apply in all urban states as there is no rural wage index. 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 (Connecticut). In another part of the rule, CMS indicates that the imputed floor will increase payment to 81 hospitals by $249 million.

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. As all hospitals in Nevada have a wage index of over 1.0, the provision will have no effect in Nevada. The provision does not require a budget neutrality adjustment. The frontier wage index increases payments by about $58 million to 43 hospitals in Montana, North Dakota, South Dakota and Wyoming.

Low-Wage Index Hospital Policy. For FY 2020, CMS adopted a low-wage index policy where it increased 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. CMS indicated that it would adopt this policy for four years in order to allow low-wage hospitals to use the increase in the wage index to raise wages and receive a higher wage index. The policy was adopted for four years because it takes four years for a hospital's cost report data to be reported, desk reviewed and available to be used in the wage index (e.g., FY 2020 hospital cost report data is being used for the FY 2024 wage index).

This policy was scheduled to expire after FY 2023. However, CMS has indicated that it only has one year of data under the low-wage index policy to determine whether the policy has successfully resulted in hospital raising wages in order to get a higher wage index. For this reason, CMS is proposing to continue the low-wage index policy for FY 2024. For FY 2024, the 25th percentile wage index value across all hospitals is 0.8615. CMS is proposing to apply a budget neutrality adjustment of -0.26 percent for this policy.

This policy has been the subject of pending litigation. On March 2, 2022 the D.C. 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 has appealed the District Court decision in Bridgeport. Although CMS proposes to continue this policy for FY 2024, it may take a different approach in the final rule, depending on public comments or developments in the court proceedings.

Cap on Wage Decreases. In the FY 2023 IPPS rule, CMS adopted a 5 percent cap on year-to-year decreases in a hospital's wage index regardless of the circumstances causing the decline. A newly opened hospital is paid the wage index for the area in which it is geographically located for its first full or partial fiscal year without any cap applied as there is no prior wage index upon which to determine the cap. CMS estimates the wage index reduction cap will require a budget neutrality adjustment of -0.34 percent for FY 2024.

G. Wage Index Tables

Proposed rule wage index tables 2, 3 and 4 can be found at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-proposed-rule-home-page. Select #2 under FY 2024 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 of that area (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 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. CMS adopted this policy in response to adverse litigation against the agency in *Bates County Memorial Hospital v. Azar*.

Geographic Reclassifications. There are 621 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2024. There are 262 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2022 that will continue for FY 2024. There are 266 hospitals approved for wage index reclassification in FY 2023 that may continue for FY 2024. CMS indicates that there will be 1,149 hospitals in MGCRB reclassification status for FY 2024 (with 196 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 2024 proposed rule in the *Federal Register* (June 15, 2023). 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 2024 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.

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 2024 outmigration adjustment that it has been using since FY 2012. This provision is not budget neutral. CMS estimates the outmigration adjustment will increase payments by about $46 million to 159 hospitals.

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.

CMS restates policies adopted in earlier years regarding urban to rural reclassifications and also notes that it is adopting a new policy with respect to the effective date for hospitals that qualify for urban to rural reclassification to become sole community hospitals (SCH). See section V. C. of this summary for more detail.

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. 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 time. For the FY 2024 wage index timetable go to: https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2024-wage-index-home-page. Select option #1.

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.

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 2024 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 2023 Medicare DSH estimates, which were based on the September 2022 update of the HCRIS and the FY 2023 IPPS final rule impact file. Starting with these data sources, OACT applies inflation updates and

assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

OACT's January 2023 Medicare estimate of DSH payments for FY 2023 is $13.621 billion. **The proposed Factor 1 amount is seventy-five percent of this amount, or $10.216 billion.** The proposed Factor 1 for 2024 is about $245 million less than the final Factor 1 for FY 2023.

The Factor 1 estimate for FY 2024 began with a baseline of $13.257 billion in Medicare DSH expenditures for FY 2020. The table below shows the factors applied to update this baseline to the current proposed estimate for FY 2024.

Factors Applied for FY 2021 through FY 2024 to Estimate Medicare DSH Expenditures Using 2020 Baseline

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2021	1.029	0.940	1.029	0.9850	0.9804	12.997
2022	1.025	0.943	0.997	1.0011	0.9647	12.539
2023	1.043	0.975	1.005	1.0484	1.0715	13.435
2024	1.028	0.976	1.005	1.0055	1.0139	13.621

- 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 difference between the total inpatient hospital discharges and the IPPS discharges and the 20 percent add-on for COVID-19 discharges). The "other" column also includes a factor for Medicaid expansion due to the ACA.[38]

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
2021	2.4	0	0.5	2.9
2022	2.7	-0.7	0.5	2.5
2023	4.1	-0.3	0.5	4.3
2024	3.0	-0.2	0.0	2.8

[38] The "Other" column also includes the estimated impacts on Medicaid enrollment; estimated increase of 12.3 percent in FY 2021, 8.1 percent in FY 2022, 2.0 percent in FY 2023, and -11.1 percent in FY 2024.

2. Proposed FY 2024 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 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.[39]

For FY 2024, CMS estimates that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2023 and 2024 is 9.3 percent and 9.2 percent, respectively. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates the proposed Factor 2 for FY 2024 (weighting the portion of calendar years 2023 and 2024 included in FY 2024) as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2023: 9.3 percent.
- Percent of individuals without insurance for CY 2024: 9.2 percent.
- Percent of individuals without insurance for FY 2024 (0.25 times 0.093) + (0.75 times 0.092): 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 2024 proposed rule to be 0.6571 or 65.71 percent, and the uncompensated care amount for FY 2024 to be $10.216 billion x 0.6571 = $6.713 billion which is about $161 million less than the FY 2023 UCP total of about $6.874 billion; the percentage decrease is 2.3 percent. The table below shows the Factor 1 and Factor 2 estimates for FY 2023 and the proposed factors for FY 2024.

FY 2024 Proposed Change in UCP

($ in billions)

	FY 2023	FY 2024	$ Change	% Change
Factor 1	$10.461	$10.216	-$0.245	-2.3%
Factor 2	0.6571	0.6571	0.00	0.0%
UCP	$6.874	$6.713	-$0.161	-2.3%

[39]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 2024

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.[40]

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).[41] 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).[42]

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.

[40] 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.
[41] 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).
[42] 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.

In FY 2023, CMS finalized a policy of using a multi-year average of audited Worksheet S-10 data to determine Factor 3 for subsequent fiscal years, specifically the 3 most recent fiscal years for which audited data were available. CMS believed that this would address commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. In FY 2023, CMS used a 2-year average of audited FY 2018 and FY 2019 Worksheet S-10 data to calculate Factor 3 for FY 2023. It also indicated that it expected FY 2024 would be the first year that 3 years of audited data would be available to use in the calculation. In addition to the using the 3 most recent years of audited data in the calculation, CMS made the following technical changes in 2023:

- To address the effects of calculating Factor 3 using data from multiple fiscal years, CMS finalized a policy to apply a scaling factor so that the total projected uncompensated care payments to hospitals does not exceed the total uncompensated care payments available for that fiscal year.
- New hospitals are defined as those that do not have cost report data for the most recent year of data being used in the Factor 3 calculation.

In FY 2023, CMS also finalized its policy to determine Factor 3 for IHS/Tribal hospitals and Puerto Rico hospitals based on uncompensated care data reported on Worksheet S-10, and discontinued the use of low-income insured days as a proxy for uncompensated care for these hospitals. Given the significant financial disruption for these hospitals, CMS established a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

b. Methodology for Calculating Factor 3 for FY 2024

CMS plans to use the same methodology applied in FY 2023 to determine Factor 3 except CMS will be using the most recent 3 years of audited cost reports from FY 2018, FY 2019, and FY 2020. This approach will be used for all eligible hospitals, including IHS/Tribal and Puerto Rico hospitals. It is using the December 2022 HCRIS extract to calculate Factor 3 for the proposed rule, but intends

to use the March 2023 update of HCRIS to calculate the final Factor 3 for the final rule.

CMS states that it is not proposing any changes to the methodology for determining supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals and will calculate these payments consistent with methodology described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051).

CMS describes the steps it uses to calculated Factor 3 and how it calculated uncompensated care payments for new and newly merged hospitals. Consistent with its past policy, a 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.

Consistent with the methodology used in prior years, CMS provides details on the methodology it uses to trim CCRs for hospitals with aberrant uncompensated care cost data. Specifically, the statewide average CCR was applied to a small number of hospitals with potentially aberrant data; this included 7 hospitals for FY 2018 reports, 13 hospitals for FY 2019 reports, and 10 hospitals for FY 2020 reports. In these cases, CMS recalculates the hospitals' uncompensated care costs (Line 30 on Worksheet S-10) using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

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.

Consistent with the approach adopted in FY 2023, CMS proposes to calculate the average of FY 2019, FY 2021, and FY 2022 historical discharge data, rather than the 3-year average of the most recent 3 years of discharge data from FY 2020, FY 2021, and FY 2022. It is concerned about using FY 2020 discharges that were significantly lower due to the effect of the COVID-19 pandemic and thus would potentially underestimate the number of discharges if used in the calculation for FY 2024. **CMS requests comment on this proposal.**

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.[43]

For FY 2024 and subsequent years, CMS is proposing to no longer have the 15-business day period after display of the final rule for hospitals to submit any updated information on mergers and/or to report upload discrepancies. CMS believes there will be sufficient opportunity for hospitals to provide this information during the comment period for the proposed rule. It notes that for the FY 2023 IPPS/LTCH final rule it did not receive comments during this notification period regarding mergers or data upload issues. **CMS invites comment on this proposal.**

C. Payment Impacts

The regulatory impact analysis presented in Appendix A of the proposed rule includes the estimated effects of the changes to uncompensated care payments and supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals for FY 2024 across all hospitals by geographic location, number of beds, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,395 hospitals that are projected to be eligible for DSH in FY 2024.

The proposed total amount of uncompensated care payments ($6.713 billion) combined with supplement payments for IHS/Tribal hospitals and Puerto Rico hospitals ($90.3 million) is $6.803 billion. This is a 2.40 percent decrease from FY 2023 payments (about $167 million). Changes in FY 2024 payments are driven by a proposed decrease in Factor 1.

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 supplemental payment. A percent change in payments lower than negative 2.40 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 2.40 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.

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

Hospital Type	Dollar Difference FY 2023-FY 2024 ($ in millions)	Percent Change
All Hospitals	-$167	-2.40%
Urban	-172	-2.61
Large Urban	-99	-2.43
Other Urban	-73	-2.89
Rural	4	1.17
Beds: 0-99 (Urban)	-2	-0.76
Beds: 250+ (Urban)	-144	-2.97
New England (Urban)	2	0.88
Middle Atlantic (Urban)	-21	-2.77
South Atlantic (Urban)	-36	-4.70
East South Central (Urban)	-54	-3.18
West North Central (Urban)	-14	-3.28
West South Central (Urban)	-8	-0.59
Pacific (Urban)	-18	-2.96
Middle Atlantic (Rural)	1	10.83
Puerto Rico	-6	-6.42
Teaching with 100 or more residents	-59	-2.20
Teaching with fewer than 100 Residents	-84	-3.39
Non-Teaching	-25	-1.36
Voluntary	-112	-2.79
Proprietary	-11	-1.10
Government	-44	-2.24

Under this proposal, rural hospitals are projected to receive an increase in uncompensated care payments of 1.17 percent compared to a decrease in UCP payments of 2.62 percent for urban hospitals in FY 2024 compared to FY 2023. Urban hospitals are projected to receive larger than average decreases in uncompensated care payments and supplemental payments in most regions. Teaching hospitals with fewer than 100 residents are projected to receive a larger than average payment decrease of -3.39 percent. Nonteaching hospitals and teaching hospitals with 100 or more residents are expected to receive smaller than average decreases of 1.36 and 2.20 percent respectively. Proprietary and government hospitals are expected to receive smaller than average decreases of -1.10 and 2.24 percent, respectively.

V. Other Decisions and Changes to the IPPS for Operating System

A. Post-Acute Care Transfer Policy

1. Background

A post-acute care transfer is a discharge occurring prior to the geometric mean length of stay to a post-acute care setting.[44] CMS makes payment to the transferring hospital at:

[44] A post-acute care setting is rehabilitation hospital or unit, a psychiatric hospital or unit, a skilled nursing facility, a hospice or the patient's home with a written plan for home health services from a home health agency and those services begin within 3 days of the date of discharge.

- Twice the per diem amount for the first day with each subsequent day paid at the per diem amount up to the full MS-DRG payment; or
- 50 percent of the full MS-DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days up to the full MS-DRG payment (known as the "special payment methodology" for types of cases with large costs early in the stay).

If the MS-DRG's total number of discharges to post-acute care equals or exceeds the 55th percentile for all MS-DRGs and the proportion of short-stay discharges to post-acute care to total discharges in the MS-DRG exceeds the 55th percentile for all MS-DRGs, CMS will apply the post-acute care transfer policy to that MS-DRG and to any other MS-DRG that shares the same base MS-DRG. CMS does not revise the list of DRGs subject to the post-acute care transfer policy annually unless it is also making a change to a specific MS-DRG.

2. Proposed Changes for FY 2024

CMS proposed to make changes to a number of MS-DRGs effective for FY 2024. As a result of its review, CMS is proposing to add two new MS-DRGs to the post-acute care transfer MS-DRG list (MS DRGs 276 and 277, Cardiac Defibrillator Implant with and without MCC respectively). CMS also proposes to make these MS-DRGs subject to the special payment methodology.

B. Inpatient Hospital Update

The proposed inpatient hospital update for FY 2024 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 2024 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 2024 inpatient hospital update will be reduced by three-quarters of the market basket update.

The IHS Global Insight, Inc. (IGI) 4th quarter 2022 forecast (with historical data through the 3rd quarter of 2022) for the hospital market basket is 3.0 percent. IGI's 4th quarter 2022 forecast of total factor productivity is 0.2 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 2024	Scenario 1: Hospital Submitted Quality Data and is a Meaningful EHR User	Scenario 2: Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Scenario 3: Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Scenario 4: Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.75	-0.75
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.25	0.0	-2.25
Productivity Adjustment	-0.2	-0.2	-0.2	-0.2
Applicable Percentage Increase	**2.8**	**0.55**	**2.05**	**-0.2**

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 as illustrated in scenario 3 above.

C. Sole Community Hospitals (SCHs)

An SCH is a hospital located more than 35 road miles from another hospital or is the only source of care for patients in its catchment area by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals. Hospitals qualifying as SCHs may receive IPPS payment based on a hospital-specific rate that is based on updated cost per discharge in a prior year updated for inflation.

Some hospitals must do an urban to rural reclassification to qualify for SCH status. Urban to rural reclassifications are effective as of the filing date of the application with CMS. Prior to FY 2019, the effective date of SCH status was 30 days from the date CMS approves the application. In the FY 2019 IPPS rule, CMS aligned the effective date of SCH status with the effective date of an urban to rural reclassification. Under the newer rule, the effective date of SCH status is the date that a complete application is received by the MAC. Analogous changes were made to the MDH rules.

In the FY 2024 IPPS proposed rule, CMS proposes to make an additional change to the effective date for SCHs in the case of a merger of two hospitals. In these cases, CMS has not considered the application to be complete unless the application indicates that the merger was approved. However, the effective date of the merger may be retroactive. In this case, CMS' current policy does not allow the hospital to be paid as an SCH between the approval date of the merger and the time its SCH application is considered to be complete.

For this reason, CMS is proposing that the effective date of an SCH application be made retroactive to approval date of a merger provided the complete application for SCH status is received by the MAC within 90 days of CMS' notification of the merger's approval. If the MAC does not receive the complete application within 90 days of CMS' notification of the merger approval, SCH classification would be effective as of the date the MAC receives the complete application, including documentation of the merger approval.

CMS is only proposing this policy for SCHs and not MDHs because it does not believe MDHs will be in a situation where its qualification for special status will be dependent on a merger.

D. 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 2024, CMS proposes to use FY 2022 data to set the CMI criteria. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2023, 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 2022, and a CMI greater than or equal to the lower of 1.8067 (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)	1.5284
2. Middle Atlantic (PA, NJ, NY)	1.5771
3. East North Central (IL, IN, MI, OH, WI	1.6712
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7382
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6569
6. East South Central (AL, KY, MS, TN	1.6593
7. West South Central (AR, LA, OK, TX	1.8334
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.86195
9. Pacific (AK, CA, HI, OR, WA)	1.8116

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

E. 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 statutorily 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 - 2024	15 miles	3,800 Total Discharges	Total Discharges<500=25%; Declining Linear Adjustment up to 3,800 discharges applied to each Medicare Discharge
2025 and later	25 miles	200 Total Discharges	25%

Prior to the most recent statutory enactments, the distance and discharge criteria and the payment methodology would have expired on September 30, 2022 and reverted to the criteria and methodology in place from FYs 2005 through 2010. Following two short-term temporary extensions, section 4101 of the CAA, 2023 extended the criteria and payment methodology in place from FYs 2019 through FY 2022 through FY 2024.

CMS implemented the statutory extension of the low volume hospital distance and discharge criteria and the payment methodology through Change Request 13103 (Transmittal 11878) issued on February 23, 2023 (https://www.cms.gov/files/document/r11878otn.pdf). In the proposed rule, CMS is proposing conforming changes to the low-volume hospital regulations consistent with the statutory changes.

CMS is proposing to continue the past process for hospitals to apply for low-volume hospital status. A hospital must submit a written request for low-volume hospital status to its MAC by September 1, 2023 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 2024, CMS indicates that if a hospital that qualified for the low-volume hospital payment adjustment for FY 2023, it may continue to receive a low-volume hospital payment adjustment for FY 2024 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 2024.

If a hospital's written request for low-volume hospital status for FY 2024 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.

F. Medicare-Dependent Small Rural Hospitals (MDH)

Prior to the most recent statutory enactments, section 1886(d)(5)(G) of the Act provided special payments under the IPPS to an MDH through September 30, 2022. Following two temporary short-term extensions, section 4102 of the CAA, 2023 extended the MDH program through FY 2024.

The two temporary short-term MDH extensions were both enacted prior to the MDH program expiring, negating the need for an approved MDH to reapply for that special status. However, the CAA, 2023 provision was enacted shortly after the statutory expiration of the MDH program.

CMS is unaware of any hospitals that cancelled MDH status in order to become an SCH upon the MDH program's expiration. Nevertheless, CMS did revise 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. If any providers cancelled an urban to rural reclassification that was needed to qualify as an MDH and became an SCH, these providers must request to be reclassified as rural and reapply for MDH classification. MDH status would be effective on the date a completed application is received. All other hospitals with MDH status as of September 30, 2022 continue to be classified as MDHs effective October 1, 2022. Change Requests 12970 and 13103 provide further details on the MDH extension through FY 2024.

G. 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.

The law also provides incentives to reduce the number of residents and disincentives to increase the number of residents by basing DGME and IME payment on a 3-year rolling average count of residents (e.g., the hospital would only gain or lose 1/3 of each FTE resident for each resident added or subtracted from the training program).

One component of the IME payment formula considers the hospital's ratio of residents to beds (known as the IRB). A higher IRB will result in higher IME payments. The law caps a hospital's IRB ratio used for payment at its actual IRB from the prior year. The provision also provides disincentives to increase the number of residents as a hospital will not receive the higher payments from a higher IRB until the following year.

There are rules that allow hospitals that are affiliated to jointly train residents to apply the FTE caps on an aggregate basis. These rules provide affiliated hospitals with the flexibility to continue those training relationships and allow increases in resident training above the cap at one hospital to be offset by lower resident training in another hospital. The increase in a hospital's resident count due to an affiliated group arrangement is also added to the numerator of a hospital's IRB subject to the 3-year rolling average count of residents but after accounting for the IRB cap (e.g., the additional residents due to an affiliated group arrangement are allowed to increase the hospital's IRB from one year to the next).

2. Cost Reporting Instructions Clarification

CMS is not proposing any policy or regulatory changes to the IME regulations. It is merely using the FY 2024 IPPS rule to respond to questions it has received regarding application of the affiliated group provisions to the IRB ratio. The proposed rule indicates how the cost reporting instructions are being revised to clarify the complex calculations involved in determining a hospital's IME payments inclusive of the rules related to the 3-year rolling average count of residents and the IRB cap.

3. Training in a Rural Emergency Hospital (REH)

Section 125 of CAA, 2021 established REHs as a new Medicare provider type, effective January 1, 2023. REHs are facilities that that do not provide acute care inpatient hospital services. Only critical access hospitals (CAH) or rural hospitals (or hospitals treated as rural for IPPS payment purposes) with fewer than 50 beds may convert to REH status. REHs and CAHs are included in the section 1861(u) of the Act definition of "provider of services." However, they are excluded from the definition of "hospital" in section 1861(e) of the Act.

Hospitals may count residents training in "non-provider" sites for DGME and IME payment as long as the resident is engaged in patient care activities and the hospital incurs the costs of the resident salaries and benefits while the resident is training in the non-provider site. For cost reporting periods beginning on or after October 1, 2019, a hospital may include FTE residents training at a CAH in its direct GME and IME FTE counts as long as the hospital meets the non-provider setting requirements. Public comments on a prior rule implementing the REH program asked CMS to allow hospitals to be able to count training time in an REH for DGME and IME payment under the non-provider setting rules analogous to its policies for CAHs.

While CMS acknowledges that CAHs are "providers of services," it indicates that the term "non-provider" is not explicitly defined in the statute. Further, CAHs are excluded from the definition of a hospital. CMS indicates that the "ambiguous status of CAHs" in the statute and the fact that residents training in a CAH are engaged in patient care activities provides it with the flexibility within the current statutory language to consider a CAH as a "non-provider" setting for DGME and IME payment purposes. CMS uses the same logic to allow hospitals to count resident training time in REHs in their DGME and IME FTE counts as long as the residents are engaged in patient care activities and the hospital incurs the cost of the resident salaries and fringe benefits while training in the REH.

As an alternative to the hospital counting the resident for DGME and IME payment purposes, a CAH may incur the costs of the resident training at the CAH and be paid for the training at 101 percent of reasonable cost. CMS proposes an analogous policy for REHs except the REH would be paid 100 percent rather than 101 percent of reasonable cost under section 1861(v) of the Act that authorizes payment based on reasonable cost principles.

4. Teaching Hospital Closure: Application Process for Resident Slots

Section 5506 of the ACA authorizes the Secretary to redistribute residency slots after closure of a hospital that trained residents in an approved medical residency program. CMS is notifying the public of the closure of St. Vincent Charity Medical Center located in Cleveland, Ohio.

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
360037	St. Vincent Charity Medical Center	Cleveland, Ohio	17460	November 11, 2022	56.73	64.66

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. To be eligible for additional slots under section 5506, hospitals must submit an application form using the Medicare Electronic Application Request Information System™ (MEARIS™) **no later than July 10, 2023**. The Section 5506 application can be accessed at: https://mearis.cms.gov/public/home.

CMS has not established a deadline for making final determinations regarding hospitals that will receive slots under section 5506. However, CMS reviews all applications received by the deadline and will notify applicants of its determinations as soon as possible.

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

1. Background

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 are 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.

2. Initial Implementation and Subsequent Implementation through 2019

For initial implementation of these provisions more than 20 years ago, 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 used a sub-regulatory process (change requests) for subsequent years.

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.

As detailed below, this 17-year delay in updating the figures for nursing and allied health education MA payments resulted in overpayments of hundreds of millions of dollars to hospitals with provider operated schools of nursing and allied health education and underpayment of MA DGME payments.

