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

On August 1, 2023, the Centers for Medicare & Medicaid Services (CMS) released its final 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 final rule will be published in the *Federal Register* on August 28, 2023.

The payment rates and policies described in the IPPS/LTCH final rule (CMS-1785-F) 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 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 also finalizing a policy it made in a separate proposed rule regarding how the Medicare disproportionate share (DSH) adjustment is determined. The change relates to the counting of days associated with individuals eligible for certain Medicaid benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage.

The final rule also includes an addition to its payment impacts as part of CMS' initiative to advance health equity. The payment impacts will show average payment per case and changes in estimated average payment per case relative to other providers according to certain beneficiary characteristics (e.g., race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low-income subsidy (LIS) enrollment, etc.)

CMS makes many data files available to support analysis of the final rule. These data files are generally available at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-final-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 final rule will increase FY 2024 combined operating and capital payments to approximately 3,131 acute care hospitals by an estimated $2.2 billion. CMS indicates that this net impact results from a combined $2.6 billion increase in FY 2024 operating payments, including uncompensated care payments and capital payments, and a decrease of $0.364 billion from changes in new technology add-on payments.

Elsewhere in the rule, CMS reports that uncompensated care/supplemental payments are decreasing by $0.943 billion. That suggests that operating and capital payments are increasing $3.5 billion with reductions due to uncompensated care/supplemental payments of $0.943 billion and $0.364 billion for new technology add-on payments to approximate the $2.2 billion reported by CMS.

A. Inpatient Hospital Operating Update

The above are changes to IPPS payments. The estimated percentage increase in IPPS *payment per service* is estimated at 3.1 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 3.1 percent rate increase is the net result of a market basket update of 3.3 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 Medicare Dependent Hospitals (MDH) are paid.

Factor	Percent Change
FY 2024 Market Basket	3.3%
Total Factor Productivity	-0.2
Net increase before application of budget neutrality factors	3.1%

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 hospitals 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	3.3%	3.1%	-0.825	2.275%	65
No EHR	75% of the MB	3.3%	3.1%	-2.475	0.625%	110
No IQR/EHR	100% of the MB	3.3%	3.1%	-3.3	-0.20%	31

B. Payment Impacts

The final rule includes an addition to its payment impacts as part of CMS' initiative to advance health equity. The payment impacts will show average payment per case and changes in estimated average payment per case relative to other providers according to beneficiary characteristics. The specific beneficiary characteristics shown are: race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low income subsidy (LIS) enrollment, a joint indicator for dual or LIS enrollment, presence of an ICD-10-CM Z code indicating a "social determinant of health" (SDOH), presence of a behavioral health diagnosis code, receiving ESRD Medicare coverage, qualifying for Medicare due to disability, living in a rural area, and living in an area with an area deprivation index (ADI) greater than or equal to 85.

CMS' impact table for IPPS operating costs shows FY 2024 payments increasing 3.1 percent. Not all policy changes are reflected in this total. For example, the total does not include estimated changes in uncompensated care payments and new technology add-on payments. 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	3.1%
Outliers	-0.3[1]
Residual	-0.3[2]
Total	3.1%

[1] CMS targets 5.1 percent of IPPS payments as outliers but estimates that it will pay 5.4 percentage of IPPS payments as outliers in FY 2023. As a result, CMS estimates total payments will decline by 0.3 percentage points for FY 2024.

[2] CMS indicates that there are also "interactive effects among the various factors…which may contribute to…the changes in payments per discharge from FY 2023 and FY 2024" that CMS cannot identify. Typically, this residual is 0.1 percentage point or less. HPA has asked CMS if it can explain what other factors (perhaps non-budget neutral wage index changes) would explain a portion of this residual.

Table I Impact Analysis

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

Hospital Type	All Proposed Rule Changes
All Hospitals	3.1%
Urban	3.1%
Rural	3.5%
Major Teaching	2.6%

To the extent the impact on a given hospital category deviates from the national average of 3.1 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.