3. Implementation 2020 through 2022

For 2020 and 2021, CMS used the FY 2023 IPPS rule to furnish the nursing and allied health MA add-on payment rates and the MA DGME offset. For 2022, CMS is proposing to use data from cost reports ending in FY 2020 (the fiscal year that is 2 years prior to CY 2022) to notify the public of key statistics regarding nursing and allied health education MA payments.

CMS uses the 4th quarter 2022 update of the 2020 HCRIS projected forward two years to estimate 2022 payments. For 2022, CMS is proposing to distribute $60 million in nursing and allied health education MA payments with an offset of 3.27 percent to MA DGME payments. These figures are the result of applying the statutory formula, which leads to capped payments of $60 million for nursing and allied health education MA payments.

4. Retroactive Implementation for Cost Years 2010 through 2018

As noted above, CMS did not update the nursing and allied health education MA payments for more than 17 years from May 23, 2003 until December 14, 2020. While CMS did not update the data used to determine these payments, the MACs continued to make them using data that was in the May 23, 2003 change request that included an offset to MA DGME payments of 14.13 percent—a percent reduction that exceeded the amounts that otherwise would have been applied had CMS annually updated the data needed for the calculations. During this period, nursing and allied health education payments exceeded the $60 million cap and resulted in CMS seeking refunds of hundreds of millions from hospitals in Medicare reasonable cost payments for the period 2010 through 2019. CMS also repaid hospitals for the underpayment for MA DGME payments.

Section 4143 of the CAA, 2023 provides relief for hospitals subjected to recoupment of overpayments for 2010 through 2019. CAA, 2023 does this by not applying the $60 million payment limit to nursing and allied health education MA payments during these years. This relief only applies to hospitals that, as of the date of enactment of the CAA, 2023, were continuing to operate a school of nursing or allied health entitled to receive reasonable cost education

payments. Section 4143 also provided that CMS shall not reduce a hospital's DGME MA payments to offset the increase in nursing and allied health MA education payments.

The proposed rule details the process CMS is instructing the MAC to use to implement section 4143. In summary, CMS instructs the MACs to recalculate a hospital's total nursing and allied health education MA payment for 2010 through 2019 using information in the table reproduced below from the proposed rule. Each hospital would receive a share of payments in the column labeled "Section 4143 CAA POOL" based on the ratio of its own MA days compared national aggregate MA days.

The MAC will then compare the hospital's share of nursing and allied health MA payments from these calculations and reconcile them with any prior amounts already paid or recouped from the hospital. Amounts previously recouped will be returned to hospitals, and recoupments that would have occurred if not for the enactment of Section 4143 of the CAA 2023 will not occur.

CALCULATION TABLE FOR SECTION 4143 OF CAA OF 2023						
	Section 4143 CAA POOL	**FFS NAH PAYMENTS**	**FFS INPATIENT DAYS**	**MA INPATIENT DAYS**	**(FFS NAH/FFS INPT DAYS) X MA INPT DAYS**	**PERCENT REDUCTION TO MA DGME PAYMENTS**
CY 2010	$62,997,033	$213,862,393	45,409,814	3,114,194	$14,666,631	9.77%
CY 2011	$66,438,422	$226,645,225	49,217,935	3,825,354	$17,615,494	7.85%
CY 2012	$76,035,672	$240,958,503	55,551,047	4,376,532	$18,983,667	7.16%
CY 2013	$84,753,118	$245,304,017	54,965,956	4,945,724	$22,071,952	6.41%
CY 2014	$93,598,893	$248,506,989	54,405,730	5,360,315	$24,484,107	5.86%
CY 2015	$102,448,386	$247,076,161	55,223,064	5,907,933	$26,432,967	5.32%
CY 2016	$110,412,962	$253,272,740	55,717,901	6,376,818	$28,986,630	4.99%
CY 2017	$119,165,456	$249,546,528	58,599,068	7,241,576	$30,838,548	4.44%
CY 2018	$130,335,289	$267,714,849	61,066,487	7,888,809	$34,584,457	4.12%
CY 2019	$140,589,366	$262,043,840	62,649,285	8,481,459	$35,475,490	4.07%

I. 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. This may also occur in "expanded access use" cases that are also known as compassionate use. There are also occasions where a CAR-T case is part of a clinical trial but the hospital incurs the cost of the CAR-T product because another drug is under investigation. Beginning with FY 2021, CMS adopted a differential payment for the first two of these three situations to recognize hospitals' lower costs.

To identify clinical trial cases, CMS excludes claims from the relative weight calculation with diagnosis codes Z00.6 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. Until this time, there have been no indicators on the claims to identify expanded access use cases that should also be excluded from the relative weight calculation or a when a case is part of a clinical trial but a different drug is under investigation and the hospital has a cost for the CAR-T product.

CMS is proposing to adopt these same policies for FY 2024 with the following changes:

- It is no longer using $373,000 in drug costs as a proxy for determining that a case is a clinical trial case as it believes the use of code Z00.6 is sufficient for this purpose. CMS is finding relatively fewer cases in the FY 2022 data (4 percent) than in prior years (18 percent) where there is not a clinical trial indicator on the claim and drug costs of less than $373,000.
- The claims data now includes condition code ZB for expanded access use cases that CMS is using to eliminate these claims from the relative weight calculation.
- The claims data now includes condition code ZC to identify clinical trial cases where a different drug is under investigation. CMS will include these claims in the relative weight calculation.

For FY 2024, CMS estimates that the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($89,379) were 28 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($323,903). Accordingly, CMS is proposing to adjust the payment for MS-DRG 018 by applying an adjustor of 0.28 to the full payment amount in those situations where the hospital does not have a cost for the CAR-T or other immunotherapy product.

J. Hospital Readmissions Reduction Program (HRRP): Updates and Changes

The HRRP is established under section 1886(q) of the Act.[45] Under the HRRP, 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 2024 are unchanged from FY 2023: 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).

There are no proposals or updates in the proposed rule for the HRRP.

The estimated percentage of hospitals that will be penalized under the HRRP for the FY 2024 HRRP is 84.12 percent (2,448 of the 2,910 hospitals), with total penalties for all such penalized hospitals estimated to be 0.53 percent of total payments for such hospitals.

[45] 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.

K. Hospital Value-Based Purchasing (HVBP) Program: Updates

In the proposed rule, CMS proposes to:

- Substantively modify two existing measures:
  - The Medicare Spending per Beneficiary (MSB)-Hospital Measure; and
  - The THA/TKA Complication Measure;
- Add one new measure, the Severe Sepsis and Septic Shock: Management Bundle; and
- Add technical changes to the administration of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, and change the scoring policy to include a health equity scoring adjustment and modify the Total Performance Score (TPS) maximum to be 110.

CMS also provides estimated and newly established performance standards for the FY 2026 through FY 2029 program years. The proposed rule also contains an RFI on potential additional changes to the HVBP Program that would address health equity.

No changes are proposed to the existing policies on domain weighting,[46] the policies on retention and removal of measures from the HVBP measure set, the minimum numbers of measures for hospital domain scores, or the Extraordinary Circumstances Exception (ECE) policy.

The impact analysis of base operating DRG payment amounts resulting from the FY 2024 HVBP Program shows for the 2,526 hospitals an average net percent payment adjustment of 0.025 percent. There is no estimated change in burden associated with the proposals since the proposals use data that are already submitted to CMS for other quality programs or payment purposes.

1. Background

a. Program Overview

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

The 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

[46] Per the FY 2018 IPPS/LTCH PPS final rule (82 FR 38265 through 38266), equal weight of 25 percent is given for each of the four domains in the HVBP Program for hospitals that receive a score in all domains. Per the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085) hospitals must receive domain scores on at least 3 quality domains in order to receive a TPS. If there's sufficient data on only 3 domains, then TPSs are proportionately reweighted. The 4 domains are Person and Community Engagement, Clinical Outcomes, Safety, and Efficiency and Cost Reduction.

themselves are summed as the TPS. 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.

b. FY 2024 Program Year Payment Details

The estimated amount of base operating MS-DRG payment reductions for the FY 2024 program year (and also the amount available for the FY 2024 VBP incentive payments) is approximately $1.7 billion, based on the December 2022 update of the FY 2022 MedPAR file.

2. Retention and Removal of Quality Measures

a. Retention of Measures; Relationship Between the Hospital IQR and HVBP Program Measure Sets

Once a measure is adopted into the HVBP Program Measure set for a program year it is retained for subsequent program years unless otherwise proposed and finalized. To adopt a measure into the HVBP Program, the measure must be selected from the Hospital IQR Program measure set and data on that measure must be included on Hospital Compare for at least one year prior to its inclusion in a HVBP Program performance period. At that point the measure is not required to continue to remain in the Hospital IQR Program. No changes are proposed to these policies.

b. Proposal to Codify Current HVBP Program Measure Removal

CMS proposes to codify at 42 CFR §412.164(c) the 8 measure removal factors[47] for the Program that were finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446) as well as the policies for updating and retaining measures.

c. Proposed Substantive Measure Modifications

[47] The current measure Removal Factors are:
(1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped out" measures).
(2) Measure does not align with current clinical guidelines or practice.
(3) Measure can be replaced by a more broadly applicable measure (across settings or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic.
(4) Measure performance or improvement does not result in better patient outcomes.
(5) Measure can be replaced by a measure more strongly associated with desired patient outcomes for the particular topic.
(6) Measure collection or public reporting leads to negative intended consequences other than patient harm.
(7) Measure is not feasible to implement as specified.
(8) The costs associated with a measure outweigh the benefit of its continued use in the program.

Updates to the Medicare Spending per Beneficiary (MSPB)—Hospital Measure (CBE #2158):

CMS proposes to adopt, beginning with the FY 2028 Program Year (performance period for discharges beginning January 1, 2026), 3 substantive measure updates to the MSPB measure included under the Program's Efficiency/Cost Domain. CMS would post the updated measure on Care Compare beginning in January 2024. The updates align with the updated MSPB measure adopted in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule. The updates are:

- An update to allow readmissions to trigger new episodes to account for episodes and costs that are currently not included in the measure but that could be within the hospital's reasonable influence.
- A new indicator variable in the risk adjustment model for whether there was an inpatient stay in the 30 days prior to the episode start date.
- An update to the MSPB amount calculation methodology. The update changes one step in the measure calculation to use the mean of the ratios of observed costs to expected costs (instead of the current use of the ratio of the sum of observed costs to the sum of expected costs).

The performance standards calculation methodology for the updated measure would be the same as that currently used for the measure.

The re-evaluated measure is endorsed by the consensus-based entity (CBE) and received a recommendation of support from the Measure Applications Partnership (MAP).

Updates to the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (CBE #1550) Measure (THA/TKA Complication Measure)

CMS proposes to adopt, beginning with the FY 2030 Program Year (performance period of April 1, 2025, through March 31, 2028), substantive measure updates (which were adopted in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule) to the THA/TKA Complication measure included under the Program's Clinical Outcomes Domain. CMS would post the updated measure on Care Compare beginning in July 2023. The refined measure differs from the original version by including index admission diagnoses and in-hospital comorbidity data from Medicare Part A claims, adding 26 ICD-10 diagnostic codes for mechanical complications in the outcome (numerator) specifications. The data source for the codes are Part A claims.[48]

The performance standards calculation methodology for the updated measure would be the same as that currently used for the measure.

The MAP conditionally supported the re-evaluated measure pending CBE endorsement. CMS intends to submit the re-evaluated measure to CBE for endorsement in Fall 2024.

[48] Further information on the additional included ICD-10 codes, as adopted for the Hospital IQR Program, can be found in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49264).

3. Proposed New Measure for HVBP Program Set

a. Proposed New Measure: Severe Sepsis and Septic Shock: Management Bundle (CBE #0500)

Overview of Measure. The measure was adopted into the Hospital IQR Program beginning with FY 2017 payment determination. Public reporting on measure performance results on Care Compare began with the July 2018 refresh. CMS proposes to adopt, beginning with the FY 2026 Program Year, the same measure in the HVBP Program with technical updates to address hospital abstractor and clinician feedback about the documentation required for fluid resuscitation within three hours of tissue hypoperfusion presentation.

The measure provides a standard operating procedure for the early management of patients with severe infection. CMS describes that when care interventions in the measure are provided reductions in hospital length of stay, readmission rates, and mortality have been observed. CMS also believes that adoption of the measure would further the goal of advancing health equity as the standardized protocols could mitigate potential biases that lead to variation in outcomes.

Pre-Rulemaking. The measure was submitted to the MAP for the 2022-2023 pre-rulemaking cycle and received conditional support. Public comments were mixed, including concern raised over burden associated with data abstraction. Concern was also raised that adoption of the measure could lead to overuse of antibiotics since the measure includes administering antibiotic therapy to all patients with possible sepsis, though CMS believes there's enough flexibility to incorporate clinician judgment in the measure.

Calculation.

- Numerator. The number of patients who received all of the following interventions for which they qualify: (Table replicated from section V.K.3.a. of the rule.)

Time frame	Intervention
Within 3 hours of presentation of severe sepsis	• Initial lactate level measurement • Broad spectrum or other antibiotics administered • Blood cultures drawn prior to antibiotics
AND	
Within 6 hours of presentation of severe sepsis, only if the initial lactate is elevated	• Repeat lactate level measurement
AND	
Within 3 hours of initial hypotension, OR within 3 hours of septic shock	• Resuscitation with 30 mL/kg crystalloid fluids
AND	
Within 6 hours of septic shock presentation, only if hypotension persists after fluid administration	• Vasopressors are administered

AND	
Within 6 hours of septic shock presentation, if hypertension persists after fluid administration, or initial lactate >=4mmol/L	• Repeat volume status and tissue perfusion assessment is performed

- Denominator. The number of patients with an ICD-10-CM Principal or Other Diagnosis Code for sepsis, severe sepsis without septic shock, or severe sepsis with septic shock.[49]
- Exclusions. Patients under 18 years of age; patients admitted as a transfer from an inpatient, outpatient, or emergency/observation department of another hospital or an ambulatory surgical center, or who are enrolled in a clinical trial associated with treatment of patients with sepsis; patients with advanced directives for comfort care or palliative care; patients who decline or are unwilling to consent to interventions; patients with severe sepsis or septic shock who are discharged within 6 hours of presentation; patients who received IV antibiotics for more than 24 hours before severe sepsis presentation; and patients with an ICD-10-CM Principal or Other Diagnosis Code of U07.1 (COVID-19).

b. Summary of Previously Adopted Measures for the FY 2024 and FY 2025 Program Years, and Previously Adopted Measures and Newly Proposed Measures Beginning with the FY 2026 Program Year

No changes are proposed to FY 2024 and FY 2025 measure sets.

Table V.K-01 in the rule shows adopted measures for FY 2024 and FY 2025 measure sets and Table V.K-02 in the rule shows adopted measures and proposed measures for the FY 2026 through FY 2030 program years. The below table consolidates the information, with X showing adopted measures and P showing proposed measures.

Measure	CBE #	2024-2025	2026-2029	2030
Acute Myocardial Infarction (AMI) 30-day mortality rate	0230	X	X	X
Heart Failure (HF) 30-day mortality rate	0229	X	X	X
Pneumonia (PN) 30-day mortality rate	0468	X	X	X
Complication rate for elective primary total hip arthroplasty/total knee arthroplasty (COMP-HIP-KNEE)	1550	X	X	X
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate	1893	X	X	X
Coronary Artery Bypass Graft (CABG) 30-day mortality rate	2558	X	X	X
Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)**	1550	X	X	X**
Central Line Associated Blood Stream Infection (CLABSI)	0139	X	X	X
Catheter Associated Urinary Tract Infection (CAUTI)	0138	X	X	X
Colon and Abdominal Hysterectomy Surgical Site Infections (SSI)	0753	X	X	X

[49] The rule describes that the denominator is refined as the number of patients confirmed with severe sepsis or septic shock through medical record review for the presence of a suspected infection, two or more SIRS criteria, and a sign of organ dysfunction that are all documented within 6 hours of each other.

Measure	CBE #	2024-2025	2026-2029	2030
Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Bacteremia	1716	X	X	X
Clostridium Difficile Infection (CDI)	1717	X	X	X
Severe Sepsis and Septic Shock: Management Bundle (SEP-1)	0500		P	P
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
Medicare Spending per Beneficiary*	2158	X	X*	X

* Substantive updates proposed to the MSPB measure beginning with FY 2028 program year
**Substantive updated proposed to the THA/TKA Complications measure beginning with the FY 2030 program year.

c. Technical Changes: Proposed Updates to Data Collection and Submission Requirements for HCAHPS Survey Measure (CBE #0166) Beginning with FY 2027 Program Year

CMS proposes to make the same updates to the form and manner of administration of the HCAHPS Survey measure under the HVBP Program as are proposed for under the Hospital IQR Program under section IX.C.10.h of the proposed rule. Those changes are, beginning with January 2025 discharges:

- Adding 3 new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Telephone Only, and Mail-Phone modes;
- Removing the requirement that only the patient may respond to the survey (allowing a proxy to respond);
- Extending the data collection period for the HCAHPS Survey from 42 to 49 days;
- Limiting the number of supplemental items to 12;
- Requiring hospitals to collect information about the language that the patient speaks while in the hospital and requiring the official CMS Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish; and
- Removing two options for administration of the HCAHPS Survey (Active Interactive Voice Response (IVR) survey mode and the "Hospitals Administering HCAHPS for Multiple Sites" option), both of which are not currently used by participating hospitals.

4. Previously Adopted and Newly Proposed Baseline and Performance Periods

The below table shows the baseline and performance periods previously updated for FY 2025 and FY 2026, as well as proposed periods for the SEP-1 measure in italics:

Proposed Program Year FY 2025 and FY 2026 Baseline and Performance Periods Updates by Measure				
Measure	**Baseline Period 2025**	**Performance Period 2025**	**Baseline Period 2026**	**Performance Period 2026**
Person and Community Engagement Domain				
HCAHPS	1/1/19 – 12/31/19	1/1/23 – 12/31/23	1/1/22-12/31/22	1/1/24-12/31/24
Safety Domain				
CAUTI	1/1/19 – 12/31/19	1/1/23 – 12/31/23	1/1/22-12/31/22	1/1/24-12/31/24
CLABSI	1/1/19 – 12/31/19	1/1/23 – 12/31/23	1/1/22-12/31/22	1/1/24-12/31/24
SSI	1/1/19 – 12/31/19	1/1/23 – 12/31/23	1/1/22-12/31/22	1/1/24-12/31/24
CDI	1/1/19 – 12/31/19	1/1/23 – 12/31/23	1/1/22-12/31/22	1/1/24-12/31/24
MRSA	1/1/19 – 12/31/19	1/1/23 – 12/31/23	1/1/22-12/31/22	1/1/24-12/31/24
SEP-1			*1/1/22-12/31/22*	*1/1/24-12/31/24*
Clinical Outcomes Domain				
MORT-30-AMI	7/1/15 – 6/3/18	7/1/20-6/30/23	7/1/16-6/30/19	7/1/21-6/30/24
MORT-30-HF	7/1/15 – 6/3/18	7/1/20-6/30/23	7/1/16-6/30/19	7/1/21-6/30/24
MORT-30-COPD	7/1/15 – 6/3/18	7/1/20-6/30/23	7/1/16-6/30/19	7/1/21-6/30/24
MORT-30-CABG	7/1/15 – 6/3/18	7/1/20-6/30/23	7/1/16-6/30/19	7/1/21-6/30/24
MORT-30-PN	7/1/15 – 6/3/18	7/1/20-6/30/23	7/1/16-6/30/19	7/1/21-6/30/24
COMP-HIP-KNEE	4/1/15-3/31/18	7/1/20-3/31/23	4/1/16-3/31/19	4/1/21-3/31/24
Efficiency and Cost Reduction Domain				
MSPB	1/1/21-12/31/21	1/1/23-12/31/23	1/1/22-12/31-22	1/1/24-12/31/24
Source: Tables V.K.-03 through V.K.-04 in the rule, excerpted and combined by HPA				

5. Performance Standards for HVBP Program

CMS updates the performance standards for the measures in the FY 2025 program year in Table V.K-08 to reflect a correction to display the correct performance standards using CY 2019 data for the FY 2025 program year. The five hospital-associated infection (HAI) measures had incorrectly displayed performance standards using CY 2021 data.

The previously established and estimated performance standards for the measures in the FY 2026 program year have been updated and are set out in Tables V.K.-09, V.K.-10, V.K.-11, and V.K.-12 of the proposed rule.

6. Proposed Changes to the Scoring Methodology

a. Background. CMS describes that the agency previously adopted a methodology for scoring clinical process of care, patient experience of care, and outcome measures (76 FR 26513 through

26531), and is now proposing modifications to the existing scoring methodology to reward high level care in underserved populations.

b. Proposal to Revise the HVBP Program Scoring Methodology to Add a New Adjustment That Rewards Hospitals Based on Their Performance and the Proportion of Their Patients Who Are Dually Eligible for Medicare and Medicaid

Background and Overview. Extensive background is provided on the need to address health disparities and the actions the agency has undertaken to do so. CMS states the goal of using health equity-focused scoring modification in the VBP programs to create better outcomes for all populations in the programs. CMS points to dual enrollment status in Medicare and Medicaid (DES) as a strong predictor of poorer health outcomes even when other social and functional risk factors are accounted for, and as a way to capture common socioeconomic challenges.

Proposed Adjustment. CMS proposes, beginning with the FY 2026 program year, to add Health Equity Adjustment (HEA) bonus points to a hospital's TPS. The HEA bonus points would be calculated using a methodology that incorporates a hospital's performance across all four domains for the program year and its proportion of patients with DES. This would be similar to the health equity adjustment finalized in the Shared Savings Program and the health equity adjustment proposed in the FY 2024 Skilled Nursing Facility VBP Programs PPS proposed rule.

Calculation. The bonus points would be calculated and added to the total of weighted domain scores to determine the TPS as follows:

- First, calculate the measure performance scaler.[50] The scaler is the sum of all points awarded to a hospital for each domain based on the hospital's performance. For each domain, a hospital would earn 4 points if its performance falls in the top third, 2 points if its performance falls in the middle third, or 0 points if its performance falls in the bottom third of performance of all hospitals for the domain (with a maximum of 16 performance scaler points across the 4 domains).
- Second, calculate (using a logistic exchange function) the underserved multiplier, which is the number of inpatient stays for patients with DES out of the total number of inpatient Medicare (FFS and MA) stays during the calendar year two years before the start of the respective program year.
    - The calculation would be a logistic exchange function such that hospitals that care for the highest proportions of patients with DES would have the opportunity for the most HEA bonus points.[51]
    - A stay is identified as being dually eligible if it is for a patient with Medicare and full Medicaid benefits for the month the patient was discharged from the hospital.
    - CMS is not proposing a minimum percent of patients with DES that a hospital must treat, meaning a hospital serving any percent of patients with DES will be eligible for bonus points.

[50] Table V.K-13 shows examples of the measure performance scaler a hospital would receive for each domain based on performance.
[51] See Figure V.K.-01 in the proposed rule for a comparison of logistic scoring, linear scoring, and actual scoring calculations.

    - The proposed adjustment uses DES data since the data are readily available and already used in the Hospital Readmissions Reduction Program. However, CMS may consider LIS, Area Deprivation Index (ADI), and other indicators for underserved populations in future HVBP Program proposals.
- Third, calculate the HEA bonus points,[52] which is the product of the measure performance scaler points and the underserved multiplier proportion, capped at 10 points (allowing for a maximum final TPA of 110).
- Fourth, add the calculated HEA bonus points for a hospital to the total of the weighted domain scores to calculate the hospital's TPS for the program year.