CMS provides more detail on some provisions included the payment impact table:

Rural Floor. The proposed rural floor raises the wage index of 646 urban hospitals. CMS calculates a national rural floor budget neutrality adjustment factor of 0.978183 (-2.18 percent) applied to hospital wage indexes. All impacts are relative to the rural floor not being applied. CMS projects that rural hospitals in the aggregate will experience a 0.6 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. Urban hospitals in the Pacific region can expect a 2.7 percent increase in payments primarily due to the application of the rural floor in California.

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 65 hospitals by $230 million in Connecticut, Delaware, Washington, DC, New Jersey and Rhode Island.

Frontier Wage Index and Outmigration. Frontier states are those with a population density of less than 6 persons per square mile. The statute sets a floor of 1.0 on the wage index for hospitals in frontier states. The frontier wage index increases payments about $60 million to 42 hospitals in Montana, North Dakota, South Dakota and Wyoming.

The Medicare statute provides for an increase in the wage index for hospitals that are not geographically reclassified and are located in a county where a high proportion of the hospital

employees live in that county but commute to hospitals located in adjacent areas with a higher wage index. The outmigration adjustment increases payments about $52 million to 173 hospitals.

New Technology Add-on Payment (NTAP). NTAP payments are special payments made to applicants for additional payments for technologies that are new, costly and a substantial clinical improvement. These additional payments are not subject to budget neutrality. CMS will be continuing NTAP payments for 11 technologies that remain eligible in FY 2024. CMS estimates that these 11 technologies will receive $131 million in NTAP payments in FY 2024.

CMS received another 54 applications for NTAP for FY 2024. Of these 54 applications, 26 were withdrawn, 3 missed the July 1 deadline for FDA approval, 3 were rejected and 4 were treated as 2 applications as the technologies are substantially similar to each other. Of the remaining 20 applications, CMS approved 12 under the alternative pathways that only require CMS to evaluate whether the technology meets cost criterion (not the substantial clinical improvement or the substantial similarity criteria). Total NTAP spending for these 12 technologies is estimated at $305.2 million. CMS is approving the remaining 8 applications under the traditional pathway. NTAP costs for these technologies is estimated at $59.2 million.

Total NTAP spending is estimated at $495.49 million for FY 2024 or about $364 million less than CMS estimates will be its expenditures for NTAP in FY 2023.

Section 1115 Waiver Days in the Medicare DSH Calculation. CMS is finalizing a proposal from a separate proposed rule regarding how section 1115 waiver days are counted in the Medicaid fraction of the Medicare disproportionate patient percentage. CMS indicates that it does not have data that distinguishes section 1115 demonstration days separately from other types of days to analyze the potential payment impact of this policy. CMS used alternative data to provide a potential impact analysis that is discussed in more detail in section IV. F. of this summary.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by 14 percent or about $943.5 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 included 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 2,855 hospitals or 82.52 percent of all hospitals eligible to receive a readmissions penalty. The readmissions penalty is estimated to affect 0.44 percent of payments to the hospitals that are being penalized for excess readmissions. Table I.G.-03 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.-04 illustrates the 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 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 final rule shows the number of hospitals participating the program (2,997) and the number (749) 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. Using finalized cost reports from prior years, CMS estimates costs of an additional $15.7 million that had not previously been incorporated into budget neutrality adjustments. The total costs of the Rural Community Hospital Demonstration Program for FY 2024 that will be subject to IPPS budget neutrality are $53.4 million. CMS is applying a budget neutrality adjustment to the IPPS standardized amounts of -0.05 percent based on these total costs.