Impact Analysis. CMS assessed the potential impact of the proposal on hospitals and payments, using FY 2023 program year data, as compared to the existing scoring methodology and to an alternative HEA bonus point approach that would award 4 measure performance scaler points only to the hospitals in the top third of performance for each domain, with hospitals in the bottom 2/3 of performance receiving 0 points. Both the proposed and alternative HEA scoring options increase the number of hospitals getting a bonus compared to the existing scoring methodology. Increases in the number of hospitals receiving a bonus occurred primarily among hospitals in the top DSH quintile (i.e., safety net hospitals). The proposed methodology resulted in the largest percent of hospitals gaining from the HEA bonus overall. The mean payment adjustment was 0.20 percent compared to 0.18 percent under the existing methodology. The assessments showed a smaller number of hospitals gaining from the alternative health equity scoring adjustment among rural hospitals, large hospitals, and safety net hospitals relative to the proposed approach.[53] The simulated analysis predicts for the FY 2026 program year the average bonus payment with the HEA bonus points, as proposed, would be $3,724 and the average penalty would be -$4,246.

Proposal to Modify TPS Maximum. TPS is currently defined in regulation as a numeric score ranging from 0 to 100. CMS proposes to modify the TPS maximum to be 110 (and codify the modification at 42 CFR §412.160, §412.162(b)(3), and §412.165(b)(6)), resulting in a numeric score range of 0 to 110, beginning with the FY 2026 program year, which would allow hospitals that have achieved top performance (100 points) to still be eligible to earn HEA bonus points.

RFI on Potential Additional Changes to Address Health Equity. CMS invites public comment on the following:

- Should CMS consider using any of the previously detailed variables, ADI of greater than or equal to 85 and Medicare Part D LIS, in combination with or instead of DES? For example, should CMS use the higher of a few selected factors based on a hospital's inpatient population in a given program year, including (1) the proportion of the hospital's patient population residing in a census block group with an ADI national percentile rank of at least 85 (or another threshold); (2) the proportion of the hospital's patients that are dually eligible for Medicare and Medicaid; or (3) the proportion of the hospital's patients receiving LIS? Should CMS consider patients with partial-dual eligibility in addition to full-dual eligibility? Are there additional variables CMS should

[52] See Table V.K.-14 in the proposed rule for an example of a Calculation of Health Equity Adjustment Points
[53] See Table V.K.-16 in the proposed rule.

consider using to identify populations that have been disadvantaged, marginalized, and/or underserved by the healthcare system?

- Should CMS consider other thresholds for scoring, such as using a quintile-based scoring approach whereby hospitals are awarded measure performance scaler points based on 5 levels of performance rather than 3?
- CMS is considering further refining this scoring methodology change in the future to only look at a hospital's quality performance on patients in the focus population (for example, patients with DES). CMS collects patient-level data on claims measures in the clinical domain and the MSPB measure, but not on all other measures in the HVBP Program. CMS seeks feedback on ways to assess patient-level data in the future.
- Should CMS use a linear scoring function or actual scoring for calculating the underserved multiplier instead of the proposed logistic exchange function?
- Are there other approaches that the HVBP Program could propose to adopt in order to effectively address healthcare disparities and advance health equity? For example, should measure performance scaler points be awarded to only the top third of performance whereby a hospital in the middle and bottom thirds of performance would receive 0 performance scaler points? Alternatively, should CMS only provide measure performance scaler points to the Clinical, Safety, and Patient and Community Engagement Domains, excluding the Cost and Effectiveness Domain from performance scaler points?

c. Minimum Numbers of Cases for HVBP Program Measures

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for a fiscal year, hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. The previously adopted minimum numbers of cases for the HVBP measures, as well as the proposed minimum number of cases for the proposed Severe Sepsis and Septic Shock: Management Bundle measure beginning with the FY 2026 program year, are set forth in Table V.K.-18. For HCAHPS measures there is a minimum number of 100 completed HCAHPS surveys required; for each measure in the clinical outcome's domain there's a minimum of 25 cases required to be reported; for each measure in the safety domain (other than the proposed SEP-1) there is a minimum of 1,000 predicted infections as calculated by the CDC; and for the measure (MSPB) in the efficiency and cost reduction domain there is a minimum number of 25 cases required to be reported. For the proposed SEP-1 measure, hospitals would be required to report a minimum number of 25 cases.

L. Hospital-Acquired Conditions (HAC) Reduction Program: Updates and Changes

CMS proposes to add to the HAC Reduction Program a validation reconsideration process, beginning with the FY 2025 program year (affecting 2022 discharges). CMS also issues a request for comment on potential methods to advance patient safety within the HAC Reduction Program, including potentially adopting patient safety related eCQMs that are being used in the Hospital IQR Program.

No additions to or removals from the HAC Reduction Program measure set are proposed. No changes are proposed to the measure removal and retention policy, to the measure technical specifications, nor to the scoring calculations review[54] and correction period process.

CMS estimates that for the FY 2024 HAC Reduction Program, out of 2,946 hospitals, 736 hospitals will be included in the worst-performing quartile (and subject to the program's penalty). CMS also estimates that the proposed changes to the validation process under the Program would not result in a change in information collection burden for the FY 2025 program year and subsequent years.

1. Background

The HAC Reduction Program was implemented beginning in FY 2015. Under the Program, a 1.0 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 at 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.

2. Measures for FY 2024 and Subsequent Years

a. Current Measures

CMS does not propose any additions to or removals from the measure set. There are currently the following 6 measures in the HAC Reduction Program for FY 2024 and subsequent years:

- 5 Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) hospital-associated infection (HAI) measures:
    - Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (CBE 0138);
    - Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (CBE 1717);
    - Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure (CBE 0139);

[54] Hospitals must register and submit quality data through the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal) in order to access their annual hospital-specific reports.

    - Colon and Abdominal Hysterectomy Surgical Site Infection (SSI) Outcome Measure (CBE 0753); and
    - Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) bacteremia Outcome Measure (CBE 1716); and
- The CMS PSI 90 measure (CBE 0531).

3. Request for Comment: Advancing Patient Safety

CMS describes that the HAC Reduction Program has an opportunity to advance both healthcare safety and equity by encouraging hospitals to further focus their improvement efforts on eliminating disparities in the rate and severity of hospital acquired conditions among different patient populations.

CMS is reviewing patient safety and healthcare-associated infection measures. CMS seeks input on the adoption of new measures, and specifically on safety focused eCQMs. CMS describes the RFC issued in the FY 2023 IPPS/LTCH PPS final rule regarding the potential future adoption of the digital NHSN Healthcare-associated Clostridioides difficile Infection Outcome measure and digital Hospital-Onset Bacteremia & Fungemia Outcome measure, and that there was public input in support of the 2 measures but concern regarding baseline data testing, measure definitions, and the risk adjustment methodology. **CMS is seeking feedback** on potentially adopting patient safety related eCQMs that are being used in the Hospital IQR Program (the Hospital Harm—Opioid-Related Adverse Events eCQM, Hospital Harm-Severe Hypoglycemia eCQM, and Hospital Harm-Severe Hyperglycemia eCQM) and the 3 eCQMS proposed for adoption in the Hospital IQR in sections IX.C.5.a and IX.C.5.b of the proposed rule.

CMS invites comment on potential future measures and on how the HAC Reduction Program can further promote patient safety, specifically:

- What measures should be introduced in the HAC Reduction Program to address emerging high priority patient harm events and healthcare-associated infections?
- What measures should be introduced in the HAC Reduction Program to address equity gaps in the rate and severity of patient harm events and healthcare-associated infections?
- How can weighting and scoring methods be improved to better assess hospital performance and promote equity in the HAC Reduction Program payment assessments?
- How can the HAC Reduction Program be strengthened to encourage patient safety best practices, which also prioritize the delivery of equitable care, in inpatient facilities?

4. Validation of Program Data

a. Validation Reconsideration Beginning with FY 2025 Program Year

Background. CMS conducts an annual random selection of up to 200 hospitals for inpatient validation, and an annual targeted selection of up to 200 additional hospitals using targeting criteria.[55] After validating all quarters of the fiscal year, CMS calculates a total score reflecting a

[55] Targeted selection of hospital uses the following criteria: (1) any hospital that failed validation the previous year; (2) any hospital that submits data to NHSN after the HAC Reduction Program data submission deadline has passed; (3) any hospital that has not been randomly selected for validation in the past 3 years; (4) any hospital that

hospital's reporting accuracy for the HAI measures used in the Program. CMS uses the calculated total score to compute a confidence interval. If the estimated reliability upper bound (ERUB) of the confidence interval is below 75 percent, the hospital fails the validation requirement, and the hospital is assigned the maximum Winsorized z-scores (i.e., the worst score) for the set of measures that were subject to the validation process.

Proposal to Adopt Validation Reconsideration Process. CMS proposes to add a validation reconsideration process, beginning with the FY 2025 program year (affecting 2022 discharges). Hospitals that fail validation would be allowed to request reconsideration of their final validation scores before use of the scores in the Program scoring calculation (similar to the reconsideration processes used in the Hospital IQR Program).[56] The validation reconsideration process would be conducted once per program fiscal year after the validation of HAIs for all four quarters of the relevant fiscal year's data period and after the confidence interval has been calculated. Hospitals that fail verification would receive notification on how to submit to CMS a reconsideration request. The request would be required to be submitted to CMS within 30 days and include at least the basis for requesting reconsideration and all documentation that supports the request (limited initially to the scope of information submitted during the initial validation process). CMS anticipates a determination would be provided to the hospital 90 days after receipt of the request. The hospital's confidence interval would be recalculated based on the results of the reconsideration to determine if the hospital passed or failed validation. The updated validation results would be used and could impact the hospital's payment adjustments.

Proposal to Update the Targeting Criteria for Hospitals Granted an Extraordinary Circumstances Exception (ECE). As proposed in the Hospital IQR Program in section IX.C.11.b of the proposed rule, CMS proposes to also add under the HAC Reduction Program a new criterion to the targeting criteria used to select up to 200 additional hospitals for purposes of validation. CMS proposes that, beginning with the FY 2027 program year, affecting validation of calendar year 2024 discharges, a hospital subject to validation that received an ECE for one or more quarters for the data period validated and has an ERUB of the two-tailed confidence interval that is less than 75 percent would be targeted for validation in the subsequent validation year and would not fail data validation in the HAC Reduction Program for the validation year involved. This exception would not except a hospital from participation in the HAC Reduction Program, and the hospital would still receive a Total HAC Score. The proposal would align targeting criteria across HAC Reduction, Hospital IQR, and Hospital OQR Programs, by adding the following to the existing 5 target criteria: "Any hospital with a two-tailed confidence interval that is less than 75 percent, and received an ECE for one or more quarters for the data period validated".

passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent; and (5) any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

[56] Details on the Hospital IQR Program validation reconsideration process can be found in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through 51651).

M. 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 period of participation for the last hospital under the CAA, 2021 authority would extend until June 30, 2028.

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. Proposed FY 2024 Budget Neutrality Adjustment

CMS proposes to continue to use its general budget neutrality methodology applied in previous years. It identifies 26 hospitals that will participate in the program in FY 2024. Using data from submitted cost reports with a cost report end date in 2021, CMS estimates that the demonstration program will cost $37,658,408 in FY 2024, which it will incorporate into the budget neutrality offset adjustment for FY 2024.

As of the date of publication of the proposed rule, not all of the finalized cost reports for the 29 hospitals that completed cost report periods beginning in FY 2018 under the demonstration payment methodology are available; all those finalized cost reports are needed to reconcile actual and estimated costs of the demonstration for that fiscal year. CMS expects all of those finalized cost reports to be available by the time of the final rule; thus, it proposes to include the difference between the actual and estimated costs of the demonstration for FY 2018 as determined from finalized cost reports within the budget neutrality offset amount in the final rule.

The total budget neutrality adjustment for FY 2024 is estimated to be $37,658,408. The overall amount may change if there are any revisions before the final rule to the data used to formulate this estimate, and CMS expects to revise the budget neutrality offset amount when it calculates the actual costs of the demonstration for FY 2018 upon receipt of all finalized cost reports for that fiscal year.

VI. Changes to the IPPS for Capital-Related Costs

A. Annual Update

National Capital Federal Rate for FY 2024. For FY 2023, CMS established a national capital federal rate of $483.79. CMS is proposing a national capital federal rate of $505.54 for FY 2024, 4.5 percent increase over FY 2023, as a result of the update factor and other adjustments.

Update Factor:

For FY 2024, CMS will increase the national capital federal rate by 3.5 percent based on the capital input price index (CIPI) of 2.6 percent and other factors shown in Table 1 below.

CMS is not adopting any change to the capital update for intensity. For FY 2024, 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 2024. 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 2024.

For purposes of the capital update factor, CMS builds in an adjustment for reclassification and recalibration of the MS-DRGs based on the forecast changes in payments in the 2nd year preceding the payment year compared to the actual increase. 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 2022. Therefore, CMS is proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2024.

CMS makes an adjustment for forecast error if the difference between the actual index in a past year (FY 2022 in this case) is 0.25 percentage points different than the CIPI used to update the capital rate. For FY 2022, CMS used a CIPI of 1.1 percent to update the capital rate. The actual index was 2.0 percent. As the difference (0.9 percentage points) is greater than 0.25 percentage points, CMS is proposing a 0.9 percentage point adjustment for forecast error.

Table 1

CMS FY 2024 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE		
FY 2018-based CIPI		2.6
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 2022 Reclassification and Recalibration		0.0
Forecast Error Correction		0.9
Total Update		3.5

Other Adjustments:

For FY 2024, CMS estimates that outlier payments would be 5.51 percent of total capital IPPS payments. CMS estimates that capital outlier payments will be 4.41 percent of total capital payments in FY 2023. Capital outlier reconciliation will have no effect on this estimate. Therefore, the proposed FY 2024 outlier adjustment factor is 0.9584 (-4.16 percent), compared to 0.9449 (-5.51 percent) in FY 2023. The net change is percent 1.0143 percent (1 - 0.9584/0.9449. Thus, the proposed outlier adjustment increases the FY 2024 capital federal rate by 1.43 percent.

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 0.9972, which was the effect of these policy adjustments in FY 2023.

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 0.9977 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 0.9934 for this factor.

CMS also incorporates an adjustment for FY 2024 MS-DRG changes and recalibration of the relative weights of 1.0015 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 0.9992 (1.0015 x 0.9977, or -0.08 percent). The Quartile/Cap adjustment of 0.9934 (-0.66 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 2024 national capital federal rate compared to the FY 2023 national capital federal rate.

Comparison of Factors and Adjustments:
FY 2023 and FY 2024 Capital Federal Rate

	FY 2023	FY 2024	Change	Percentage Change
Update Factor*	N/A	1.0350	1.0350	3.5
GAF/DRG Adjustment Factor*	N/A	0.9992	0.9992	-0.08
Quartile/Cap Adjustment Factor**	0.9972	0.9934	0.9962	-0.38
Outlier Adjustment Factor**	0.9449	0.9584	1.0143	1.43
Capital Federal Rate	$483.79	$505.54	1.0450	4.5

* 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 2023 to FY 2024 resulting from the application of the GAF/DRG budget neutrality adjustment factor for FY 2024 is a net change of 0.9992 (or -0.08 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 2024 outlier adjustment factor is 0.9584/0.9449, or 1.0143 (1.43 percent). The net change to the Quartile/Cap adjustment is 0.9934/0.9972 or 0.9962 (-0.38 percent).

Considering the update factor and the budget neutrality adjustments, CMS is proposing to adopt a national capital federal rate for FY 2024 of $505.54, a 4.5 percent increase over the FY 2023 rate of $483.79.

B. Urban to Rural Reclassifications for Capital DSH.

Under the capital IPPS, only urban hospitals with 100 or more beds are eligible for capital DSH payments.[57] Section 1886(d)(8)(E)(i) of the Act indicates that when a hospital reclassifies from urban to rural, it is treated as rural for all IPPS operating payment purposes. Since October 1, 2006, CMS has been treating an urban to rural reclassified hospital as rural for capital DSH payments—e.g., ineligible to receive them.

On September 30, 2021, in Toledo Hospital v. Becerra, the U.S. District Court for the District of Columbia found that CMS's policy of not providing capital DSH payments to urban hospitals that are reclassified as rural was arbitrary and capricious. The court concluded, the record did not demonstrate that CMS took relative costs into account when considering the rule and the policy at issue. In response to the court's ruling, CMS is proposing that effective for discharges occurring on or after October 1, 2023, hospitals reclassified as rural will no longer be considered rural for purposes of determining eligibility for capital DSH payments.

[57] 42 CFR §412.320(a)(1)(iii)

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, 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. Although not technically not paid under TEFRA, there is one "extended neoplastic disease care hospital" (Calvary Hospital in the Bronx, New York) that qualifies under section 1886(d)(1)(B)(vi) of the Act to be paid on a reasonable cost basis subject to a limit.

The annual update to the TEFRA limit or the otherwise applicable reasonable cost limit is 3.0 percent. This figure is based on IGI's 4th quarter 2022 forecast with historical data through the 3rd quarter of 2022 of the FY 2024 hospital market basket.

B. Critical Access Hospitals (CAHs)

The Frontier Community Health Integration Project (FCHIP) Demonstration[58] 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. Among the 10 CAHs eligible to participate in the demonstration project in the extension period, five have elected to continue their participation.

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 adopted a policy 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.

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

CMS is not proposing to make any budget neutrality adjustment for FY 2024 for the FCIP demonstration project.

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

A. Background of the 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 2024:

- 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. The FY 2020 IPPS/LTCH PPS final rule implemented payment adjustments for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which those LTCHs may have the payment adjustment discontinued.

With respect to data used for FY 2024 LTCH PPS rate setting, CMS proposes to use the most recent data available, including FY 2022 MedPAR claims and FY 2021 cost report data.

Summary of Proposed Changes to LTCH PPS Rates for FY 2024*	
Standard Federal Rate, FY 2023	$46,432.77
Proposed Rule Update Factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+2.9%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+2.9% (1.029)
Net update LTCHs not reporting quality data	+0.9% (1.009)

Summary of Proposed Changes to LTCH PPS Rates for FY 2024*	
Proposed Rule Adjustments	
Proposed area wage index budget neutrality adjustment	1.0035335
Proposed Standard Federal Rate, FY 2024	
LTCHs reporting quality data ($46,432.77 x 1.029 x 1.0035335)	$47,948.15
LTCHs not reporting quality data ($46,432.77 x 1.009 x 1.0035335)	$47,016.21
Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$94,378
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$40,732
Impact of Proposed Policy Changes on LTCH Payments in FY 2024	
Total estimated impact	-0.9% (≈ -$24 million)
LTCH standard federal payment rate cases (68% of LTCH cases)	-2.5% (≈ -$59 million)
Site neutral payment rate cases (32% of LTCH cases)**	10.8% (≈ $35 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 2024". Table IV does not include the impact of site neutral payment rate cases. **LTCH site neutral payment rate cases are paid a rate that is based on the lower of the IPPS comparable per diem amount or 100 percent of the estimated cost of the case.	

B. MS-LTC-DRGs and Relative Weights

1. Background

Similar to FY 2023, the annual recalibration of the MS-LTC-DRG relative weights for FY 2024 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 2024 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-DRGs that affect assignments under the proposed GROUPER Version 41 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 Development of the FY 2024 MS-LTC-DRG Relative Weights Methodology

For the FY 2023 MS-LTC-DRG Relative Weights, CMS temporarily modified its methodology for determining the relative weights; it calculated the relative MS-LTC-DRG weights both including and excluding COVID-19 cases and then averaged the two sets of relative weights for FY 2023. For FY 2024, CMS proposes to return to its 11-step historical methodology for calculating the relative weights, as described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58898 through

58907), subject to the 10-percent cap on the reduction to a MS-LTC-DRG's relative weight in a given year, which was added as a permanent policy in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49162).

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 2024 MS-LTC-DRG relative weights.

a. Proposed Relative Weights Source Data

FY 2024 proposed relative weights are derived from the December 2022 update of the FY 2022 MedPAR file. These data are filtered to identify LTCH cases that met the established site neutral payment exclusion criteria or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. CMS notes that all LTCH PPS cases in FY 2022 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 2024 (including MS-LTC-DRG relative weights), it used FY 2022 cases that met the statutory patient criteria without consideration as to how those cases were paid in FY 2022. The filtered data are trimmed to exclude all-inclusive rate providers, Medicare Advantage claims, and demonstration project participants, yielding "applicable LTCH data."

Because one LTCH received an excessive amount of high-cost outlier payments in FY 2021 and FY 2022, CMS proposes to remove claims from that provider (CCN 312024) when determining the FY 2024 MS-LTC-DRG relative weights and in all other FY 2024 ratesetting calculations, including the
calculation of the area wage level adjustment budget neutrality factor and the fixed-loss amount for LTCH PPS standard Federal payment rate cases.

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. 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. It finds that there are 235 such MS-LTC-DRGs in the claims, and the quintiles each contained 47 MS-LTC-DRGs.

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. (See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these low-volume MS-LTC-DRGs.) If in the final rule the number of MS-LTC-DRGs with less than 25 applicable LTCH cases in the best available data is not evenly divisible by 5, CMS proposes to use its historical methodology of assigning each remainder low-volume MS-LTC-DRG to the low-volume quintile that contains an MS-LTC-DRG with an average charge closest to that of the remainder low-volume MS-LTC-DRG.

c. Remove Statistical Outliers

Consistent with its current methodology, CMS proposes to remove statistical outlier cases from the LTCH 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 for FY 2024.

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

CMS proposes to continue to use its HSRV methodology in FY 2024 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.

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 2024 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.

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 (430 of these MS-LTC-DRGs are identified for the proposed rule), 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. Thus, there are 402 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 336 (766 – 430 = 336) MS-LTC-DRGs for which it calculated relative weights based on the trimmed applicable LTCH cases in the FY 2022 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 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 Relative Weights

CMS proposes to normalize relative weights using its established methodology for FY 2024. This is designed to ensure that the recalibration of the MS-LTC-DRG relative weights neither increases nor decreases the average case-mix index. In determining the proposed MS-LTC-DRG relative weights for FY 2024, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by the proposed normalization factor in the first step of the budget neutrality methodology, which produces "normalized relative weights." CMS calculated a normalization factor of 1.30980.

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 2024 MS-LTC-DRG relative weights update, including for the application of 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 2024; one before the application of the 10-percent cap (referred to as the "uncapped relative weights") and the other after application of that cap.

(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 10-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 2022 MedPAR file, and groups them using Version 41 of the GROUPER and the proposed recalibrated FY 2024 MS-LTC-DRG uncapped relative weights to calculate the average case-mix index. Next, it groups the same applicable LTCH cases using the FY 2023 GROUPER (Version 40) and FY 2023 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 2023 by the average case-mix index for FY 2024. As a result, in determining the proposed MS-LTC-DRG relative weights for FY 2024, 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 continue to determine the first budget neutrality adjustment factor (for uncapped relative weights) by calculating the ratio of estimated aggregate FY 2024 LTCH PPS standard federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2024 LTCH PPS standard federal payment rate payments for applicable LTCH cases after reclassification and recalibration. CMS calculates a proposed budget neutrality factor of 0.9962866, which is applied to each uncapped normalized relative weight.

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

Under its policy to limit reductions in relative weights to 10 percent in a given year, the 10-percent cap is only applied to the relative weights for MS-LTC-DRGs with at least 25 applicable LTCH cases. For any MS-LTC-DRG where the FY 2024 relative weight would otherwise have been reduced by more than 10 percent, CMS proposes a capped FY 2024 MS-LTC-DRG relative weight equal to 90 percent of that MS-LTC-DRG's FY 2023 relative weight.

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

CMS proposes to continue to use its 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 2024 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2024 (determined in Step 10) and proposed GROUPER Version 41;
- Simulate estimated total FY 2024 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2024 (determined in Step 9) and proposed GROUPER Version 41; and
- Calculate the ratio of the estimated total payments.

The proposed budget neutrality adjustment factor for the 10-percent cap is 0.9984223. To determine the proposed FY 2024 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 884 through 903 of the display copy).

C. Update and Other Changes to the LTCH PPS Payment Rates

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 the LTCH market basket includes both operating and capital cost categories.

2. Proposed Annual Update for LTCH PPS Standard Federal Payment Rate for FY 2024

The proposed annual update to the LTCH PPS standard federal payment rate is equal to 2.9 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 0.2 percentage points (PP) for multifactor productivity meaning an update factor of 1.029 to the FY 2023 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 2024. The proposed LTCH update for FY 2024 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	3.1%	3.1%
Multifactor Productivity	-0.2 PP	-0.2 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	2.9%	0.9%

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[59] (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

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

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 2024.

b. Labor-related Share

CMS proposes an FY 2024 labor-related share of 68.4 percent based on IGI's fourth quarter 2022 forecast of the 2017-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (64.2 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. Proposed Wage Index for FY 2024 for the Standard Federal Rate

To determine the applicable area wage index values for the FY 2024 LTCH PPS standard federal payment rate, CMS proposes to continue to use the same data it proposes to use to compute the proposed FY 2024 acute care hospital inpatient wage index, which uses wage data for cost reporting periods beginning during FY 2020. The FY 2024 standard federal payment rate area wage index values would be calculated consistent with the "urban" and "rural" geographic classifications, not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act. It also proposes to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy.

To determine area wage index values for areas where there are no IPPS wage data, CMS proposes to use existing methodology, whereby the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State. CMS notes that there are no rural areas without IPPS hospital wage data.

d. Permanent Cap on Wage Index Decreases

The FY 2023 IPPS/LTCH PPS final rule established a permanent 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 (87 FR 49440 through 49442). It believes the policy provides increased predictability in LTCH wage indexes and payments and mitigates significant payment reductions due to changes in wage index policy, such as the adoption of the revised CBSAs. To ensure budget neutrality, it includes this policy in the determination of the area wage level budget neutrality factor.

Under this policy, an LTCH's wage index will not be less than 95 percent of its wage index for the prior 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 non-reclassified hospitals in the same geographic area as the LTCH. CMS adopted, beginning with FY 2023, the application of 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 budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for non-reclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner. Under the policy, an LTCH's applicable IPPS comparable wage index cap adjustment is determined based on the wage index value assigned to the LTCH on the last day of the prior Federal fiscal year.

e. 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, the 5-percent cap on wage index decreases is included in the determination of the proposed area wage level budget neutrality factor. CMS determined a proposed FY 2024 LTCH PPS standard federal payment rate area wage level adjustment budget neutrality factor of 1.0035335.

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 continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2020 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2022 IPPS/LTCH PPS final rule. The table below shows the proposed COLAs for FY 2024 which are unchanged from the COLAs in effect for FY 2023.

Area	**Proposed FY 2024**
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

Area	Proposed FY 2024
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 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 cases, 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 2022 update of the PSF. Thus, it proposes an LTCH total CCR ceiling of 1.287 under the LTCH PPS for FY 2024 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 2022 update of the PSF. They would be effective for discharges occurring on or after October 1, 2023 through September 30, 2024.

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. CMS did not use claims from the LTCH with abnormal charging practices described above (CCN 312024) when determining the fixed-loss amount for LTCH PPS standard federal payment rate cases for FY 2024.

(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 CMS made a technical change to the methodology for determining charge inflation; the charge inflation factor is currently 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.

CMS computed a proposed charge inflation factor using the December 2022 update of the FY 2022 MedPAR file and the December 2021 update of the FY 2021 MedPAR as the basis of the LTCH PPS standard federal payment rate cases for the two most recently available federal fiscal year time periods. CMS calculated a 1-year charge inflation factor of 1.135651, and a 2-year charge inflation factor of 1.289703 (calculated by squaring the 1-year factor). It proposes to inflate the billed charges obtained from the FY 2022 MedPAR file by this 2-year charge inflation factor of 1.289703 when determining the proposed fixed-loss amount for LTCH PPS standard federal payment rate cases for FY 2024.

(2) Proposed CCRs

Historically, CMS has used CCRs from the most recently available PSF file and adjusts them by a factor calculated based on historical changes in the average case weighted CCR for LTCHs. It proposes to continue to use the following four-step methodology finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562-45566):

- Identify providers with standard federal payment rate cases from the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only

Medicare Advantage claims) and identify for each of these providers the CCR from the most recently available PSF and from the prior year 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.

Under this methodology for FY 2024, CMS used the December 2022 PSF as the most recently available PSF and the December 2021 PSF as the PSF that was made available one year prior to the most recently available PSF. It also used claims from the December 2022 update of the FY 2022 MedPAR file in calculating the average case-weighted CCRs in the last step of the methodology. CMS calculated a December 2021 national average case-weighted CCR of 0.235395 and a December 2022 national average case-weighted CCR of 0.229631, which results in a proposed 1-year national CCR adjustment factor of 0.975513.

(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. The proposed fixed-loss amount must maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard federal payment rate cases. Using LTCH claims data from the December 2022 update of the FY 2022 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2022 update of the PSF, CMS calculated a proposed fixed-loss amount for standard federal rate cases of $94,378 for FY 2024.

CMS notes that the proposed fixed-loss amount determined for FY 2024 ($94,378) is significantly higher than the fixed-loss amount finalized for FY 2023 ($38,518); **it seeks comment on its proposed methodology and the assumptions underlying it**, and will consider these comments when finalizing the methodology in the final rule.

Under the proposal, the HCO payment would continue to equal 80 percent of the difference between the estimated cost of the case and the outlier threshold. Consistent with historical practice, CMS would use the most recent available LTCH claims data and CCR data for the final rule.

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

CMS continues to believe that the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount. For FY 2024, CMS proposes a fixed-loss amount for site

neutral payment rate cases of $40,732. CMS also proposes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2024. 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 2024, 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.

D. LTCH Payment Impacts

CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the proposed payment rates and factors for all LTCHs will result in a decrease of 0.9 percent or approximately $24 million in aggregate payments. Based on the FY 2022 LTCH cases that were used for the analysis in this proposed rule, approximately 32 percent of those cases were classified as site neutral payment rate cases, and the Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be classified as site neutral payment rate cases in FY 2024 will not change significantly from the most recent historical data. Thus, CMS estimates that aggregate LTCH PPS payments for these site neutral payment rate cases would increase by approximately 10.8 percent (or approximately $35 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the proposed updates to the IPPS rates and payments reflected in its estimate of the IPPS comparable per diem amount, as well as an estimated increase in costs for these cases determined using the charge and CCR adjustment factors.

CMS found approximately 68 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2024, and will be paid based on the LTCH PPS standard federal payment rate for the full year. Total estimated LTCH PPS payments for these LTCH PPS standard federal payment rate cases in FY 2024 will decrease approximately 2.5 percent (or approximately $59 million), which is primarily due to the projected 4.7 percent decrease in high-cost outlier payments as a percentage of total LTCH PPS standard federal payment rate payments.

CMS estimates that aggregate FY 2024 LTCH PPS payments will be approximately $2.622 billion, as compared to estimated aggregate proposed FY 2023 LTCH PPS payments of approximately $2.645 billion.

Table IV "Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments For LTCH PPS Standard Federal Payment Rate Cases for FY 2024" 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.

Summary of Impact of Changes to LTCH PPS Standard Federal Payment Rate Cases for FY 2024		
	Number of LTCHs	**Estimated Percent Change in Payments per Discharge**
All LTCH providers	332	-2.5%
By Location:		
Rural	18	-1.5%
Urban	314	-2.6%
By Ownership Type:		
Voluntary	54	-4.7%
Proprietary	269	-2.2%
Government	9	-3.9%
By Region		
New England	10	-3.9%
Middle Atlantic	19	-1.4%
South Atlantic	61	-3.2%
East North Central	47	-3.9%
East South Central	31	-3.6%
West North Central	22	-6.4%
West South Central	92	-0.9%
Mountain	27	-0.2%
Pacific	23	-1.8%
*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 2024" on pages 1458-1459 of the display copy.		

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. Overview

CMS seeks comment on and proposes changes under this section to the Hospital IQR Program, PCHQR Program, LTCH QRP, and Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs).

B. Adopting the Up-to-Date COVID-19 Vaccination Among Healthcare Personnel

1. Background

Subsequent to the COVID-19 public health emergency declaration by the Secretary of HHS on January 31, 2020,[60] the HCP COVID-19 Vaccine measure was adopted across multiple quality reporting programs, including the Hospital IQR Program (86 FR 45374).[61] The measure requires each hospital to submit data on the percentage of HCP eligible to work in the hospital for at least one day during the reporting period who have received a complete vaccination course against COVID-19 (excluding persons with contraindications to the COVID-19 vaccine). CMS describes that since adoption of the measure, the agency continues to believe vaccination is a critical component to effectively countering the spread of COVID-19 and that it's important to incentivize and track HCP vaccination across care settings, including the inpatient, long-term care, and cancer hospital settings. However, CMS states it is important to update the specifications of the HCP COVID-19 Vaccine measure to reflect the most current guidance that specifies for HCP to receive primary series and booster vaccine doses in a timely manner.

2. Overview of Measure and Proposed Modification

Proposed modifications. The HCP COVID-19 Vaccine measure is a process measure (that is not risk-adjusted) developed by the CDC to track COVID-19 vaccination coverage among HCP in settings such as acute care and post-acute care facilities, and is reported via the CDC's National Healthcare Safety Network (NHSN). CMS proposes, beginning with the quarter 4 2023 reporting period/FY 2025 payment determination for the Hospital IQR Program and the FY 2025 program year for both the LTCH QRP and the PCHQR Program, to modify the HCP COVID-19 Vaccine measure to:

- Replace the term "complete vaccination course" with the term "up to date" in the HCP vaccination definition; and
- Update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID-19 vaccines, including booster doses.

[60] HHS has announced plans to let the PHE expire on May 11, 2023.

[61] In addition to adoption under the Inpatient QRP, the measure was adopted under the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Outpatient Quality Reporting Program (86 FR 63824 through 63833), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Ambulatory Surgical Center Quality Reporting Program (86 FR 63875 through 63883), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396).

Pre-rulemaking. The current version of the HCP COVID-19 Vaccine measure received endorsement by the CBE on July 26, 2022 (CBE #3636), but the measure so endorsed does not capture information about whether HCP are "up to date" with their COVID-19 vaccinations (as proposed in the CMS modifications to the measure). The CDC is pursuing CBE endorsement for the modified version of the measure.

CMS included an updated version of the HCP COVID-19 Vaccine measure on the MUC List for the 2022-2023 pre-rulemaking cycle. Comments were mixed and raised concern about the difficulty of defining "up to date" for purposes of the measure and about data collection burden. The developer noted that the model used for this measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID-19 Vaccination Coverage among HCP measure if vaccination strategy becomes seasonal. The MAP conditionally supported the rulemaking pending testing that indicates the measure is reliable and valid, and pending endorsement by the CBE.

CMS proposes to adopt the measure, consistent with the exception for non-CBE-endorsed measures,[62] having found no currently available, alternative measure that is comparable, NQF-endorsed, feasible, and practical.

Modified measure calculation. The measure would be calculated as follows:

- Denominator of Measure: The number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID-19 vaccination that are described by the CDC.[63] HCPs include employees of the facility, licensed independent practitioners, and adult students/trainees and volunteers. There are no proposed changes to the denominator from that of the current measure.
- Numerator of Modified Measure: The number of HCP in the denominator population who are considered up to date[64] with CDC recommended COVID-19 vaccines.
- Data collection: The measure includes at least one week of data collection a month for each of the three months in a quarter.
- Public reporting of the modified measure: Would begin with the October 2024 Care Compare refresh, or as soon as technically feasible, for the Hospital IQR Program, PCHQR Program, and LTCH QRP.

3. Data Submission and Reporting
    - For the FY 2025 payment determination for the Hospital IQR Program and for the FY 2025 program year for the PCHQR Program and LTCH Program, reporting on the modified measure would begin with the quarter 4 of 2023 reporting period. Providers

[62] See sec. 1886(b)(3)(B)(viii)(IX)(bb) of the Act for the Hospital IQR Program; sec. 1866(k)(3)(B) of the Act for the PCHQR Program; sec. 1886(m)(5)(D)(ii) of the Act for the LTCH QRP.
[63] Centers for Disease Control and Prevention. (2022). Contraindications and precautions. Available at: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.
[64] The definition of up to date is as of the first day of the applicable reporting quarter, and can be found at https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf. HCP would be considered up to date during Q4 of the CY 2022 reporting period if the individual received an updated bivalent booster dose; received their last booster dose less than 2 months ago; or completed their primary series less than 2 months ago.

would collect the numerator and denominator for the modified measure for at least one self-selected week during each month of the reporting quarter, and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline.
- Each quarter, the CDC would calculate a single quarterly COVID-19 HCP vaccination coverage rate for each provider, by taking the average of the data from the 3 weekly rates submitted by the provider for that quarter. CMS notes that the current hospital Conditions of Participation (CoP) require more frequent reporting, but that with the announcement that the PHE will be ending on May 11, 2023, reporting under the Hospital CoP may be reduced to a lesser frequency.
- CMS would publicly report the COVID-19 HCP vaccination coverage rate as calculated by the CDC.

CMS invites public comment on this proposal.

C. Hospital Inpatient Quality Reporting (IQR) Program

CMS proposes changes to the Hospital IQR program that would add 3 new electronic clinical quality measures (eCQMs) beginning with the CY 2025 reporting period/FY 2027 payment determination; in addition to the updated HCP COVID-19 Vaccine measure proposed in section IX.B., update 2 further measures beginning with CY 2027 payment determination; and remove 3 measures. CMS also proposes updates to the HCAHPS Survey Measure beginning with FY 2027 payment determination and changes to the measure validation process. CMS seeks public comment on the potential future adoption of two geriatric care measures.

No changes are proposed to the Data Accuracy and Completeness Acknowledgement (DACA) requirements, public display requirements, public reporting of eCQM requirements, Overall Hospital Star Ratings policies, reconsideration and appeals procedures, or Hospital IQR Program Extraordinary Circumstances (ECE) policy.

CMS estimates if the proposals are adopted there would be a total information collection burden decrease for 3,150 IPPS hospitals of 146,674 hours at a savings of $6,917,315 annually across a 4-year period from the 2024 reporting period/FY 2026 payment determination through the 2028 reporting period/FY 2030 payment determination, compared to the currently approved information collection burden estimates.

CMS further estimates that for FY 2024, 63 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 that are meaningful users under the Medicare Promoting Interoperability Program) and will receive a 2.05 percent update; 132 hospitals will not receive the full update for not being meaningful EHR users (but do meet the IQR Program requirements) and will receive a 0.55 percent update; and 32 hospitals will not receive the full update for failure to satisfy both requirements and will receive a -0.2 percent update.

CMS invites public comment on all of the proposed changes to the Hospital IQR Program under this section.

1. Background

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.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

CMS does not propose any changes to the previously finalized retention of adopted measures policy, which states that when a measure is adopted for the Hospital IQR Program beginning with a particular payment determination, that measure is automatically readopted for all subsequent payment determinations unless a different or more limited period is proposed and finalized or CMS proposes to remove, suspend, or replace the measure.[65] CMS proposes in section IX.C.7.d. to codify this policy.

3. Removal Factors for Hospital IQR Program Measures

CMS does not propose any changes to the measure removal factors policy[66] and proposes in section IX.C.7.d. to codify it.

4. Considerations in Expanding and Updating Quality Measures

CMS is not proposing any changes to the considerations used to expand and update quality measures under the Hospital IQR Program.[67]

5. Proposed New Measures for the Hospital IQR Program Measure Set

CMS proposes adoption of 3 new eCQMs to include in the eCQM measure set, from which hospitals can self-select measures to report to meet the eCQM requirement, beginning with the CY 2025 reporting period/FY 2027 payment determination:

- Hospital Harm – Pressure Injury eCQM.
- Hospital Harm – Acute Kidney Injury eCQM.
- Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) eCQM.

[65] The finalized measure retention policy can be found in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 and 53513).
[66] See FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors.
[67] See FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for considerations used to expand and update quality measures.

CMS also proposes in section IX.F. to adopt these measures in the Medicare Promoting Interoperability Program.

a. Hospital Harm – Pressure Injury eCQM

Background. CMS describes that hospital-acquired pressure injuries are one of the most common patient harms and can lead to further patient harm (such as infection, osteomyelitis, anemia, and sepsis) as well as an increased length of hospital stay. However, CMS describes best practices, including risk assessment, assessment of skin and tissue, preventive skin care, and reducing progression through treatment, can reduce the risk of developing a pressure injury.

Overview of Measure. The Hospital Harm – Pressure Injury measure is an outcome eCQM that assesses the proportion of inpatient hospitalizations for patients 18 years and older who suffer the harm of developing a new stage 2, stage 3, stage 4, deep tissue, or unstageable pressure injury. The measure is intended to provide hospitals with a reliable and timely measurement of harm reduction efforts and the ability to modify their improvement efforts in near real-time.

Pre-Rulemaking*:* An older version of the measure was reviewed by MAP and received a recommendation of conditional support pending endorsement by the CBE, and subsequently a revised measure was reviewed by MAP for the 2022-2023 pre-rulemaking cycle and received a conditional support pending CBE endorsement. The measure was submitted to the CBE, for endorsement review in the Fall 2022 cycle (CBE #3498e). CMS proposes to adopt the measure, consistent with the exception for non-CBE-endorsed measures.[68]

Measure Calculation.

- Numerator. Inpatient hospitalizations for patients with a new deep tissue pressure injury (DTPI) or stage 2, 3, 4, or unstageable pressure injury, as evidenced by:
    - A diagnosis of DTPI with the DTPI not present on admission;
    - A diagnosis of stage 2, 3, 4 or unstageable pressure injury with the pressure injury diagnosis not present on admission;
    - A DTPI found on exam greater than 72 hours after the start of the encounter; or
    - A stage 2, 3, 4 or unstageable pressure injury found on exam greater than 24 hours after the start of the encounter.
- Denominator. Inpatient hospitalizations for patients 18 years and older.
- Exclusions from the denominator. (1) Inpatient hospitalizations for patients with a DTPI or stage 2, 3, 4 or unstageable pressure injury diagnosis present on admission; (2) inpatient hospitalizations for patients with a DTPI found on exam within 72 hours of the encounter start; (3) inpatient hospitalizations for patients with a stage 2, 3, 4, or unstageable pressure injury found on exam within 24 hours of the encounter start; and (4) inpatient hospitalizations for patients with diagnosis of a COVID-19 infection during the encounter.[69]

[68] See sec. 1886(b)(3)(B)(viii)(IX)(bb) of the Act.

[69] The COVID-19 exclusion would be transitional with the intention to be removed in the future (during the routine eCQM Annual Update process) when there is better consensus about what is COVID-19-related tissue breakdown versus what is pressure injury.

Data Source. The measure would be calculated by the hospitals' certified electronic health record technology (CEHRT) using the patient-level data collected through hospitals' EHRs and then submitted by hospitals to CMS.

b. Proposed Adoption of Hospital Harm – Acute Kidney Injury eCQM

Background. CMS describes that acute kidney injury (AKI) may result in the need for dialysis and is associated with an increased risk of mortality, but a substantial proportion of AKI cases are preventable or treatable at an early stage.

Overview of Measure. The Hospital Harm – Acute Kidney Injury measure is an outcome eCQM that assesses the proportion of inpatient hospitalizations for patients 18 years and older who have a stage 2 or greater AKI[70] (i.e., moderate-to-severe AKI) that occurred during the encounter, and is intended to improve patient safety and prevent patients from developing stage 2 or greater AKI during hospitalization.

Pre-Rulemaking: The measure was submitted to MAP for the 2022-2023 pre-rulemaking cycle and received conditional support for rulemaking pending endorsement by the CBE. The measure was submitted to the CBE for endorsement review in the Fall 2022 cycle (CBE #3713e). CMS proposes to adopt the measure, consistent with the exception for non-CBE-endorsed measures.[71]

Measure Calculation.

- Numerator. Inpatient hospitalizations for patients who develop AKI (stage 2 or greater) during the encounter, as evidenced by:
    - A subsequent increase in the serum creatinine value at least 2 times higher than the lowest serum creatinine value, and the increased value is greater than the highest sex-specific normal value for serum creatinine; or
    - Kidney dialysis (hemodialysis or peritoneal dialysis) initiated 48 hours or more after the start of the encounter.
- Denominator. Inpatient hospitalizations for patients without a diagnosis of obstetrics, with a length of stay of 48 hours or longer, and who had at least one serum creatinine value after 48 hours from the start of the encounter.
- Exclusions. Inpatient hospitalizations for patients who (1) are younger than 18 years; (2) are already in AKI at the start of the encounter; (3) have CKD stage 3A or greater; (4) have fewer than two serum creatinine results within 48 hours of the encounter start; (5) have kidney dialysis initiated within 48 hours of the encounter start; (6) have at least one specified diagnosis present on admission that puts them at extremely high risk for AKI, or (7) have at least one specified procedure during the encounter that puts them at extremely high risk for AKI.

Data Source. The measure would be calculated by the hospitals' CEHRT (using the patient-level data collected through hospitals' EHRs) and then submitted by hospitals to CMS.

[70] An AKI stage 2 or greater is defined as a substantial increase in serum creatinine value or by the initiation of kidney dialysis (continuous renal replacement therapy (CRRT), hemodialysis or peritoneal dialysis).
[71] See sec. 1886(b)(3)(B)(viii)(IX)(bb) of the Act.

c. *Proposed Adoption of Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults (Hospital Level – Inpatient) eCQM (Excessive Radiation eCQM)*

Background. The increased use of computed tomography (CT) scans, while improving the diagnosis and treatment of many conditions, has also increased patients' exposure to ionizing radiation, which contributes to the development of cancer. CMS emphasizes the importance of ensuring exposure from a CT scan being the lowest possible level of radiation while preserving image quality.

Overview of Measure. The Excessive Radiation eCQM provides a standardized method for monitoring the performance of diagnostic CT. The measure is not risk-adjusted and is expressed as a percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam. Measure testing showed that availability, accuracy, validity, and reproducibility were high for all of the measures' required data elements; reporting burden was small to moderate (as compared to reporting burden for other measures); and assessing radiation doses and providing radiologists audit feedback reduced unsafe doses levels and helped identify areas for quality improvement.

Pre-Rulemaking. The measure (CBE #3663e) received CBE endorsement on August 2, 2022, and, in the 2022-2023 pre-rulemaking cycle, received a recommendation from the MAP in support of rulemaking.

Measure Calculation.