C. IPPS Standardized Amounts

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

	Update
Full Update	3.1%
No IQR	2.275%
No EHR	0.625%
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, 1.001463 (an increase of 0.15 percent);
- MS-DRG recalibration cap, 0.999928 (a decrease of 0.01 percent)
- Wage index, 1.000702 (an increase of 0.07 percent);
- Geographic reclassification, 0.971295 (a reduction of 2.87 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.997402 or -0.26 percent;
- 5 percent cap on wage index reductions, 0.999645 or -0.04 percent;

- The outlier offset factor is 0.949 or -5.1 percent; and
- The rural community hospital demonstration program adjustment is 0.999463 or -0.05 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	3.1%
DRG Recalibration	0.15%
DRG Recalibration Cap	-0.01%
Wage Index	0.07%
Geographic Reclassification	-1.33%
25th Percentile	-0.07%
5% Cap on Wage Index Reductions	0.00%
Outlier	0.00%
Rural Community Hospital	0.05%
Net Change*	1.91%

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

The increase in the capital rate is 4.1 percent from $483.79 to $503.83. The combined increase in the operating standardized amount and the capital rate will be 2.07 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 was 1 percent from April 1, 2022 through June 30, 2022.)

STANDARDIZED AMOUNTS FY 2024

	Full Update=3.1%	**Reduced Update Failed IQR = 2.275%**	**Reduced Update Failed EHR =0.625%**	**Reduced Update Failed IQR and EHR = -0.2%**
Wage Index >1.0				
Labor (67.6%)	$ 4,392.49	$4,357.34	$4,287.05	$4,251.90
Non-Labor (32.4%)	$ 2,105.28	$2,088.43	$2,054.74	$2,037.89
WI<=1.0				
Labor (62%)	$4,028.62	$3,996.38	$3,931.91	$3,899.67
Non-Labor (38%)	$2,469.15	$2,449.39	$2,409.88	$2,390.12
National Capital Rate (All Hospitals)	$503.83			

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 is adopting a final outlier threshold for FY 2024 of $42,750 (compared to $40,732 in the proposed rule), an increase of 10.2 percent and $3,962 from the FY 2023 amount. CMS projects that the outlier threshold for FY 2024 will result in outlier payments equal to 5.1 percent of operating DRG payments and 4.02 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.959757 to the capital federal rate to fund operating and capital outlier payments respectively.

Several commenters expressed concern about the increase in the outlier threshold from FY 2023 to FY 2024 and suggested various strategies for mitigating the increase, such as eliminating COVID cases or cases with extreme charges from the model. CMS responded to these comments by indicating that it does not believe the presence of COVID cases in the FY 2022 data will be appreciably different than it is expecting in FY 2024 given that COVID has become an endemic disease and the latest trends for COVID-19 hospitalizations. The comment about eliminating extremely high charge cases from the model has been addressed in past rules.

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 March 2023 update to the FY 2022 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data is the March 2023 update of the Provider-Specific File (PSF).

Charge Inflation. CMS is using the latest MedPAR files to compute the charge inflation factor for FYs 2021 and 2022 that it applied to FY 2022 charges to simulate the FY 2024 outlier threshold. For this purpose, CMS used the March 2022 MedPAR to determine FY 2021 charges and charges per case and the March 2023 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	$581,708,955,080	7,441,613	$ 78,169.74
FY 2022	$578,217,120,322	6,992,447	$ 82,691.67
Annual Rate of Increase			1.05785
Squared for 2 Years of Inflation			1.11904

CCRs. CMS is adjusting the CCRs from the March 2022 update of the PSF by comparing the percentage change in the national average case-weighted operating and capital CCRs between the March 2023 and March 2022 updates to the PSF.

	Operating	Capital
March 2022 PSF	0.251181	0.019678
March 2023 PSF	0.248881	0.01779
% Change	-0.92%	-9.59%
Factor	0.904055	0.990843

Reconciliation. Over the course of the year, Medicare makes outlier payments based on hospital data from a prior year. Outlier reconciliation occurs when the hospital's actual CCR for the period changes from the CCR used to make outlier payments by more than 10 percentage points or the hospital receives more than $0.5 million in outlier payments. Continuing a practice begun in FY 2020, CMS is reflecting reconciliation in the determination of the FY 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 final rule, CMS is using the March 2023 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 final rule, CMS estimates that reconciliation in FY 2018 resulted in 15 hospitals being owed $15.015 million or -0.02 percent of total operating IPPS payments rounded to the 2nd digit. Subtracting -0.02 percentage points from 5.10 percent is 5.12 percent. CMS will target 5.12 percent of operating payments as outliers assuming that -0.02 percentage points of that amount will be repaid to hospitals under the reconciliation process. Reconciliation will have the effect of slightly decreasing the final rule outlier threshold (from $42,909 to $42,750) to target a slightly higher percentage of operating payments as outliers.