- Numerator. The number of diagnostic CT scans that have a size-adjusted radiation dose greater than the threshold defined for the specific CT category[72] and diagnostic CT scans with a noise value greater than a threshold specific to the CT category.
- Denominator. The number of all diagnostic CT scans performed on patients 18 years and older during the one-year measurement period which have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.
- Exclusions. CT scans that cannot be categorized by the area of the body being imaged or reason for imaging[73] and CT scans missing information on the patient's age, Calculated CT Size-Adjusted Dose, or Calculated CT Global Noise.

Data Sources. The measure uses hospitals' EHR data and radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). Since eCQMs cannot access and process data elements in the Digital Imaging and Communications in Medicine (DICOM) standard format, and medical imaging information is stored according to that format, the measure developer created translation

[72] The threshold is determined by the body region being imaged and the reason for the exam, which affects the radiation dose and image quality required for that exam.

[73] This exclusion includes scans that can't be classified based on diagnosis and procedural codes, specified as Logical Observation Identifiers Names and Code (LOINC) 96914-7, CT Dose and Image Quality Category, Full Body.

software (Alara Imaging Software for CMS Measure Compliance), which would be made available to all reporting entities for free. The software links primary data elements, assesses CT scans for eligibility for inclusion in the measure, and generates three data elements to calculate the eCQM: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise.

6. Refinements to Current Measures in the Hospital IQR Program Measure Set

CMS proposes to modify three measures within the Hospital IQR Program measure set:

- The Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with the FY 2027 payment determination.
- The Hybrid Hospital-Wide All-Cause Readmission (HWR) measure beginning with the FY 2027 payment determination.
- The COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the Quarter 4 CY 2023 reporting period/FY 2025 payment determination, as proposed in section IX.B. of the proposed rule.

a. *Proposed Modification of Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measure*

Background. CMS adopted, in the FY 2022 IPPS/LTCH PPS final rule,[74] the Hybrid HWM measure into the Hospital IQR Program with one voluntary confidential reporting period beginning with performance data from July 1, 2022, through June 30, 2023, followed by mandatory data submission and public reporting in subsequent years (with mandatory reporting impacting the FY 2026 payment determination and subsequent years).

Overview of Measure. The measure is an outcome measure that captures the hospital level, risk-standardized mortality within 30 days of hospital admission for most conditions or procedures. The measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 categories of admissions grouped based on similar discharge diagnoses or procedures, including 9 non-surgical categories (cancer, cardiac, gastrointestinal, infectious disease, neurology, orthopedics, pulmonary, renal, and other) and 6 surgical categories (cancer, cardiothoracic, general, neurosurgery, orthopedics, and other). There is a separate risk model for each of the 15 categories to account for patient case mix and hospital service mix.

Measure Modification and Specifications: CMS proposes to modify the adopted measure beginning for the FY 2027 payment determination (with discharge data from July 1, 2024, through June 30, 2025) by expanding the cohort of the measure from only Medicare fee-for-service (FFS) patients to a cohort which includes both FFS and Medicare Advantage (MA) patients. All other specifications for the measure would remain the same, including the following:

- Cohort. The expanded cohort (FFS plus MA) would be limited to 65 to 94 years of age hospitalized at a non-federal, short-term acute care hospital within the one-year measurement period (July 1 to June 30).

[74] 86 FR 45365 through 45374

- All cause 30-day mortality. The outcome for the measure is all cause 30-day mortality (defined as death from any cause within 30 days of the hospital admission date).
- Sources of data. Medicare Part A claims data; a set of core clinical data elements from a hospital's EHR; and mortality status obtained from the Medicare Enrollment Database.

Pre-Rulemaking: The current Hybrid HWM measure received CBE endorsement on October 23, 2019. The modified measure with expanded cohort was resubmitted to the MAP for the 2022-2023 pre-rulemaking cycle and received conditional support, pending CBE endorsement. The modified measure is expected to be submitted to CBE for re-endorsement in Fall 2024.

Data Submission and Reporting: Hospitals would submit data to CMS using Quality Reporting Data Architecture (QRDA) I files, consistent with the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program.

b. Proposed Modification of Hybrid Hospital-Wide All-Cause Readmission (HWR) Measure

Background. CMS adopted, in the FY 2020 IPPS/LTCH PPS final rule,[75] the Hybrid HWR measure into the Hospital IQR Program with 2 voluntary reporting periods using performance data from July 1, 2021, through June 30, 2022, and July 1, 2022, through June 30, 2023, followed by mandatory data submission and public reporting in subsequent years (with mandatory reporting impacting the FY 2026 payment determination and subsequent years).

Overview of Measure. The current Hybrid HWR measure is an outcome measure that captures the hospital-level, risk-standardized readmission rate (RSRR) of unplanned, all-cause readmissions within 30 days of hospital discharge for any eligible condition. For each of the 5 specialty cohorts (surgery/gynecology, general medicine, cardiorespiratory, cardiovascular, and neurology), the measure:

- Reports a single summary RSRR, derived from the volume-weighted results of the model for the specialty cohort; and
- Indicates the hospital-level standardized readmissions ratios (SRR).

Measure Modification and Specifications. CMS proposes to modify the adopted measure beginning for the FY 2027 payment determination (with discharge data from July 1, 2024, through June 30, 2025) by expanding the cohort of the measure from only Medicare fee-for-service (FFS) patients to a cohort which includes both FFS and Medicare Advantage (MA) patients. All other specifications for the measure would remain the same, including the following:

- The outcome of the measure is unplanned readmissions for any cause within 30 days of the discharge date for the index admission.
- Inclusion of admissions for patients at least 65 years of age discharged alive from a non-federal short-term acute care hospital (and not transferred to another acute care facility). The patients would have to be enrolled in FFS (or, as proposed, MA) for the 12 months prior to the date of admission, on the date of the admission, and the 30 days following discharge of the admission.

[75] 84 FR 42465 through 42479.

Pre-Rulemaking. The current Hybrid HWR measure received CBE endorsement on December 9, 2016, and again on September 1, 2020. The modified measure with expanded cohort was resubmitted to the MAP for the 2022-2023 pre-rulemaking cycle and received conditional support, pending CBE endorsement. CMS intends to submit the modified measure for CBE re-endorsement in Spring 2024. CMS proposes to adopt the modified measure, consistent with the exception for non-CBE-endorsed measures under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act.

Data Submission and Reporting. Hospitals would submit data to CMS using QRDA I files, consistent with the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program.

7. Proposed Measure Removals for the Hospital IQR Program Measure Set and Proposed Codification of Measure Removal Factors

CMS proposes to codify the Measure Removal Factors previously adopted and remove the following 3 measures:

- Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (THA/TKA Complication measure) beginning with the April 1, 2025 through March 31, 2028 reporting period/FY 2030 payment determination.
- Medicare Spending Per Beneficiary (MSPB)—Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination.
- Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (PC–01) measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

a. Proposed Removal of Hospital Level RSCR Following Elective Primary THA and/or TKA Measure (THA/TKA Complication Measure)

CMS adopted the original THA/TKA Complication measure into the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule and subsequently adopted the same measure in the Hospital VBP Program. Therefore, in the FY 2019 IPPS/LTCH PPS final rule CMS removed the measure from the Hospital IQR Program based on measure removal factor 8, the cost associated with the measure outweighing the benefit of its continued use. The measure was then revised to include 26 additional mechanical complication ICD-10 codes, and consequently CMS adopted the revised measure with the expanded outcome in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49263 through 49267) beginning with claims data with admission dates from April 1, 2019, through March 31, 2022, with the intention to propose the revised measure for inclusion in the Hospital VBP after the required one-year period of public reporting in the Hospital IQR Program.[76]

CMS proposes to remove the modified measure from the Hospital IQR Program beginning with the April 1, 2025, through March 31, 2028, reporting period associated with the FY 2030 payment determination, contingent on finalizing the adoption of the modified measure under the

[76] Per 42 CFR §412.164(b) measures, before inclusion in the Hospital VBP Program, must be publicly reported in the Hospital IQR Program for 1 year prior to the beginning of the performance period.

Hospital VBP Program (as proposed under V.K.) beginning with the FY 2030 Program Year. The removal is based on measure removal factor 8 as well as to prevent duplicative reporting of the measure in the Hospital IQR Program and Hospital VBP Program.

b. Proposed Removal of Medicare Spending Per Beneficiary (MSPB)—Hospital Measure

CMS adopted the original MSPB Hospital measure into the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule[77] and also in that final rule adopted the same measure in the Hospital VBP Program. Therefore, in the FY 2019 IPPS/LTCH PPS final rule[78] CMS removed the measure from the Hospital IQR Program based on measure removal factor 8, the cost associated with the measure outweighing the benefit of its continued use. The measure was then updated, and consequently CMS adopted the updated measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263), with the intention to propose the updated measure for inclusion in the Hospital VBP after the required one-year period of public reporting in the Hospital IQR Program.[79]

CMS proposes to remove the updated measure (CBE# 2158) from the Hospital IQR Program beginning with the FY 2028 payment determination, contingent on finalizing the adoption of the updated measure under the Hospital VBP Program (as proposed under V.K.) beginning with the FY 2028 program year. The removal is based on measure removal factor 8 as well as to prevent duplicative reporting of the measure in the Hospital IQR Program and Hospital VBP Program.

c. Proposed Removal of Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (PC–01) Measure (Elective Delivery Measure)

CMS adopted the Elective Delivery Measure in the FY 2013 IPPS/LTCH PPS final rule.[80] CMS outlines the many steps taken in the Hospital IQR Program to continue to prioritize maternal health through quality measurement, including the adoption of the Maternal Morbidity Structural Measure beginning with the FY 2023 payment determination[81] and, in the FY 2023 IPPS/LTCH PPS final rule, the adoption of the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM as two of the eCQMs in the Hospital IQR Program measure set,[82] as well as the adoption of the Birthing-Friendly Hospital designation.

CMS proposes to remove the Elective Delivery measure beginning with the 2024 reporting period/FY 2026 payment determination based on measure removal factor 1: Measure performance is so high and unvarying that meaningful distinctions and improvements in

[77] 76 FR 51618 through 51627.
[78] 83 FR 41559 and 41560.
[79] Per 42 CFR §412.164(b) measures, before inclusion in the Hospital VBP Program, must be publicly reported in the Hospital IQR Program for 1 year prior to the beginning of the performance period.
[80] 77 FR 53528 through 53530.
[81] See the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365).
[82] The 2 new eCQMs can be self-selected by hospitals to report for the CY 2023 reporting period/FY 2025 payment determination, with mandatory reporting of these two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination.

performance can no longer be made (i.e., the measure is "topped out").[83] CMS also justifies that the addition of the 2 new eCQMs supports justification for the removal of the topped-out measure.

d. Proposed Codification of Measure Retention and Removal Policies

CMS proposes to codify the existing measure retention and removal[84] policies for the Hospital IQR Program at 42 CFR §412.140(g)(1) through (3).[85]

8. Summary of Previously Finalized and Proposed Hospital IQR Program Measures

CMS provides tables (Table IX.C-01 through Table IX.C-04) showing the Hospital IQR Program measure set for each of the FY 2025 through FY 2028 payment determinations and subsequent years, if the policies as proposed are adopted. 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				
	2025	**2026**	**2027**	**2028**
Chart-Abstracted Process of Care Measures				
Severe sepsis and septic shock: management bundle (NQF #500)	X	X	X	X
PC-01 Elective delivery < 39 weeks gestation (CBE#0469)	X	*Proposed Removal*		
Electronic Clinical Quality Measures				
AMI-8a Primary PCI w/in 90 minutes arrival CAC-3 Home Mgmt Plan Document to Caregiver	Report 4 calendar quarters of data for Safe Use of	Report 4 calendar quarters of data for Safe Use of	Report 4 calendar quarters of data for Safe Use of	Report 4 calendar quarters of data for Safe Use of Opioids AND

[83] See Table IX.C. in the proposed rule showing PC-01 data from reporting hospitals for Q1 2016 through Q4 2021.
[84] The following current measure Removal Factors for the Hospital IQR Program are also applied in the HVBP program and proposed in section V.K.2.b to be codified under that program as well:
(1) Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made ("topped out" measures).
(2) Measure does not align with current clinical guidelines or practice.
(3) Measure can be replaced by a more broadly applicable measure (across setting or populations) or a measure that is more proximal in time to desired patient outcomes for the particular topic.
(4) Measure performance or improvement does not result in better patient outcomes.
(5) Measure can be replaced by a measure more strongly associated with desired patient outcomes for the particular topic.
(6) Measure collection or public reporting leads to negative intended consequences other than patient harm;
(7) Measure is not feasible to implement as specified.
(8) The costs associated with a measure outweigh the benefit of its continued use in the program.
[85] The measure retention policy (see 77 FR 53512 and 53513) is that once a measure is adopted into the Hospital IQR Program beginning with a payment determination, the measure is automatically retained for subsequent payment determinations, unless CMS proposes to remove, suspend, or replace the measure

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting				
	2025	**2026**	**2027**	**2028**
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-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) HH-01 Hospital Harm-Severe Hypoglycemia (NQF #3503e) HH-02 Hospital Harm-Severe Hyperglycemia (NQF #3533e) Hospital Harm Opioid Related Adverse Events HH-ORAE ePC-02 Cesarean Birth ePC-07/SMM Sever Obstetric Complications	Opioids and 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	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	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 *HH-PI* *HH-AKI* *ExRad*	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 *HH-PI* *HH-AKI* *ExRad*

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting				
	2025	**2026**	**2027**	**2028**
Global Malnutrition Composite Score GMCS (NQF #3592e) *HH-PI Hospital Harm-Pressure Injury (CBE 3498e)#* *HH-AKI Hospital Harm-Acute Kidney Injury (CBE 3713e)#* *Excessive Radiation Does or Inadequate Image Quality for Diagnostic CT in Adults#*				
National Healthcare Safety Network Measures				
Healthcare Personnel Influenza Vaccination (NQF #0431)	X	X	X	X
Healthcare Personnel COVID-19 Vaccination*	X*	X*	X*	X*
Claims-Based Measures				
Mortality				
Stroke 30-day mortality rate	X	X	X	X
Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA (CBE # 1550)	X	X	X	X
Readmission/Coordination of Care				
Hospital-wide all-cause unplanned readmission (NQF #1789)	X	Removed		
Excess days in acute care after hospitalization for AMI (NQF #2881) Refined	X	X	X	X
Excess days in acute care after hospitalization for HF (NQF #2880)	X	X	X	X
Excess days in acute care after hospitalization for PN (NQF #2882)	X	X	X	X
Claims and Electronic Data Measures (Hybrid)				
Hybrid HWR (all-cause readmission) (CBE #2879)**	V	X	X	X
Hybrid HWM (all-cause mortality) (CBE #3502)***	V	X	X	X

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting				
	2025	**2026**	**2027**	**2028**
Patient Safety				
PSI-04 Death among surgical inpatients with serious, treatable complications (NQF #0351)	X	X	X	X
THA/TKA complications (refined)	X	X	X	X
Claims-Based Efficiency/Payment				
AMI payment per 30-day episode of care (CBE #2431)	X	X	X	X
Heart Failure payment per 30-day episode of care (CBE # 2436)	X	X	X	X
Pneumonia payment per 30-day episode of care (CBE #2579)	X	X	X	X
THA/TKA payment per 30-day episode of care (CBE#3474) Refined	X	X	X	X
MSPB-Hospital (CBE#2158)	X	X	X	*Proposed Removal*
Patient Experience of Care				
HCAHPS survey (NQF #0166) (including care transition measure) (0228)	X	X##	X	X
Patient-Reported Outcome-Based Performance Measure (PRO-PM)				
Hospital-Level THA/TKA PRO-PM (CBE 3559)		V	X	X
Structural Measures				
Maternal Morbidity	X	X	X	X
Hospital Commitment to Health Equity HCHE	X	X	X	X
Process Measures				
SDOH-1 Screening for social Drivers of Health****	V	X	X	X
SDOH-2 Screen Positive Rate for Social Drivers of Health****	V	X	X	X
*Proposed Update beginning for FY 2025 Payment Determination ** In the FY 2020 IPPS/LTCH PPS final rule, CMS finalized removal of the HWR claims-only measure (CBE #1789) and will replace it with the Hybrid HWR measure (CBE #2879), beginning with the FY 2026 payment				

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting				
	2025	2026	2027	2028
determination (84 FR 42465 through 42481). CMS proposes to revise the measures beginning with the FY 2027 payment determination in this proposed rule. *** In the FY 2022 IPPS/LTCH PPS final rule, CMS finalized the adoption of the HWM measure beginning with one voluntary reporting period (July 1, 2022-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023-June 30, 2024 reporting period, impacting the FY 2026 payment determination (86 FR 45365 through 45374). CMS proposes to revise the measures beginning with the FY 2027 payment determination in this proposed rule. **** In the FY 2023 IPPS/LTCH PPS final rule, CMS finalized the adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure with voluntary data collection for the CY 2023 reporting period, and then mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and subsequent years (87 FR 49201 through 49220). # Proposed inclusion beginning with CY 2027 payment determination. ##Including Care Transition Measure (CBE 0228)				

9. Future Considerations

CMS seeks public feedback on the following potential future measures.

a. Potential Future Inclusion of Two Geriatric Care Measures

Background. CMS describes that some of the Hospital IQR Program quality measures may not capture the full spectrum of geriatric care needs and after reviewing various research concludes that a more holistic approach that includes patient-centered care would be beneficial. Therefore, CMS is considering two attestation-based structural measures, the Geriatric Hospital measure and the Geriatric Surgical measure, for the Hospital IQR Program, and **requesting public comment on** the potential future proposal for a hospital designation focused on hospitals that participate in patient-centered geriatric care health system improvement initiatives.

Overview of measures. The measure developer, ACS, designed both structural measures to assess geriatric care across various domains across the care continuum to further patient-centered care for aging populations with multiple chronic conditions. This goal aligns with the Meaningful Measures Framework priority focus on patient-centered care.

Pre-Rulemaking. The 2 measures were included in the 2022 MUC list. During the MAP review, concern was raised about burden in reporting 2 potentially overlapping measures, especially for rural hospitals, and that there is limited evidence that attestation measures improve health outcomes that further health equity. The MAP conditionally supported the Geriatric Hospital Measure pending CBE endorsement, and supported consideration of combining the 2 measures or focusing on 1 measure to reduce burden. The MAP conditionally supported the Geriatric Surgical measure for rulemaking pending CBE endorsement, further reducing elements included in the attestations, and providing further information on the gaps in the measure components.

Geriatric Hospital Structural Measure Specifications and Calculation. The measure assesses hospital commitment to improving outcomes for patients 65 years or older through patient-centered competencies and includes 14 attestation-based questions across eight domains (i.e., 1.

Identifying goals of care, 2. Medication management, 3. Cognition and delirium, 4. Preventing delirium related events, 5. Function and mobility, 6. Social determinants of health, 7. Care transitions, and 8. Ensuring quality care for high-risk patients). Table IX.C–06 of the proposed rule includes the 8 attestation domains and 14 attestation questions.

Hospitals would receive one point for each domain for which the hospital attests to each of the corresponding statements included in the domain (for a total of zero to eight points). The measure would be calculated as follows:

- Numerator. The number of complete domain attestations (i.e., domains for which the hospital attested to each statement within the domain).
- Denominator. The total number of domain attestations (which would be 8 for all hospitals).

Geriatric Surgical Structural Measure Specifications and Calculation. The measure assesses hospital commitment to improving surgical outcomes for patients 65 years or older through patient-centered competencies, and includes 11 attestation-based questions across 7 domains (i.e., identifying goals of care, medication management, cognition and delirium, function and mobility, social determinants of health, care transitions, and ensuring quality care for high-risk patients). A hospital would receive one point for each domain for which the hospital attests to each of the statements included within the domain (for a total of 0 to 7 points). The measure would be calculated as follows:

- Numerator. The number of complete domain attestations, with attestation of each statement within a domain required for "complete domain attestation" of that domain.
- Denominator. The total number of domain attestations (which would be 7 for all hospitals).

b. Potential Establishment of a Publicly Reported Hospital Designation to Capture the Quality and Safety of Patient-Centered Geriatric Care

CMS is considering a geriatric care hospital designation to be publicly reported on a CMS website, which could initially be based on data from hospitals reporting on both Geriatric Hospital and Geriatric Surgical structural measures considered above, if such measures were to be proposed and finalized in the future.

CMS is soliciting comment on the potential future designation, additional measures to consider for incorporation in the designation for future years, and on the following specific questions:

- What are some of the key barriers and challenges faced by rural providers in reporting the attestation measures discussed in section IX.C.9.a. of the proposed rule?
- What are the best practices for hospitals to actively engage with PAC facilities? What barriers do providers (especially rural providers) face in establishing protocols for bi-directional communication?
- What are the best practices that hospitals are implementing to provide education for and conduct outreach to patients in underserved communities to increase access to timely geriatric care?
- Among rural providers, do hospitals face barriers when identifying care goals between patients and providers, establishing protocols for ensuring patients' goals are met, and

documenting the decision-making process? Are there specific barriers to providing education regarding the coordination of care to meet the patient's goals?

- Are there barriers to implementing protocols for delirium and cognition screenings to flag high risk patients among geriatric populations? What challenges do providers face when implementing care management plans for high-risk patients?
- What barriers do hospitals face when implementing multidisciplinary evaluations of older adults? Are there challenges hospitals face with the early utilization of palliative care consultations for older populations with serious illness?
- Are any of the proposed elements of these measures potentially duplicative of existing measures in the Hospital IQR Program?
- How should the potential future hospital designation for geriatric care capture the role of family caregivers in hospital care delivery, care transitions, or discharge planning?

10. Form, Manner, and Timing of Quality Data Submission

CMS reviews technical specifications and procedural and data submission, collection, and reporting requirements, including certification requirements for eCQM reporting for the Hospital IQR Program, the requirement that EHRs be certified to all available eCQMs, the file format for EHR data, the submission deadlines for eCQM data, submission and reporting requirements for hybrid measures, sampling and case thresholds for chart-abstracted measures, and data submission and reporting requirements for CDC NHSN measures, structural measures, and PRO-PMs. No changes are proposed to these policies, except for the HCAHPS survey measure data submission and reporting requirements described below.

Proposed Updates to the HCAHPS Survey Measure (CBE #0166) Beginning with the FY 2027 Payment Determination:

The HCAHPS Survey was adopted into the Hospital IQR Program in the CY 2007 OPPS/ASC final rule (71 FR 68202 through 68204) beginning with the FY 2008 payment determination. The measure is the first national, standardized, publicly reported survey of patients' experience of hospital care, and asks a random sample of eligible discharged adult patients (who received medical, surgical, or maternity care between 48 hours and 6 weeks after discharge, and who are not limited to Medicare beneficiaries) 29 questions about their recent hospital stay.

In 2021, CMS conducted a large-scale mode experiment to test adding the web mode (Web-Mail, Web-Phone, and Web-Mail-Phone) to the current 3 modes (Mail Only, Phone Only, and Mail-Phone); test new survey content related to care coordination, discharge experience, communication with patients' families, emotional support, sleep, and summoning help; and to test other updates to the form, manner, and timing of HCAHPS Survey data collection and reporting.

Proposed Addition of 3 New Modes of Survey Implementation. Based on the mode experiment finding that the addition of the 3 modes resulted in increased response rates, CMS proposes to add the new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Phone Only, and Mail-Phone modes, beginning with January 2025 discharges.

Proposed Removal of Prohibition of Proxy Respondents to HCAHPS Survey. Based on the mode experiment finding that excluding proxies did not impact HCAHPS measure scores, CMS proposes to remove the requirement that only the patient may respond to the survey and thus allow a patient's proxy to respond to the survey, beginning with January 2025 discharges.

Proposed Extension of Data Collection Period. Based on the mode experiment finding showing increased rate of completion of the survey, including from patients typically under-represented in HCAHPS, when the data collection period is extended, CMS proposes to extend the period from 42 to 49 days, beginning with January 2025 discharges.

Proposed Limit on Number of Supplemental HCAHPS Survey Items. Based on analysis in the mode experiment that increased supplemental items that may be added to the survey decreased the response rate, CMS proposes to limit the number of supplemental items permitted to be added to the survey to 12 items, which aligns with other CMS CAHPS Surveys. **CMS invites public comment**, including suggestions for alternative limits below 12 supplemental items.

Proposed Requirement to Use Official Spanish Translation for Spanish Language-Preferring Patients. CMS proposes that hospitals be required to collect information about the language that the patient speaks while in the hospital and that the official CMS Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish, beginning with January 2025 discharges. **CMS invites public comment**, including suggestions for additional translations beyond the existing translations in Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic.

Proposed Removal of 2 Administration Methods. CMS proposes to remove, beginning in January 2025, the Active Interactive Voice Response (IVR) survey mode and the Hospitals Administering HCAHPS for Multiple Sites option (which allows a hospital to administer the survey for other hospitals). Neither method is currently used by participating hospitals.

Request for Information on Potential Addition of Patients with a Primary Psychiatric Diagnosis to the HCAHPS Survey Measure. CMS seeks public comment on the potential inclusion in the HCAHPS Survey of patients with a primary psychiatric diagnosis who are admitted to short-term, acute care hospitals, specifically on:[86]

- Whether all patients in the psychiatric service line (that is, MS-DRG codes of 876, 880-887, 894-897) or particular sub-groups thereof should be included in the HCAHPS Survey;
- Whether the current content of the HCAHPS Survey is appropriate for these patients; and
- Whether the current HCAHPS Survey measure implementation procedures might face legal barriers or pose legal risks when applied to patients with primary psychiatric diagnoses.

[86] The HCAHPS Survey measure instrument can be found at https://hcahpsonline.org/en/survey-instruments/.

11. Validation of Hospital IQR Program Data

a. Background

Beginning with validation affecting the FY 2024 payment determination, eCQMs will be incorporated into the existing validation process for chart-abstracted measures such that there would be one pool of up to 200 hospitals selected through random selection and one pool of an additional 200 hospitals selected based on targeting criteria, for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). The targeting criteria are as follows:

- Any hospital with abnormal or conflicting data patterns (such as extremely high or low data patterns for a measure).
- Any hospital with rapidly changing data patterns.[87]
- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed.
- Any hospital that joined the Hospital IQR Program within the previous 3 years and which has not been previously validated.
- Any hospital that has not been randomly selected for validation in any of the previous 3 years.
- Any hospital that passed validation in the previous year but had a two-tailed confidence interval that included 75 percent.
- Any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

b. Proposed Addition to Targeting Criteria for Validation

CMS proposes to modify the targeting criteria for validation of hospitals granted an extraordinary circumstances exception (ECE). Beginning with validations of CY 2024 reporting period data for the FY 2027 payment determination, CMS proposes to add to the targeting criteria described above a criterion for any hospital with a two-tailed confidence interval that is less than 75 percent and which submitted less than 4 quarters of data due to receiving an ECE for one or more quarters.

Hospitals would not fail the validation-related requirements for the APU determination for the payment year for which an ECE provides hospitals with an exception from data reporting or validation requirements. These hospitals could be selected for validation in the following year.[88]

[87] A rapidly changing data pattern is defined as a hospital which improves its quality for one or more measure sets by more than two standard deviations from one year to the next and has a statistically significant difference in improvement.

[88] A hospital is subject to both payment reduction and targeting for validation in the subsequent year if it either: (a) has less than four quarters of data, but does not have an ECE for one or more quarters and does not meet the 75 percent threshold; or (b) has four quarters of data subject to validation and does not meet the 75 percent threshold (77 FR 53539 through 53553).

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

CMS proposes to adopt 4 new measures for the PCHQR Program, including 3 health equity-focused measures (the Facility Commitment to Health Equity measure, the Screening for Social Drivers of Health measure, and the Screen Positive Rate for Social Drivers of Health measure) and a patient preference-focused measure (the Documentation of Goals of Care Discussions Among Cancer Patients measure). CMS proposes under section IX.B. of the preamble modifications of the COVID-19 HCP Vaccination measure in the PCHQR. CMS also proposes to publicly report the Surgical Treatment Complications for Localized Prostate Cancer measure beginning with data from the FY 2025 program year, and proposes modified data submission and reporting requirements for the HCAHPS survey measure beginning with the FY 2027 program year.

If the proposals are adopted, CMS estimates a total information collection burden increase for the 11 PCHs of 188 hours at a cost of $4,088 annually beginning with the FY 2027 program year compared to the currently approved information collection burden estimates.

CMS invites public comment on all of the proposed changes to the PCHQR Program under this section.

1. Background

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 that focus on the care of oncology patients and are paid on a cost basis, subject to a per discharge limit (target amount), rather than through a prospective payment system (PPS). The program requires quality reporting by PCHs and measure data are publicly available but the results have no associated payment consequences.

2. Measure Retention and Removal Factors

CMS does not propose any changes to the measure removal or retention policies.

3. Proposal to Adopt the Facility Commitment to Health Equity Measure Beginning with the FY 2026 Program Year

Background. CMS describes significant and persistent disparities in healthcare outcomes and notes the numerous and diverse demographic and social risk factor variables to be considered during disparities analysis, including gender identity, race, ethnicity, minority groups, religion, geographic location, sexual orientation, and income level. CMS points to studies demonstrating that facility leadership can influence patient outcomes and quality and experience of care, and notes that such leadership can assist in setting goals for assessing progress towards achieving equity goals and ensuring accessibility to high-quality care.

Proposed Measure. CMS proposes to adopt an attestation-based structural measure, the Facility Commitment to Health Equity, to address health equity beginning with the FY 2026 program

year. The measure is consistent with the Hospital IQR Program's adoption of an attestation-based structural measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191-49201).

The measure assesses (and requires PCH attestation on) PCH commitment to health equity across 5 domains (equity in a strategic priority, data collection, data analysis, quality improvement, and leadership engagement). Some of the domains have multiple elements. A point is awarded for each domain to which a PCH attests affirmatively. For a PCH to attest "yes" to a domain and receive credit for that domain, the PCH would evaluate and determine whether it engages in each of the elements that comprise that domain. A complete list of domains and elements are described in Table IX.D.-01 of the proposed rule.

Measure calculation:

- Numerator. Number of domains for which the PCH attests to completing all of the required elements.
- Denominator. Five points (one for each domain available for attestation).

Data Collection, Submission, and Reporting. PCHs would be required to submit information for the measure once annually using a CMS-approved web-based data collection tool available within the HQR System beginning with the 2026 program year.

Pre-rulemaking. The measure was included on the MUC List for December 1, 2022. The MAP provided conditional support for the measure, pending endorsement by CBE, commitment to look at outcomes in the future, more clarity on the measure, and verification of accurate attestation by accountable entities. Concerns raised included that the measure does not evaluate outcomes and may not directly address health inequities at a systemic level.

The measure is not CBE-endorsed, but CMS proposes to adopt the measure under the exception under section 1866(k)(3)(B) of the Act, which allows the Secretary to select non-CBE-endorsed measures when the Secretary is unable to identify a suitable CBE-endorsed measure that is available, feasible, and practical.

4. Proposal to Adopt the Screening for Social Drivers of Health Measure Beginning with Voluntary Reporting in the FY 2026 Program Year and Mandatory Reporting in the FY 2027 Program Year

Background. CMS describes the CMMI Accountable Health Communities (AHC) Model, which extensively tested and assessed the relationship between identifying core health-related social needs (HRSNs) and improving healthcare costs, utilization, and outcomes. The 5 core domains[89] to screen for HRSNs that were applied in the AHC Model are used in the Screening for Social Drivers of Health (SSDOH) Measure and the Screen Positive Rate for Social Drivers of Health Measure (SPRSDOH). Both Social Drivers of Health measures were adopted into the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule.[90]

[89] The 5 domains are described in detail in Table IX.D-02 of the proposed rule.
[90] FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220).

The proposed SSDOH measure (alongside the proposed SPRSDOH measure described in section IX.D.5 of the proposed rule) would be the first measurement of social drivers of health in the PCHQR Program.

Proposed measure. The SSDOH measure assesses the percent of patients admitted to the PCH who are 18 years or older at time of admission and are screened for 5 HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety).

Measure calculation. The measure would be calculated as follows:

- Numerator. Number of patients admitted to the PCH who are screened for all 5 HRSNs.
- Denominator. Number of patients admitted to the PCH.
- Exclusions. Patients younger than 18 years of at the time of admission, patients who opt out of screening, and patients who are unable to complete the screening themselves and without a caregiver available to do so on the patient's behalf.

Data Collection, Submission, and Reporting. PCHs would report on the measure once annually, using a CMS-approved web-based data collection tool available within the HQR System, beginning with voluntary reporting in the FY 2026 program year and followed by required reporting beginning in the FY 2027 program year.

PCHs would have flexibility with selecting the tool to screen for the 5 HRSNs. CMS describes potential sources of data as including electronic clinical data, standardized patient assessments, administrative claims data, and patient-reported data, and encourages PCHs to use digital standardized screening tools.[91]

Pre-Rulemaking. The measure was included on the MUC List. The MAP Review resulted in a recommendation to conditionally support for rulemaking pending testing of the measure's reliability and validity, endorsement by the CBE, additional details on how potential tools map to the individual HRSNs and best practices, identification of resources that may be available to assist patients with HRSNs, and the measure's alignment with data standards. The measure is not CBE-endorsed, but CMS proposes to adopt the measure under the exception under section 1866(k)(3)(B) of the Act.

5. Proposal to Adopt the Screen Positive Rate for Social Drivers of Health Beginning with Voluntary Reporting in the FY 2026 Program Year and Mandatory Reporting in the FY 2027 Program Year

Background. The SPRSDOH measure is a companion measure to the SSDOH measure (proposed in section V.D.3.). Whereas the SSDOH measure enables identification of individuals with HRSNs, the SPRSDOH measure would capture the extent of such needs and estimate the impact of individual-level HRSNs on healthcare utilization. The Hospital IQR Program adopted

[91] CMS references the Social Interventions Research and Evaluation Network (SIREN) website for additional information on resources.

this proposed measure in the FY 2023 IPPS/LTCH PPS final rule.[92] CMS proposes consistent adoption in the PCHQR Program.

Proposed Measure. CMS proposes adding this process measure to enhance standardized data collection for identifying high-risk individuals who could benefit from connection via the PCH to community-based services relevant to their HRSNs. CMS notes that the measure is not intended for comparing PCHs.

The measure would provide information on the percent of patients, 18 or older on the date of admission to the PCH, who were screened for an HRSN, and who screened positive for at least one of the 5 HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety).

Measure calculation.

- Numerator. For each HRSN, the number of patients who screen positive (calculated separately for each of the 5 HRSNs). A patient who screens positive for more than one HRSN would be included in the numerator for each of such HRSNs.
- Denominator. For each HRSN, the number of patients screened.
- Exclusions. Patients younger than 18 years at the time of admission, 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 PCH for screen-positive patients divided by screened patients.

Data Collection, Submission, and Reporting. CMS proposes PCHs would report on the measure once annually, using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System, beginning with voluntary reporting in the FY 2026 program year and followed by required reporting beginning in the FY 2027 program year.

Pre-Rulemaking. The proposed measure was included on the MUC List. The MAP Review resulted in a vote of conditional support for rulemaking, pending endorsement by the CBE, attentiveness to how results are shared for public reporting, and examination of any differences in reported rates by reason of PCHs using different reporting processes. The measure is not CBE-endorsed, but CMS proposes to adopt the measure under the exception under section 1866(k)(3)(B) of the Act.

6. Proposal to Adopt Documentation of Goals of Care Discussions Among Cancer Patients Measure Beginning with the FY 2026 Program Year

Background. Goal of care discussions are discussions between a patient with advanced cancer and the oncology team that are intended to inform future treatment decisions by taking into account the patient's goals of care. The primary oncologist is responsible for ensuring documentation of these discussions.

[92] 87 FR 49215 through 49220.

Proposed Measure. The Documentation of Goals of Care Discussions Among Cancer Patients Measure is a process measure. PCHs would report on an annual basis the percent of cancer patients who died during the reporting period and had their goals of care documented before death.

Measure Calculation.

- Population. The population would be defined using PCH administrative data (non-claims) and discrete documentation in the EHR, and would include patients who:
  - Died at the PCH in the measurement period;
  - Had a diagnosis of cancer; and
  - Had at least 2 eligible contacts (inpatient admissions and hematology or oncology ambulatory visits) at the PCH within the 6 months prior to death.
- Denominator. The number of patients meeting the above criteria in the reporting period.
- Numerator. The number of patients included in the denominator for whom a Goals of Care conversation was documented in a structured field in the medical record. To meet the requirements for inclusion in the numerator, the documentation in the EHR would need to include either of the following:
  - Any documentation in one or more patient goals fields in the EHR; or
  - Documentation that the patient opted not to have a goals of care discussion.
- Calculation of Performance Score. Performance is reported as a percentage determined by calculating (Numerator ÷ Denominator) x 100. A higher score is better.

Data Submission and Reporting. CMS proposes PCHs would submit information for the measure once annually using a CMS-approved web-based data collection tool available within the HQR System, beginning with the FY 2026 program year.

Pre-Rulemaking. The measure was included on the MUC List. The MAP recommended conditional support pending CBE endorsement and testing indicating the measure is reliable and valid. The measure is not CBE-endorsed, but CMS proposes to adopt the measure under the exception under section 1866(k)(3)(B) of the Act.

7. Summary of Previously Adopted and Newly Proposed PCHQR Program Measures for FY 2026 Program Year and Subsequent Years

CMS summarizes the PCHQR program's measure set in table IX.D.-03. The below table shows the adopted measures as well as proposed measures, with corresponding public display start date.

PCHQR Program Measures for FY 2026 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

PCHQR Program Measures for FY 2026 and Subsequent Years	
Measure	**Public Display Start Date**
*NHSN COVID-19 vaccination coverage among health care personnel**	October 2022
NHSN CLABSI (NQF #0139)	October 2022
NHSN CAUTI (NQF #0138)	October 2022
Clinical Process/Oncology Care	
The Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (EOL-Chemo) (NQF #0210)	July 2024 or as soon as feasible thereafter
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (NQF #0215)	July 2024 or as soon as feasible thereafter
Intermediate Clinical Outcomes	
The Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (EOL-3DH) (NQF #0216)	July 2024 or as soon as feasible thereafter
The Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (EOL-ICU) (NQF #0213)	July 2024 or as soon as feasible thereafter
Patient Experience of Care	
HCAHPS (NQF #0166)	2016
*Documentation of Goals of Care Discussions Among Cancer Patients***	*Proposed July 2026 or as soon as feasible thereafter*
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	April 2020
30-Day Unplanned Readmissions for Cancer Patients (NQF # 3188)	October 2023 or as soon as feasible thereafter
Surgical Treatment Complications for Localized Prostate Cancer	July 2024 or as soon as feasible thereafter
Health Equity Measures	
*Facility Commitment to Health Equity***	*Proposed July 2026 or as soon as feasible thereafter*
*Screening for Social Drivers of Health***	*Proposed July 2027 or as soon as feasible thereafter*
*Screen Positive Rate for Social Drivers of Health***	*Proposed July 2027 or as soon as feasible thereafter*
Source: Tables IX.D.-03 and IX.D.-04 of the rule, consolidated and modified by HPA * Indicates proposed update to this previously finalized measure. ** Indicates new measures proposed in the proposed rule.	

8. No changes are proposed to CMS' process for maintenance of technical specifications for PCHQR Program measures.

9. Public Display Requirements

a. Background

Section 1866(k)(4) of the Act requires CMS to establish procedures for making the data submitted under the PCHQR Program available to the public. No changes to the previously finalized public display requirements are proposed.

b. Proposal to Begin Public Display of Surgical Treatment Complications for Localized Prostate Cancer (PCH-37) Measure Beginning with the FY 2025 Program Year

The FY 2020 IPPS/LTCH PPS final rule finalized the inclusion of the PCH-37 measure in the PCHQR measure set beginning with the FY 2022 program year (84 FR 42514 through 42517), and the provision by CMS of confidential report of PCH performance on this measure to individual PCHs. CMS is proposing to publicly display the PCH-specific results for the PCH-37 measure beginning with the FY 2025 program year data in the summer of 2024, which would reflect PCH performance for the July 1, 2021 through June 30, 2022 reporting period.

10. Form, Manner, and Timing of Data Submission

a. Background

Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website.

b. Proposed Updates to the Data Submission and Reporting Requirements for the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (CBE #0166) Beginning with the FY 2027 Program Year

CMS proposes to make similar updates to the form and manner of administration of the HCAHPS Survey measure under the PCHQR Program as are proposed under the Hospital IQR Program under section IX.C.10.h of the proposed rule. Those changes are, beginning with January 2025 discharges:

- Adding 3 new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Telephone Only, and Mail-Phone modes;
- Removing the requirement that only the patient may respond to the survey (allowing a proxy to respond);
- Extending the data collection period for the HCAHPS Survey from 42 to 49 days;
- Limiting the number of supplemental items to 12;
- Requiring hospitals to collect information about the language that the patient speaks while in the hospital and requiring the official CMS Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish; and

- Removing 1 option for administration of the HCAHPS Survey - the Active Interactive Voice Response (IVR) survey mode, which has not been used by any hospital since 2016.

CMS invites public comment on the proposal, specifically for suggestions for alternative limits below 12 supplemental items, and for additional translations beyond the existing translations in Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic.

11. No changes are proposed to the ECE policy[93] under the PCHQR Program.

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

CMS proposes to modify one measure, adopt 2 new measures, and remove 2 existing measures. CMS also seeks information on principles CMS could use to select and prioritize LTCH QRP quality measures in future years, provides an update on efforts to close the health equity gap, proposes to change the LTCH QRP data completion thresholds, and proposes to begin public reporting of 4 measures.

If the proposals are adopted, CMS estimates a total information collection burden decrease for the 330 eligible LTCHs of 1,301 hours for a total cost reduction of $127,048 annually across the FY 2025 and FY 2026 program years compared to the currently approved information collection burden estimates.

CMS invites public comment on all of the proposed changes to the LTCH QRP.

1. Background

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.[94] 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.

For a detailed discussion of consideration used for the selection of quality measures for the LTCH QRP, see FY 2016 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (80 FR 49728), and for a detailed discussion of the factors used for removal of measures, see FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634).

[93] See FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624) for the finalized ECE policy.
[94] Post-acute care providers required to report SPADEs are long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.

Quality measures currently adopted for the FY 2024 LTCH QRP are shown in Table IX.E.-01 of the proposed rule. A summary table of Program measures for FY 2024-2027, if the proposed changes in the rule are adopted, is provided below.

LTCH QRP Measure Set, by Rate (Program) Year				
Measure Title	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
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
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	X	X	X	X
Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431)	X	X	X	X
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	R X	R X	R 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	R X	R X	R X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (NQF #2632)	X	X	X	X
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	X	X
Transfer of Health Information to the Patient – PAC Measure	X	X	X	X
COVID-19 Vaccination Coverage among Healthcare Personnel	X	X*	X*	X*
Discharge Function Score Measure		P	P	P

LTCH QRP Measure Set, by Rate (Program) Year				
Measure Title	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date			P	P
*Proposed modification to measure beginning for FY 2025 program year X shows adopted measures P shows proposed inclusion of a new measure R shows proposed removal of an existing measure				

2. Overview of LTCH QRP Quality Measures Proposals

a. Proposed Modification of the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) Measure Beginning with the FY 2025 LTCH QRP

CMS proposes to modify the COVID-19 Vaccination Coverage among HCP (HCP COVID-19 Vaccine) measure to use the term "up to date" in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID-19 vaccines, including booster doses, beginning with the FY 2025 LTCH QRP. The full proposal can be found in section IX.B. of the proposed rule and IX.B. above.

b. Proposed Discharge Function Score Measure Beginning with the FY 2025 LTCH QRP

Background. Section 1886(m)(5)(F)(i) of the Act requires CMS to develop and implement standardized quality measures from 5 quality measure domains, including the domain of functional status, cognitive function, and changes in function and cognitive function, across the PAC settings, including LTCHs.

The proposed cross-setting Discharge Function Score (DC Function) Measure would include the LTCH population regardless of ventilator status (unlike any other adopted measure in the LTCH QRP). CMS emphasizes the importance of assessing functional status as a health outcome in LTCHs, since the overall goals of LTCH care often include optimizing functional improvement, returning to a previous level of independence, maintaining functional abilities, or avoiding institutionalization; the assessment may provide valuable information in treatment determinations across the continuum of care.

Overview of Measure. CMS is proposing to adopt this assessment-based outcome measure in the LTCH QRP beginning with the FY 2025 LTCH QRP. The measure evaluates functional status by calculating the percentage of LTCH patients who meet or exceed an expected discharge function score. The measure uses standardized patient assessment data from the current LTCH assessment tool, the LCDS, so no provider burden would be added.

The proposed measure would replace the topped-out Application of Functional Assessment/Care Plan cross-setting measure proposed for removal in section IX.E.4.c. of the proposed rule. The DC Function measure uses a set of cross-setting assessment items, which would facilitate data collection, quality measurement, outcome comparison, and interoperable data exchange among

PAC settings, whereas existing functional outcome measures do not use a set of cross-setting assessment items. The DC Function measure considers two dimensions of function (self-care and mobility activities) and accounts for missing data by recoding missing functional status data to the most likely value had the status been assessed (i.e., using statistical imputation). In contrast, the topped-out measure treats patients with missing values the same as patients who were coded to the lowest functional status.

Measure testing. Validity was assessed for the measure performance,[95] the risk adjustment model,[96] face validity, and statistical imputation models.[97]

Pre-Rulemaking. Interested parties expressed support of the measure's reliability, validity, and feasibility. In accordance with the CMS pre-rulemaking process, the DC Function measure was included on the MUC list for December 1, 2022. The MAP recommended conditional support. The measure is not CBE-endorsed, but CMS proposes to adopt the measure under the exception at section 1899B(e)(2)(B) of the Act.[98] CMS intends to submit the proposed measure to CBE for consideration of endorsement when feasible.