There is not a separate capital outlier threshold. CMS establishes a single unified outlier threshold based on the operating outlier threshold. Accordingly, CMS adjusts the capital rate to reflect the percentage of total payments estimated to be paid as capital outliers. For capital, CMS estimates the ratio of reconciled outlier payments to total payments is -0.02 percent rounded to the 2nd digit based on $1,494,671 in reconciled capital outlier payments owed to 10 hospitals.

FY 2022 Outlier Payments. CMS' current estimate, using available FY 2022 claims data, is that actual outlier payments for FY 2022 were approximately 6.78 percent of actual total MS-DRG payments or 1.68 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 the final rule, CMS estimates that, using FY 2022 data, outlier payments will be 0.3 percentage points higher (or 5.4 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. In summary, CMS adopted a preemptive negative rate adjustment of -4.8 percent for FY 2008 to offset increases in IPPS spending due to improvements in documentation and coding that resulted in a higher case mix index but not a real increase in severity of illness. Under the statute, CMS believed it needed to do this preemptive adjustment to maintain budget neutrality for the adoption of the MS-DRGs.

Subsequent statutory amendments required different adjustments over the years. 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 between FY 2018 and FY 2023 leaving a residual of 0.9412 percentage points that has, to date, not been restored to IPPS rates. Hospitals believe that CMS is required to return this 0.9412 percentage points to IPPS rates.

The issue arose because 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 points of CMS' estimated (at that time) 3.2 percent in recoupment adjustments. CMS later determined that an additional 0.7 percentage point reduction was needed after MACRA was enacted that brought the total

aggregate reduction to 3.9 percent. Subsequent legislation reduced the first-year adjustment from 0.5 to 0.4588 percentage points.

Public comments argued that section (7)(B)(2) and (4) of the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90) is explicit that CMS may not carry forward any documentation and coding adjustments applied in fiscal years 2010 through 2017 into IPPS rates after FY 2023. However, CMS responded that it believes section 414 of the MACRA and section 15005 of the 21st Century Cures Act set forth the levels of positive adjustments for FYs 2018 through 2023. The agency sees "no evidence that Congress enacted these adjustments with the intent that CMS would make an additional +0.7 percentage point adjustment in FY 2018 to compensate for the higher-than-expected final [American Tax Relief Act] adjustment made in 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 FY 2024 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 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 indicates 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.

For the proposed rule, CMS posted a test version of the ICD-10 MS-DRG GROUPER Software, Version 41 on its website. This test software reflected the proposed GROUPER logic for FY 2024; it included the new diagnosis and procedure codes effective for FY 2024 and did not include the diagnosis codes that are invalid beginning in FY 2024. CMS also made available a supplemental file in Table 6P.1a that included 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 proposed 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 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; CMS 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 expansion of 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-DRG into severity levels and the request is for a two-way split, CMS will not also evaluate the criteria for a three-way split.

Application of the NonCC subgroup criteria. As discussed in the proposed rule, 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 provided additional related analysis. Associated with the proposed rule, 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 discussed 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 (associated with the proposed rule) 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 discussed 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 reiterated 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 6P group of tables, CMS provided additional files reflecting application of the NonCC subgroup criteria in connection with the FY 2024 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. 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 made these additional analyses reflecting application of the NonCC subgroup criteria to inform application of the NonCC subgroup criteria for FY 2025 rulemaking. CMS requested feedback for consideration for the development of the FY 2025 proposed rule.

Commenters supported the proposal to delay application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split for FY 2024 and to maintain the current structure of these 45 MS-DRGs. Commenters also expressed support for the proposal to exclude the 12 obstetric related MS-DRGs from application of the NonCC subgroup criteria. In response to comments expressing concern that the criterion of a 500-case volume may be too high for low

volume services and MS-DRGs, CMS notes that the minimum case volume requirements were established to avoid overly fragmenting the MS-DRG classification system.