Measure Calculation. The measure would be calculated as follows:

- Numerator. The number of LTCH stays with an observed discharge function score that is equal to or greater than the calculated expected discharge function score.
    - Observed discharge function score is the sum of individual function item values at discharge.
    - Calculated expected discharge function score is computed by risk-adjusting (for resident characteristics, such as admission function score, age, and clinical conditions) the observed discharge function score for each LTCH stay.
- Denominator. The total number of SNF stays with an LCDS record in the measure target period (four rolling quarters) that do not meet the measure exclusion criteria.[99]

c. Proposed Removal of the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan) Measure Beginning with the FY 2025 LTCH QRP

Proposed Removal. CMS proposes to remove the Application of Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH QRP. Public reporting of

[95] Validity testing of measure performance tested the strength and directional correlations between the proposed measure's performance for providers with 20 or more stays and the performance of other publicly reported LTCH quality measures. Results indicated that the proposed DC Function measure captures the intended outcome, as detailed in Table IX.E.-02 of the proposed rule.
[96] Validity testing of the risk adjustment model showed the measure model has the predictive ability to distinguish residents with low expected functional capabilities from those with high expected functional capabilities.
[97] Validity testing of the measure's statistical imputation models indicated that the models demonstrate good discrimination and produce more precise and accurate estimates of function scores for items with missing scores when compared to the current imputation approach.
[98] Section 1899B(e)(2)(B) of the Act allows the Secretary to select non-CBE-endorsed measures when the Secretary is unable to identify a suitable CBE-endorsed measure that is available, feasible, and practical.
[99] For additional details regarding the numerator, denominator, risk adjustment, and exclusion criteria, refer to the Discharge Function Score for Long Term Care Hospitals (LTCH) Technical Report. https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.

the measure would end by the September 2024 Care Compare refresh or as soon as technically feasible, when public reporting of the proposed DC Function measure would begin (see section IX.E.9.b. of the proposed rule). Beginning for the FY 2025 LTCH QRP:

- LTCHs would not be required to report a Self-Care Discharge Goal (GG0130, Column 2) or a Mobility Discharge Goal (GG0170, Column 2) beginning with residents admitted on October 1, 2023.
- CMS would remove the items for Self-Care Discharge Goal (GG0130, Column 2) and Mobility Discharge Goal (GG0170, Column 2) with the next release of the LCDS.

Basis for Removal. CMS explains that the proposed removal is based on the measure satisfying 2 of the 8 factors considered for removal of a measure.[100]

- Measure removal factor one: The measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. The average performance rates on the measure over the 3-year period (2019-2021) have been near 100 percent, indicating the measure has "topped out," and the measure no longer provides for any variation that would show distinction among LTCHs.[101]
- Measure removal factor six: There is an available measure that is more strongly associated with desired resident functional outcomes. CMS points to the proposed DC Function measure discussed in section IX.E.4.b. of the proposed rule.

d. Proposed Removal of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan (Functional Assessment/Care Plan) Measure Beginning with the FY 2025 LTCH QRP

Proposed Removal. CMS proposes to remove the Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH QRP. Public reporting of the measure would end by September 2024 or as soon as technically feasible.

Basis for Removal. The proposed removal is based on factor one of the removal factors (i.e., the measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made).[102] The measure reports the percent of LTCH patients with, both at admission and discharge, a functional assessment and a care plan that addresses function. CMS describes that functional assessment and function outcomes in LTCH settings would still be represented in the LTCH QRP through the Functional Outcome

[100] Section 412.560 of title 42, CFR, specifies eight factors considered for measure removal from the LTCH QRP.
[101] The proposed rule states the average performance scores ranged from 99.4 percent to 99.6 percent during CYs 2019-2021; were 99.4 percent for July 1, 2020 through June 30, 2021 (with nearly 70 percent of LTCHs scoring 100 percent); and were 99.4 percent for CY 2021 (with nearly 63 percent of LTCHs scoring 100 percent).
[102] CMS provides that average performance scores rates reached nearly 100 percent over the past three years (ranging from 99.3 percent to 99.5 percent during CYs 2019-2021).

Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.

e. Proposed COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) Measure Beginning with the FY 2026 LTCH QRP

Background. CMS describes how COVID remains a major challenge to PAC facilities, including LTCHs, and emphasizes that older persons are at a significantly higher risk of mortality and severe disease following infection. CMS details that studies have shown COVID vaccines provide strong protection against severe disease, hospitalization, and death in adults. The agency also describes that since the emergence of the Omicron variants and availability of boosters, multiple studies have shown protection is higher among individuals receiving booster doses (specifically the bivalent booster in the case of Omicron subvariants) than among those only receiving the primary series.

CMS also details significant gaps and disparities in vaccination rates between those receiving the primary vaccination series and the boosters. Variations are also present when examining vaccination rates by race, gender, and geographic location.

Proposed Measure. CMS is proposing to adopt the Patient/Resident COVID-19 Vaccine measure for the LTCH QRP beginning with the FY 2026 LTCH QRP. The proposed measure is an assessment-based process measure that reports the percent of stays in which patients in a LTCH are up to date[103] on their COVID-19 vaccinations per the CDC's latest guidance. The measure has no exclusions and is not risk adjusted. CMS explains the measure's potential to:

- Increase the rate of COVID vaccination of patients in LTCHs;
- Support the goal of CMS' Meaningful Measure Initiative 2.0;
- Provide patients and caregivers with information for informed decision-making (since the measure would be reported on Care Compare);
- Allow for educating at discharge from LTCHs patients about vaccination; and
- Promote measure harmonization across quality reporting programs.

Pre-rulemaking. The proposed measure was included on the MUC List for December 1, 2022. The MAP workgroups recognized the importance of patient COVID-19 vaccination, but concerns raised included the evolving vaccine recommendations, the lack of denominator exclusions, and the reporting frequency for the measure. CMS responded that the measure is to promote transparency of data for residents to make informed decisions regarding care and is not intended to be a measure of LTCH action. However, the MAP recommended not adopting the measure, with 3 potential mitigation strategies presented:

- Reconsider exclusions for medical contraindications;
- Complete reliability and validity measure testing; and
- Seek CBE endorsement.

[103] The definition of "up to date" may change based on CDC's latest guidelines and can be found on the CDC webpage, "Stay Up to Date with COVID-19 Vaccines Including Boosters," at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html (updated January 9, 2023).

The measure is not CBE-endorsed, but CMS proposes (despite the MAP recommendation) to adopt the measure under the exception at section 1899B(e)(2)(B) of the Act.[104] CMS proposes the measure adoption explaining (1) exclusions for medical contraindications were not included because they believe raw vaccination rate would be most helpful in resident and family/caregiver decision-making; (2) CMS plans to conduct reliability and validity measure testing once there is enough data; and (3) CMS intends to submit the measure to the CBE when feasible.

Measure calculation and Specifications. The measure would be calculated as follows:

- Numerator: Total number of LTCH stays in the denominator in which patients are up to date with their COVID-19 vaccination (per CDC's latest guidance) during the reporting period.
- Denominator: Total number of LTCH stays discharged during the reporting period.
- Data Source: The LCDS assessment instrument for LTCH patients.

3. Request for Information (RFI): Principles for Selecting and Prioritizing LTCH QRP Quality Measures and Concepts under Consideration for Future Years

In the RFI **CMS solicits public comment on**:

- The set of principles for selecting measures for the LTCH QRP discussed below;
- The identification of measurement gaps in the current LTCH QRP; and
- Measures that are available for immediate use, or that may be adapted or developed for use in the LTCH QRP, to fill such gaps.

CMS states the agency will not be responding to specific comments submitted in response to this RFI in the FY 2024 IPPS/LTCH PPS final rule, but intends to use the comments to inform future policies.

a. Background

CMS describes the established National Quality Strategy (NQS) for supporting a high-value health care system promoting quality outcomes, safety, equity, and accessibility for all individuals. CMS describes the "Universal Foundation"[105] of quality measures as a building-block approach to support these goals by streamlining quality measures across quality programs for adult and pediatric populations. The Universal Foundation is intended to reduce provider burden, identify disparities in care, prioritize development of interoperable digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps.

b. Guiding Principles

CMS identifies guiding principles for inclusion and maintenance of measures in the future LTCH QRP measure set. These principles intend for the measures to be meaningful to beneficiaries and

[104] Section 1899B(e)(2)(B) of the Act allows the Secretary to select non-CBE-endorsed measures when the Secretary is unable to identify a suitable CBE-endorsed measure that is available, feasible, and practical.
[105] Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS – The Universal Foundation. N Engl J Med. 2023 Mar 2; 338:776-779. doi: 10.1056/NEJMp2215539. PMID: 36724323.

caregivers, not impose undue burden on LTCHs, align with PAC program goals, and be readily operationalized. The following 4 objectives are specified as follows:

- Actionability: Measures should focus on structural elements, health care processes, and outcomes of care that have been demonstrated (through clinical evidence or other best practices) to be amenable to improvement and feasible for LTCHs to implement.
- Comprehensiveness and Conciseness: Measures should assess performance of all SNF core services using the smallest number of measures that comprehensively assess the value of care provided in LTCH settings.
- Focus on Provider Response to Payment: LTCH performance measures should neither exacerbate nor induce unwanted responses to the payment system, and as feasible mitigate adverse incentives of the system.
- Compliance with Statutory Requirements: Measures must comply with the governing statutory authorities and CMS' policy to align QRP measures with broader policy initiatives, such as the Meaningful Measures Framework.

c. Gaps in LTCH QRP Measure Set and Potential New Measures

Using the above principles, CMS identified measurement gaps in the domains of cognitive function, behavioral and mental health, patient experience and patient satisfaction, and chronic conditions and pain management.

Cognitive Function. Section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act. CMS identifies that cognitive function and changes in cognitive function are not currently represented in the LTCH QRP. CMS describes that LTCHs currently collect and report to CMS data on cognitive function using the Brief Interview for Mental Status (BIMS) and Confusion Assessment Method (CAM), both of which are incorporated in the LCDS as standardized resident assessment data elements, but neither of which have been developed into quality measures for the LTCH QRP. CMS also identifies Patient-Reported Outcomes Measurement Information Set (PROMIS) Cognitive Function forms and the PROMIS Neuro-Quality of Life (Neuro-QoL) measures as alternative sources of information on cognitive functioning, from which quality measures may be construed.

CMS is requesting comment on:

- The availability of cognitive functioning measures outside of the LTCH QRP that may be available for immediate use in the LTCH QRP, or that may be adapted or developed for use in the LTCH QRP, using instruments such as the BIMS, CAM, PROMIS Cognitive Function forms, and PROMIS Neuro-QoL;
- The feasibility of measuring improvement in cognitive functioning during a LTCH stay;
- The cognitive skills that are more likely to improve during a LTCH stay;
- Conditions for which measures of maintenance (rather than improvement in cognitive functioning) are more practical; and
- The types of intervention that have been demonstrated to assist in improving or maintaining cognitive functioning.

Behavioral and Mental Health. CMS states that information on the availability and appropriateness of behavioral health measures in PAC settings is limited, and the 2021 National

Impact Assessment of CMS Quality Measures Report identified PAC program measurement gaps in behavioral and mental health.

Looking at mental health quality measures used in other quality reporting programs, CMS identifies the Home Health QRP measure, which assesses the extent to which patients have been screened for depression, but notes the measure doesn't assess performance in management of depression and related mental health concerns. CMS also identifies possible instruments that may be adapted in PAC settings to assess management of mental health, including CAHPS Experience of Care and Health Outcomes Survey (ECHO), the PROMIS suite of instruments, the NIH Toolbox for the Assessment of Neurological and Behavioral Health Function, and the Screening, Brief Intervention, and Referral to Treatment (SBIRT) approach developed by SAMHSA.

CMS seeks feedback on:

- Measures and instruments (including those described in the proposed rule and above) that may be directly applied, adapted, or developed for use in the LTCH QRP;
- The degree to which measures have been or will require validation and testing prior to application in the LTCH QRP; and
- The availability of data, the manner in which data could be collected and reported to CMS, and the burden on LTCHs.

Patient Experience and Patient Satisfaction. Patient experience measures focus on how patients experienced aspects of care; patient satisfaction measures focus on if patients' expectations were met. These measures are often reported through instruments that use patient self-reported data, such as the CAHPS surveys, but CAHPS instruments have not been developed for use in LTCHs. CMS has developed the LTCH Experience of Care Survey, which measures certain patient experience, such as goal setting, interaction with staff, respect and privacy, and cleanliness of the facility. CMS also refers to the CoreQ: Short Stay Discharge (CoreQ: SS DC) measure, which is being proposed for adoption in the SNF VBP, as a possibility for adoption in the LTCH QRP as well.

CMS seeks comment on:

- The feasibility and challenges of adapting, for use in the LTCH QRP, existing patient experience and patient satisfaction measures and instruments, such as the LTCH Experience of Care Survey and the CoreQ;
- The extent to which patient experience measures offer LTCHs sufficient information to assist in quality improvement; and
- The challenges of collecting and reporting patient experience and patient satisfaction data.

Chronic Conditions and Pain Management. CMS describes that existing LTCH QRP measures do not directly address aspects of care rendered to populations with chronic conditions (such as chronic kidney disease or cardiovascular disease) nor concisely measure LTCHs' actions for patients' pain management. CMS notes that beginning October 1, 2022, LTCHs began collecting standardized patient assessment data elements, including items that assess pain interference with (1) daily activities, (2) sleep, and (3) participation in therapy.

CMS seeks comments on:

- Measures of chronic condition and pain management for patients that may be used to assess LTCH performance; and
- The feasibility and challenges of measuring and reporting LTCH performance on existing QRP measures, such as Discharge to the Community and Potentially Preventable 30-day post-discharge readmissions, for subgroups of patients defined by type of chronic condition.

d. Solicitation of Comments

CMS specifically solicits comments on the following questions:

- *Principles for selecting and prioritizing QRP measures*: To what extent do you agree with the principles for selecting and prioritizing measures? Are there principles that you believe CMS should eliminate from or add to the measure selection criteria?
- *Measurement Gaps*: CMS requests input on the identified measurement gaps. Specifically, are there gaps in the LTCH QRP measures that have not been identified in this RFI?
- *Suitable Measures for Filling Gaps*: Are there measures that are either currently available for use or that could be adapted or developed for use in the LTCH QRP program to assess performance in the 5 areas identified above or other areas not mentioned in this RFI?
- *Data:* CMS seeks input on data available to develop measures, approaches for data collection, perceived barriers or challenges, and approaches for addressing challenges.

4. Health Equity Update

CMS notes that health inequity, manifested by significant disparities in healthcare outcomes, persists in the United States, particularly for individuals belonging to underserved communities. The agency describes goals outlined in the CMS *Framework for Health Equity 2022-2023* as consistent with Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government."

CMS seeks to advance health equity[106] and whole-person care as one of eight goals comprising the CMS NQS. The NQS identifies potential methods of supporting the advancement of equity, including by: establishing a standardized approach for patient-reported data and stratification; using quality programs and VBPs to address closing equity gaps; and developing equity-focused data collections, regulations, oversight strategies, and quality improvement initiatives.

[106] CMS describes health equity as "the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes."

CMS solicited public comment in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28570 through 28576) on principles for measuring equity and healthcare quality disparities across CMS quality programs and will take comments into account as they continue work in this area. CMS is considering including social determinants of health (SDOH) as part of new LTCH QRP quality measures. SDOH are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. CMS is considering whether health equity measures adopted for other settings, such as hospitals, could be adopted in PAC settings. CMS describes the possibility of specifying a health equity measure using the same SDOH data items as is currently collected as standardized resident assessment data elements under the LTCH. The agency emphasizes the value in aligning SDOH items across all care settings, consistent with the Universal Foundation.

5. Form, Manner, and Timing of Data Submission under the LTCH QRP[107]

a. Proposed Reporting Schedule for LCDS Assessment Data for the Discharge Function Score Measure Beginning with the FY 2025 LTCH QRP

- Beginning with patients admitted or discharged on October 1, 2023, for purposes of the FY 2025 LTCH QRP, LTCHs would be required to report these LCDS assessment data.
- Beginning in 2024, beginning for purposes of the FY 2026 LTCH QRP, LTCHs would be required to submit data for the entire calendar year.
- No new burden since measure is calculated based on currently submitted data.

b. Proposed Reporting Schedule for LCDS Assessment Data for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning with the FY 2026 LTCH QRP

- For the FY 2026 LTCH QRP, LTCHs would be required to submit LCDS data beginning with patients admitted or discharged on October 1, 2024.
- Beginning with the FY 2027 LTCH QRP, LTCHs would be required to submit data for the entire calendar year (i.e., for 2025 in the case of the FY 2027 QRP).
- CMS proposes to add a new item to the discharge item sets to collect data on whether a patient is up to date with the COVID-19 vaccine at time of discharge.

c. Proposed Increase to the LTCH QRP Data Completion Thresholds for LCDS Data Items Beginning with the FY 2026 Payment Determination

- Beginning in 2024, beginning for purposes of the FY 2026 program year, LTCHs would be required to report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on at least 90 percent of the assessments they submit through the CMS-designated submission system.

[107] The current policies for reporting LTCH QRP data can be found at 42 CFR §412.560(b).

6. Policies Regarding Public Display of Measure Data for the LTCH QRP[108]

a. Proposed Public Reporting of the Transfer of Health Information to the Patient Post-Acute Care (TOH-Patient) and Transfer of Health Information to the Provider Post-Acute Care (TOH-Provider) Measures Beginning with the FY 2025 LTCH QRP

CMS proposes to publicly display data for these 2 measures based on 4 rolling quarters, initially using discharges from January 1, 2023, through December 31, 2023, and to begin publicly reporting these measures with the September 2024 refresh of Care Compare, or as soon as technically feasible. CMS would not publicly report an LTCH's performance on a measure if the LTCH had fewer than 20 eligible cases in any four consecutive rolling quarters for the measure.

b. Proposed Public Reporting of the Discharge Function Score (DC Function) Measure Beginning with the FY 2025 LTCH QRP

CMS proposes to publicly display data for the measure based on 4 quarters of data, initially using data collected from January 1, 2023, through December 31, 2023, and to begin publicly displaying data beginning with the September 2024 refresh of Care Compare, or as soon as technically feasible. Provider preview reports would be distributed in June 2024, or as soon as technically feasible. CMS would not publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases in any quarter.

c. Proposed Public Reporting of the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning with the FY 2026 LTCH QRP

CMS proposes to publicly display data for the measure beginning with the September 2025 refresh of Care Compare or as soon as technically feasible, initially using data collected from Q4 of 2024 (October 1, 2024-December 31, 2024). Provider preview reports would be distributed in June 2025 for data collected in Q4 2024, or as soon as technically feasible. Data publicly displayed would be based on one quarter of data and updated quarterly. CMS would not publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases in any quarter.

F. 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.

[108] The Secretary is required under section 1886(m)(5)(E) of the Act to establish procedures to make the LTCH QRP data available to the public after ensuring the LTCHs have an opportunity to review the data.

1. EHR Reporting Periods

a. CY 2025

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 PIP, 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.

CMS proposes that the EHR reporting period in CY 2025 would be a minimum of any continuous 180-day period within CY 2025. CMS is considering a longer EHR reporting period in CY 2026 for eligible hospitals and CAHs to report though no specific proposal is made in this rule. The agency will monitor CEHRT utilization by eligible hospitals and CAHs to determine if a longer EHR reporting period would be feasible.

b. EHR Reporting Period for a Payment Adjustment Year

Paragraphs (2)(vii) and (viii) of 42 CFR 495.4 define the term "EHR reporting period for a payment adjustment year" for eligible hospitals for CYs 2023 and 2024. Generally, reporting periods occur 2 years before the payment adjustment year, unless an eligible hospital is demonstrating meaningful use for the first time, in which case the EHR reporting period occurs 1 year before the payment adjustment year subject to an October 1 deadline for registration and attestation.

Starting with the EHR reporting period in CY 2025, CMS proposes to apply the same reporting period (i.e., 2 years before the payment adjustment year) for all eligible hospitals, including for eligible hospitals that have not successfully demonstrated they are a meaningful EHR user in a prior year. CMS explains that because of technological modifications to the data submission process for the PIP, an October 1 deadline is no longer feasible. **Comment is invited on this proposal**.

CMS proposes to continue its existing policy for CAHs; thus, for CAHs in CY 2025, the EHR reporting period would be any continuous 180-day period within CY 2025 and would apply for the FY 2025 payment adjustment year.

2. Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)

CMS adopted the SAFER Guides measure under the Protect Patient Health Information Objective beginning with the EHR reporting period in CY 2022. Eligible hospitals and CAHs must attest to whether they have conducted an annual self-assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs. Beginning in CY 2022, the attestation of this measure was required, but eligible hospitals and

CAHs were not scored, and an attestation of "yes" or "no" were both acceptable answers without penalty.

CMS proposes to require a "yes" attestation to satisfy this measure; attesting "no" would mean that the eligible hospital or CAH had not met the measure and thus is not a meaningful EHR user for the reporting period, subjecting the facility to a downward payment adjustment. This would first apply for the CY 2024 EHR reporting period.

3. Scoring Methodology for the EHR Reporting Period in 2024

CMS does not propose any changes to the scoring methodology for the EHR reporting period in CY 2024. See Table IX.F.-01 (reproduced below) for the scoring methodology.

TABLE IX.F.-01.: PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN CY 2024

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 must choose one of the three reporting options)
	-AND-		
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following 5 measures: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Electronic Reportable Laboratory Result Reporting AUR Surveillance Reporting	25 points	Required
	Report one of the following 2 measures: Public Health Registry Reporting Clinical Data Registry Reporting	5 points (bonus)	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at the Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the next EHR reporting period. See FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement.

If an exclusion is claimed, Table IX.F.-02 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 e-Prescribing 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.

4. Proposed Changes to Calculation Considerations Related to Counting Unique Patients or Actions

In tables summarizing objectives and measures for the Medicare PIP for the EHR reporting period for previous years, CMS includes a column "calculation considerations related to unique patients or actions." The column indicates whether the measures that count unique patients or actions may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT or must be calculated by reviewing all patient records. It has found that in some cases, the description is not applicable to certain measures (e.g., measures requiring a "Yes/No" response).

CMS proposes to modify the way it refers to calculation considerations related to unique patients or actions for measures or actions for which there is no numerator and denominator, as well as for which unique patients or actions are not counted, to read "N/A (measure is Yes/No)".

The following measures would be affected by the proposal: Query of PDMP measure; HIE Bi-Directional Exchange measure; Enabling Exchange under TEFCA measure; Immunization Registry Reporting measure; Syndromic Surveillance Reporting measure; Electronic Case Reporting measure; Electronic Reportable Laboratory (ELR) Result Reporting measure; Public Health Registry Reporting measure; Clinical Data Registry Reporting measure; Antimicrobial Use and Resistance (AUR) Surveillance measure; Security Risk Analysis measure; and the SAFER Guides measure. **Comment is invited on this proposal.**

5. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2024

Table IX.F.-03. lists the objectives and measures for the Medicare PIP for the EHR reporting period in CY 2024 as revised to reflect the proposals made in the proposed rule. Table IX.F.-04. lists the 2015 Edition certification criteria required to meet the objectives and measures.

CMS also proposes a change to its regulatory text at §495.40 to correct an omission it should have made in the FY 2023 IPPS/LTCH PPS final rule. It neglected to make the associated changes to the demonstration of meaningful use criteria requirements at §495.40(b)(2)(i), which should state that for CY 2024 and subsequent years, an eligible hospital or CAH attesting to CMS would satisfy the required objectives and associated measures for meaningful use as defined by CMS.

6. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare PIP

a. Background

Tables IX.F.-05 and IX.F.-06 of the proposed rule summarize the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare PIP for the 2023 reporting period, the 2024 reporting period, and the 2025 reporting period and subsequent years. The tables show that the Safe Use of Opioids – Concurrent Prescribing measure (NQF #3316e) was finalized as mandatory for reporting beginning with the 2022 reporting period, and the Severe Obstetric Complications eCQM and Cesarean Birth eCQM are mandatory beginning with CY 2024 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 the following three new eCQMs for the Medicare PIP eCQM measure set beginning with the 2025 reporting period, which hospitals may self-select to report:

- Hospital Harm – Pressure Injury eCQM (CBE #3498e).
- Hospital Harm – Acute Kidney Injury eCQM (CBE #3713e).
- Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) eCQM (CBE #3663e).

CMS refers readers to the discussion of these measures for purposes of the Hospital IQR Program in section IX.C.5 (described above). Table IX.F.-07 shows the proposed and previously finalized eCQMs for the 2025 reporting period and subsequent years.

c. Proposed eCQM Reporting and Submission Requirements for the 2025 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 2024 reporting period, CMS modified its previously finalized requirements for eligible hospitals and CAHs; beginning with the 2024 reporting period they must report four calendar quarters of data for each required eCQM: (i) three self-selected eCQMs; (ii) the Safe Use of Opioids-Concurrent Prescribing eCQM; (iii) the Severe Obstetric Complications eCQM; and (iv) the Cesarean Birth eCQM. The total number of eCQMs is six for the 2024 reporting period and subsequent years. CMS reminds stakeholders that the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM are available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the 2023 reporting period, but they are mandatory beginning with the 2024 reporting period and for subsequent years.

If the proposals to adopt the Hospital Harm – Pressure Injury eCQM, the Hospital Harm – Acute Kidney Injury eCQM, and the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient) 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 2025 reporting period and subsequent years. **CMS invites comment on these proposals.**

X. Other Provisions

A. Rural Emergency Hospitals (REHs)

As indicated in section IV. G of this summary, an REH is a new provider type that became eligible to enroll in Medicare on January 1, 2023. By law, REHs do not provide acute care inpatient hospital services but must provide emergency department and observation services and, at their own election, may provide other outpatient hospital services. Only CAHs or rural hospitals (or hospitals treated as rural for IPPS payment purposes) with fewer than 50 beds may convert to REH status.

CMS implemented enrollment requirements for the REH program in the 2023 Outpatient Prospective Payment System Final Rule published on November 23, 2022 (87 FR 71748). On January 26, 2023, CMS released memorandum QSO-23-07-REH (https://www.cms.gov/files/document/qso-23-07-reh.pdf), which provided additional information and guidance regarding REH enrollment. CMS proposes to codify into regulation these additional information requirements already in effect.

CMS is also proposing to revise the definition of a "provider of services or provider" at 42 CFR §488.1 to include REHs as well as add REHs to other applicable provisions of the regulations. CMS proposes to further revise §488.18(d) to specify that if the state agency receives information that an REH has violated the regulatory provisions implementing the Emergency Medical Treatment and Labor Act (EMTALA), the state agency must report the information to CMS promptly.

REHs are also subject to the following requirements that CMS is proposing to codify in regulations. REHs must:

1. Have a plan for initiating services including mandatory provision of emergency department services and observation care;
2. Have a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH;
3. Have a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and
4. Provide CMS with information regarding how the provider intends to use the additional facility payment[109] including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services.

[109] The Medicare statute provides REHs with a monthly facility payment that CMS calculated at $272,866 for CY 2023.

B. Physician Self-Referral Law and Physician-Owned Hospitals

1. Background

Section 1877(i) of the Act prohibits hospitals subject to the rural exception and the whole hospital exception from increasing the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed (referred to as its "baseline number") on specific dates. The Secretary is permitted to provide exceptions to the limits on facility expansion to an "applicable hospital" or "high Medicaid facility."

Some of the statutory provisions regarding expansion of facility capacity apply only to applicable hospitals, not to high Medicaid facilities. For instance, the statute explicitly limits applications for an exception to the expansion limit up to once every 2 years to an applicable hospital. Further, the statute only explicitly requires CMS to provide an opportunity for public input on the exception from applicable hospitals. However, CMS extended these provisions to high Medicaid facilities under its regulatory authority, citing program integrity concerns and the desirability of having a uniform set of requirements apply to both facility types. If granted an exception, CMS' regulations, as finalized in 2012, limited the increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital or high Medicaid facility is licensed to the extent such increase does not exceed 200 percent of its baseline number. By regulation, the increases may only occur on the hospital's main campus.

In the CY 2021 OPPS/ASC rulemaking cycle, CMS reconsidered these policies as applied to high Medicaid facilities as part of the Patients over Paperwork initiative, and, citing burden, the final rule removed a number of these restrictions on expansion requests for these facilities. Thus, as of January 1, 2021, a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years; may request to expand its facility capacity beyond 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and, if its request is granted, is not restricted to locating approved expansion facility capacity on the hospital's main campus.

2. Proposed Reinstatement of Program Integrity Restrictions on Approved Facility Expansion

CMS is confident that its 2012 regulations were both a permissible and an appropriate use of the agency's authority in treating high Medicaid facilities in the same manner as applicable hospitals are treated under the statute. Noting that the purpose 2021 final rule on this issue was to eliminate burden by streamlining regulations, CMS has reevaluated those 2021 regulatory changes to consider whether they pose a risk of program or patient abuse that the physician self-referral law was designed to prevent. It concludes that the elimination of those 2012 regulatory restrictions on high Medicaid facilities does in fact pose a significant risk of program or patient abuse (such as overutilization, patient steering, cherry-picking, and lemon-dropping) that overrides the burden concerns expressed as the rationale for the changes made in the 2021 rulemaking cycle.

CMS proposes, effective October 1, 2023, to reinstate the program integrity restrictions regarding the frequency of expansion exception requests, maximum aggregate expansion of a

hospital, and location of expansion facility capacity as they apply to high Medicaid facilities. Thus, the same program integrity restrictions would once again apply to both applicable hospitals and high Medicaid facilities. Under the proposal, the reinstated program integrity restrictions would not apply to an expansion exception request submitted by a high Medicaid facility between January 1, 2021 and the effective date of the revised regulations if the proposals are finalized, which CMS anticipates being October 1, 2023. CMS also clarifies that no changes are proposed for program integrity restrictions for applicable hospitals.

CMS notes that nothing in the physician self-referral regulations or its proposals would affect a hospital's ability to relocate some or all of the "original" operating rooms, procedure rooms, or beds that are part of its baseline facility capacity. See the relevant FAQ at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf, which CMS notes has not changed.

3. Proposed Revisions to the Process for Requesting an Exception from the Prohibition on Expansion of Facility Capacity

CMS conducted a review of the process by which applicable hospitals and high Medicaid facilities may apply for an exception. It proposes a number of changes to the existing regulations that implement the statutory requirement for that process, including adding a new §411.363, which would contain provisions relevant to the process. CMS would clarify a number of issues and make changes to certain requirements for an application for an expansion exception request.

a. Eligibility

CMS would clarify that the applicant must first demonstrate it meets the criteria for an applicable hospital or high Medicaid facility and that, notwithstanding the fact that those criteria are met, CMS still has the discretion to approve or deny the application.

b. Decisions to Approve or Deny an Application

CMS would be able to approve or deny an application for an expansion request based on information submitted and factors considered, including community input, publicly available data and information, information provided by interested parties, and information from government agencies and from CMS law enforcement partners. CMS would always consider the following factors in making decisions on applications and could also consider other factors:

- The specialty (e.g., maternity, psychiatric, or substance use disorder care) of the hospital or the services furnished by, or to be furnished by, the hospital if CMS approves the request;
- Program integrity or quality of care concerns related to the hospital;
- Whether the hospital needs additional operating rooms, procedure rooms, or beds; and
- Whether there is a need for additional operating rooms, procedure rooms, or beds in
    - the county in which the main campus of the hospital is located,
    - any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request, or

- any county in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request.

CMS notes that the statute waives administrative or judicial review of its decision to approve or deny an expansion exception application; CMS proposes to expand on this to specify that this waiver applies to any determination or decision under the process.

An application would be denied if the hospital's or facility's capacity was already expanded to 200 percent of its baseline facility capacity under a previous application or if it has been less than two years since a previous expansion application.

c. Required Information

CMS proposes to expand and clarify existing requirements for information included in an application. First, it would expand to requirement to provide the name of the county where the main campus of the hospital is located to also include the names of any counties in which the hospital provides inpatient or outpatient hospital services or plans to provide inpatient or outpatient hospital services if CMS approves the request. The currently required nondiscrimination statement[110] would be expanded such that the hospital would have to show how it meets the nondiscrimination requirement and provide supporting information if available.

CMS also proposes to require information on whether and how the hospital has used any previously-approved expansion facility capacity and whether it plans to use expansion facility capacity to provide specialty services if the request is approved. An application would also have to describe the hospital's need for additional operating rooms, procedure rooms, or beds. CMS believes that any expansion should be used, at least in part, to address the needs of Medicaid beneficiaries and other underserved populations in the community.

All expansion requests would be submitted electronically, and they should provide an email address as well as a hardcopy mailing address for the contact person for the hospital.

d. Community Input

CMS proposes to define "community" to include the geographic area served by the hospital (as defined at §411.357(e)(2)) and the counties in which (i) the requesting hospital's main campus is located, (ii) the requesting hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request, and (iii) the requesting hospital plans to provide inpatient or outpatient hospital services if CMS approves the request. CMS would also clarify that community input applies to any matter under the process, including whether the hospital qualifies as an eligible applicant and the factors that CMS will consider in deciding whether to approve or deny an application.

[110] Currently, the application must include a statement that the hospital or facility does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

CMS also proposes to double the length of the period for community input from 30 to 60 days. It would retain the 30-day period for the hospital's rebuttal statement.

e. Permissible Data Sources.

Under the proposal, only data from HCRIS would be used for all expansion requests. Starting on the effective date of the final rule, CMS would eliminate the use of external data sources under the expansion exception process. CMS makes this proposal even though it is not fully in alignment with statutory requirements. For facilities that are provider-based to a hospital and located in a different county, CMS proposes to consider the location of a hospital to be the county or State, as applicable, in which the main campus of the hospital is located; this would apply to the requesting hospital and any hospital to which the requesting hospital must compare itself.

f. Timing of Complete Request

CMS proposes to reduce the period after which it deems an application to be complete from no later than 180 days to no later than 90 days. Thus, as proposed, an application would be deemed to be complete no later than 90 days after (i) the end
of the proposed 60-day comment period if CMS does not receive written comments from the community; or (ii) after the end of the 30-day rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement, if CMS receives written comments from the community. This is because CMS proposes to only use data from HCRIS to evaluate the eligibility of a hospital or facility to apply for an exception.

CMS also proposes a number of technical and grammatical revisions to existing regulations at §411.362.

C. Technical Corrections

A November, 16, 2020 final rule entitled "Regulatory Clean-up Initiative" (85 FR 72899) made a technical correction to 42 CFR 411.353(d) to reflect an updated cross-reference to the definition of "timely basis" at 42 CFR 1003.110. Slightly more than two weeks later, CMS published a final rule entitled "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" (85 FR 77492) which reverted to the prior regulatory text and made other typographical errors. CMS proposes to correct those errors.

D. Safety Net Request for Information (RFI)

1. Background

Consistent with Executive Orders 13985 and 14091, CMS has made advancing health equity the first pillar in its Strategic Plan. CMS defines 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, and other factors that affect access to care and health outcomes.

Among the goals of CMS' health equity pillar is to evaluate policies to determine how CMS can support safety-net providers, partner with providers in underserved communities, and ensure care is accessible to those who need it. The term "safety net provider" is commonly used to refer to health care providers that furnish a substantial share of services to uninsured and low-income patients.

While there are provisions of statute that are intended to support safety net hospitals (such as Medicare DSH and UCP, SCHs and others), CMS evaluates two potential alternatives that it believes may better target payments to these hospitals that serve vulnerable communities than the current policies

2. Safety Net Index (SNI)

MedPAC has developed the SNI calculated as the sum of: (1) the share of the hospital's Medicare volume associated with low-income beneficiaries; (2) the share of its revenue spent on uncompensated care; and (3) an indicator of how dependent the hospital is on Medicare. CMS reviews in detail how the SNI would be calculated and indicates that, when calculating the SNI, the following circumstances may be encountered: new hospitals (for example, hospitals that begin participation in Medicare program after the available audited cost report data), hospital mergers, hospitals with multiple cost reports and/or cost reporting periods that are shorter or longer than 365 days, cost reporting periods that span fiscal years, and potentially aberrant data.

CMS is soliciting comments on how MedPAC's SNI calculation should address these circumstances and whether the approaches CMS uses for addressing these same issues with the uncompensated care payment methodology might be appropriate. It is also soliciting comments on whether a multi-year approach using the three most recently available years of data may be appropriate to increase the stability of the index, similar to the approach used in the uncompensated care payment methodology.

3. Area-level Indices

Another approach CMS evaluates could be to identify safety-net hospitals using area-level indices such as the area deprivation index (ADI). The ADI was developed by researchers at the National Institutes of Health as a composite measure of 17 input variables from census data intending to capture local socioeconomic factors correlated with medical disparities and underservice. Medicare already uses ADI to assess underserved beneficiary populations in the Shared Savings Program.

4. Request for Information

CMS is requesting information on potential approaches to help safety-net hospitals by asking for responses to 23 specific questions.

E. Disclosures of Ownership and Additional Disclosable Parties Information

Under the authority of section 6101 of the Affordable Care Act, CMS requires disclosure of certain ownership, managerial and other information regarding Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities (NFs). In a *Federal Register* notice published on February 15, 2023 (88 FR 9820), CMS proposed a definition of "private equity company" (PEC) and "real estate investment trust" (REIT) for purposes of ownership disclosure on the CMS-855A Medicare enrollment form.

The proposed rule indicates that these types of ownership arrangements are associated with declining nursing home quality. CMS does not believe these quality issues are limited to SNFs and NFs. Rather, these quality issues could be associated with other providers and suppliers that also enroll using the CMS 855-A. Under the authority of sections 1866(j), 1102 and 1871 of the Act,[111] CMS is proposing that all providers and suppliers that enroll in Medicare using the CMS-855A enrollment form disclose PEC and REIT ownership information. CMS further requests comments on whether the definitions of PEC and REIT should be modified from the definition that applies to SNFs and NFs for other provider or supplier types.

XI. Medicare Payment Advisory Commission (MedPAC) Recommendations

In its March 2023 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law plus 1 percent. CMS responded it does not have the authority to implement MedPAC's recommendation. Consistent with the statute, CMS is required to propose an applicable percentage increase for FY 2024 of 2.8 percent (before the application of required budget neutrality adjustments) provided the hospital submits quality data and is a meaningful EHR without the additional 1 percent adjustment being recommended by MedPAC.

[111] 1866(j) provides the authority regarding enrollment of provider and suppliers while section 1102 and 1871 provide general authority to CMS to administer the Medicare program.

TABLE I.—FY 2024 Proposed Rule Operating Impacts

	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 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]	All Proposed FY 2024 Changes (7)[8]
All Hospitals	3,130	2.8	0.0	0.0	0.0	0.0	0.4	2.8
By Geographic Location:								
Urban hospitals	2,414	2.8	0.0	0.0	-0.2	0.0	0.4	2.8
Rural hospitals	716	2.7	0.1	-0.3	2.2	-0.5	0.1	3.3
Bed Size (Urban):								
0-99 beds	648	2.7	-0.1	-0.2	-0.9	0.3	0.6	2.5
100-199 beds	693	2.8	0.1	0.0	-0.4	0.4	0.4	2.9
200-299 beds	415	2.8	0.1	0.0	0.0	0.3	0.5	3.1
300-499 beds	405	2.8	0.0	0.0	0.2	0.5	0.3	3.4
500 or more beds	251	2.7	-0.1	0.0	-0.4	-0.5	0.4	2.3
Bed Size (Rural):								0.0
0-49 beds	362	2.6	0.0	-0.1	1.3	-0.4	0.2	2.9
50-99 beds	190	2.7	0.2	0.0	1.8	-0.4	0.2	3.6
100-149 beds	86	2.7	0.2	-0.2	2.3	-0.4	0.1	3.6
150-199 beds	45	2.8	0.2	-0.5	2.1	-0.6	0.0	3.1
200 or more beds	33	2.8	0.0	-0.7	3.2	-0.7	0.2	3.3
Urban by Region:								
New England	108	2.8	0.0	-0.4	0.7	-0.6	0.9	-0.2
Middle Atlantic	292	2.8	0.1	1.0	0.5	-0.1	1.0	4.5
East North Central	372	2.8	0.0	-0.5	-0.4	-0.7	0.1	1.7
West North Central	156	2.8	-0.1	-0.3	-0.6	-0.7	0.6	1.5
South Atlantic	403	2.8	0.0	-0.1	-0.8	-0.8	0.4	1.9
East South Central	138	2.8	0.0	0.0	-0.7	-0.7	0.1	2.5
West South Central	359	2.8	0.0	-0.1	-0.9	-0.7	0.1	1.9
Mountain	176	2.8	-0.1	-0.3	-0.8	-0.6	0.4	0.1
Pacific	360	2.7	0.0	0.1	0.8	3.2	0.1	6.4
Puerto Rico	50	2.7	0.2	-1.9	-1.6	-0.1	0.1	2.2
Rural by Region:								
New England	19	2.8	0.0	-1.2	0.9	-0.6	0.2	1.9
Middle Atlantic	47	2.8	0.0	-0.2	6.4	-0.7	0.0	7.0
East North Central	113	2.8	0.0	-0.3	1.4	-0.4	0.0	2.8
West North Central	85	2.7	0.1	-0.1	0.5	-0.2	0.3	2.9
South Atlantic	107	2.7	0.3	0.2	2.2	-0.6	0.1	3.1
East South Central	140	2.7	0.2	-0.8	2.6	-0.7	0.0	3.2
West South Central	135	2.7	0.1	-0.1	2.6	-0.6	0.0	3.1
Mountain	46	2.4	0.0	0.0	0.1	-0.1	0.8	2.2
Pacific	24	2.8	0.3	-0.2	3.8	-0.4	0.0	5.1
By Payment Classification:								
Urban hospitals	1,811	2.8	0.0	0.0	-1.0	0.5	0.6	3.2

	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 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]	All Proposed FY 2024 Changes (7)[8]
Rural areas	1,319	2.8	0.0	0.0	1.0	-0.5	0.2	2.4
Teaching Status:								
Nonteaching	1,903	2.8	0.0	-0.1	0.1	0.5	0.3	3.2
Fewer than 100 residents	949	2.8	0.0	0.0	0.1	0.0	0.5	2.9
100 or more residents	278	2.7	0.0	0.1	-0.2	-0.3	0.4	2.5
Urban DSH:								
Non-DSH	365	2.8	-0.2	0.1	-1.0	-0.5	0.9	2.3
100 or more beds	1,093	2.8	0.1	0.0	-1.0	0.6	0.6	3.4
Less than 100 beds	353	2.8	0.1	0.0	-0.9	0.7	0.5	2.8
Rural DSH:								
Non-DSH	110	2.7	-0.2	0.1	0.6	-0.8	0.2	1.2
SCH	257	2.7	0.2	0.0	0.3	-0.1	0.0	3.1
RRC	709	2.8	0.0	-0.1	1.0	-0.5	0.2	2.5
100 or more beds	32	2.7	-0.1	0.5	0.0	-0.7	0.1	2.4
Less than 100 beds	211	2.7	0.1	-0.1	2.4	-0.7	0.2	3.6
Urban teaching and DSH:								
Both teaching and DSH	639	2.8	0.1	0.0	-1.0	0.3	0.7	3.1
Teaching and no DSH	61	2.8	-0.3	0.5	-1.0	-0.5	1.0	2.8
No teaching and DSH	807	2.8	0.1	0.0	-0.9	1.4	0.3	3.9
No teaching and no DSH	304	2.8	-0.2	-0.2	-1.0	-0.5	0.7	1.9
Special Hospital Types:								
RRC	127	2.8	0.0	-0.6	2.7	-0.6	0.3	3.1
RRC with Section 401 Rural Reclassification	492	2.8	-0.1	0.0	0.9	-0.6	0.2	2.3
SCH	256	2.7	0.1	0.0	0.4	-0.1	0.1	3.0
SCH with Section 401 Rural Reclassification	45	2.8	0.2	0.0	0.1	0.0	0.0	3.1
SCH and RRC	121	2.7	0.2	-0.2	1.1	-0.3	0.1	3.2
SCH and RRC with Section 401 Rural Reclassification	41	2.8	-0.1	0.0	0.1	0.1	0.0	2.7
MDH	115	2.7	0.0	-0.2	1.7	-0.5	0.5	3.5
MDH with Section 401 Reclassification	30	2.8	0.2	-0.2	0.6	-0.3	0.0	3.3
MDH and RRC	20	2.8	0.2	-0.1	0.9	-0.3	0.1	3.0
MDH and RRC with Section 401 Reclassification	12	2.8	0.2	0.0	0.6	0.0	0.1	3.0
Type of Ownership:								
Voluntary	1,921	2.8	0.0	0.1	0.1	-0.1	0.5	2.8
Proprietary	777	2.8	0.1	-0.3	-0.3	0.6	0.2	2.8
Government	431	2.7	0.1	0.0	-0.4	0.1	0.1	3.0
Medicare Utilization as a Percent of Inpatient Days:								
0-25	994	2.7	0.1	0.1	-0.6	0.4	0.2	3.2
25-50	1,946	2.8	0.0	-0.1	0.3	-0.2	0.5	2.6
50-65	138	2.7	0.0	0.1	-0.1	1.0	0.6	3.5
Over 65	25	2.5	0.1	0.3	1.0	-0.2	0.0	3.8

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Medicaid Utilization as a Percent of Inpatient Days:								
0-25	2,065	2.8	-0.1	-0.1	0.0	-0.3	0.4	2.5
25-50	947	2.8	0.1	0.1	-0.1	0.3	0.4	3.2
50-65	86	2.6	0.6	0.6	-0.8	3.1	0.1	6.4
Over 65	32	2.6	0.9	0.4	-1.3	4.8	0.0	8.8
FY 2024 Reclassifications:								
All Reclassified Hospitals	1,134	2.8	0.0	0.0	0.9	-0.3	0.2	2.5
Non-Reclassified Hospitals	1,996	2.8	0.0	0.0	-1.1	0.4	0.6	3.2
Urban Hospitals Reclassified	939	2.8	0.0	0.0	0.9	-0.3	0.2	2.5
Urban Non-Reclassified Hospitals	1,490	2.8	0.0	0.0	-1.5	0.5	0.7	3.1
Rural Hospitals Reclassified Full Year	304	2.8	0.2	-0.3	2.7	-0.5	0.0	3.3
Rural Non-Reclassified Hospitals Full Year	397	2.6	0.1	-0.3	1.1	-0.4	0.3	3.5
All Section 401 Rural Reclassified Hospitals	660	2.8	0.0	0.0	0.8	-0.5	0.2	2.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	2.7	0.1	-0.4	4.1	-0.7	0.2	3.7

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2022, 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, including the proposed 2.8 percent update to the national standardized amount and the hospital-specific rate (the proposed 3.0 percent market basket update reduced by 0.2 percentage point for the proposed productivity adjustment).

[3] This column displays the payment impact of the proposed changes to the Version 41 GROUPER, the proposed changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2022 MedPAR data as the best available data, and the permanent 10-percent cap where the relative weight for a MS-DRG would decrease by more than ten percent in a given fiscal year. This column displays the application of the proposed recalibration budget neutrality factors of 1.001376 and 0.999925.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2020 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. The proposed wage budget neutrality factor is 1.000943.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2024 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2024. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the proposed geographic budget neutrality factor of 0.980959.

[6] This column displays the effects of the proposed rural floor and the proposed change to the rural wage index methodology. 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 0.981145.

[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 shows the estimated change in total payments from FY 2023 to FY 2024 (inclusive of the update and policy changes but exclusive of changes in utilization and case mix.