Some commenters agreed with the methodology for creating subgroups but also recommended CMS continue to collect data and identify any unintended impacts to the MS-DRG relative weights because of the redistribution of cases from application of the NonCC subgroup criteria. A few commenters requested CMS provide data analysis by hospital type for FY 2025 to facilitate review and forecast impacts. Some commenters stated providers will need time for implementation of this final policy. A commenter suggested CMS consider implementation using a phased approach over several years. CMS will consider these comments as it considers implementation.

A few commenters expressed concern that the policy may result in additional reductions to relative weights for important procedures and suggested implementing a percent cap on reductions. CMS notes the 10-percent cap on reductions to an MS-DRG's relative weight applies to new or modified MS-DRGs after the first fiscal year that the new or modified MS-DRGs take effect. Under this policy, the 10-percent cap would not apply to the relative weight for any new or renumbered MS-DRGs for the first fiscal year. CMS acknowledges that application of the NonCC subgroup criteria may warrant review of this policy and will consider this issue as it works to mitigate financial impacts resulting from significant fluctuations in the relative weights.

After consideration of comments, CMS finalizes its proposal to delay the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split until FY 2025 or later. CMS notes that it will continue to apply the criteria to create subgroups, including application of the NonCC subgroup criteria, in its annual analysis of MS-DRG classification requests.

For the final rule, the FY 2024 ICD-10 MS-DRG GROUPER and Medicare Code Editor (MCE) Software Version 41, the ICD-10 MS-DRG Definitions Manual files Version 41 and the Definitions of Medicare Code Edits Manual Version 41 are available on the CMS website at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/AcuteInpatientPPS/Ms-DRG-Classifications-and-Software.

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.

Based on its analysis of MS-DRG 023, CMS determined that the number of cases involving the RNS© neurostimulator (57 cases) was 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 and 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. This analysis showed that the average costs and length of stay were 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 did 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 concluded that additional time is still needed to evaluate these cases and did not make any related proposals. Some commenters supported CMS' proposal and a commenter opposed CMS' proposal. CMS agrees that neurostimulator cases can have average costs that are higher than the average costs of all cases in their respective MS-DRGs but it is difficult to detect patterns of complexity and resource intensity.

CMS finalizes its proposal not to reassign these cases or create a new MS-DRG. CMS also finalizes its proposal not to create a new MS-DRG for cases involving a craniectomy/craniotomy with device implant.

In the proposed rule, CMS noted 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 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 summarized its review of this request and again concluded that the small subset of patients (38 cases) with a diagnosis of CRAO or BRAO receiving a thrombolytic agent did not warrant a separate MS-DRG or reassignment.

CMS acknowledged 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 were 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 finalized its proposal 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 proposed 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 finalizes its proposal 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.

Commenters agreed with these proposals.

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 also is not clinically coherent

with other procedures assigned to these MS-DRGs. A table in the proposed rule listed the ICD-10-PCS procedure codes for cases reporting USAT for PE. CMS noted 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 USAT procedures. 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 summarized its review of this request. CMS noted the procedure codes describing USAT used for its claims analysis differs from the procedure codes identified 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) was 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) were not consistently reported.

Based on its finding that suggested that the administration of thrombolytic(s) may not have been consistently reported on claims, 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 from 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 stated the differences in resource consumption warranted reassignment of these cases. CMS did 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 concluded 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 concluded that the criteria for a three-way split and a two-way split failed.

For FY 2024, CMS finalizes its proposal to create new base MS-DRG 173 (USAT and Other Thrombolysis with Principal Diagnosis PE). CMS finalizes its proposal to define the logic for this MS-DRG using the previously diagnosis codes for USAT and CDT listed in the proposed rule. CMS will continue to monitor the claims data for this new MS-DRG after implementation to determine if additional refinements are warranted.

Commenters supported the proposal to create new MS-DRG 172. In response to concerns about a single base MS-DRG, CMS states it intends to reevaluate for future rulemaking whether the criterial for a potential “with MCC” and “without MCC” two-way split would be met. Several commenters suggested that the proposal should be delayed until more data can be collected and a few commenters stated that USAT procedures have been receiving appropriate payment and disagreed with the proposal. CMS believes that sufficient time has elapsed since implementation

of the codes in FY 2021 and the claims data indicates providers are successfully coding and reporting the procedure.

b. Respiratory Infections and Inflammations Logic

CMS discussed the logic for case assignment to MS-DRGs 177-179 as displayed in the ICD-10 MS-DRG V40.1 Definitions Manual. For FY 2024, CMS proposed 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.

Several commenters supported this proposal. In response to commenters requesting additional clarification of the proposed changes, CMS provides a case example in the final rule to demonstrate the intent of the proposed logic changes. The final rule also includes tables illustrating additional changes when reporting any one of the five influenza codes.

After consideration of public comments, for FY 2024, CMS finalizes its proposal with modification, to correct the logic for case assignment to MS-DGR 177. CMS finalizes the exclusion of 11 diagnosis codes (listed in a table in the final rule) from acting as an MCC for MS-DRG 177.

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 the data demonstrates 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 discussed 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 summarized 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 cases to MS-DRGs 216-218, CMS continued 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 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 contributes 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 showed 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 concluded that a new MS-DRG for these cases would be appropriate. Based on evaluation of the new base MS-DRG, CMS concluded that the criteria for a three-way split and a two-way split failed because of fewer than 500 or more cases in each subgroup.

CMS concluded that greater resources are needed to perform an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure. For FY 2024, CMS finalizes its proposal to create a new base MS-DRG for these cases. The 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 defined in the logic for the proposed new MS-DRG.

Commenters supported this proposal because it would result in more clinically homogenous assignments that better reflect hospital resources. Many commenters urged CMS to assign cases reporting a single AVR or MVR procedure and another concomitant procedure in MDC 05 to the proposed new MS-DRG. Some commenters urged CMS to either (1) assign all cases reporting a single AVR or MVR procedure and another concomitant procedure for the treatment of AF to the new MS-DRG; (2) create a new MS-DRG for cases reporting a single AVR or MVR procedure for treatment of AF; or (3) assign cases reporting a single AVR or MVR procedure and a concomitant surgical ablation procedure for the treatment of AF to MS-DRGs 216-218, and change the title, maintain the relative weight, and monitor the claims data for 2 years.

Other commenters were not supportive of this proposal and were concerned about the significant negative impact on the remaining MS-DRGs, notably MS-DRG 216. Another commenter requested a delay to allow interested parties to assess the impact of the proposal and to analyze other options.

In response to comments, to examine the recommendation for expansion of MS-DRG 212, CMS did additional analysis of the September 2022 update and the December 2022 update of the FY 2022 MedPAR file. This analysis is described in the final rule. Based on this analysis, CMS concludes the data do not indicate cases reporting a single AVR or MVR procedure and another concomitant procedure (with or without AF) utilize similar resources to cases proposed to be assigned to new MS-DRG 212. In addition, the data do not support creating a new MS-DRG and

does indicate that cases reporting a single AVR or MVR procedure for treatment of AF are appropriately grouped to MS-DRGs 216-221. CMS continues to believe it is not appropriate to assign cases reporting procedure code combinations describing open concomitant surgical ablations without cardiac catheterization to MS-DRGs 216-218 because these MS-DRGs are defined by the performance of cardiac catheterization. In addition, CMS believes the current data is sufficient to create a new MS-DRG and will continue to monitor for impacts in MDC 05.

In response to comments about the logic for MS-DRG 212, CMS clarifies cases reporting: (1) an aortic valve repair or replacement procedure; (2) a mitral valve repair or replacement procedure; and (3) at least one other concomitant procedure, as defined in the GROUPER logic, would be assigned to MS-DRG 212 (Concomitant Aortic and Mitral Valve Procedures). CMS has refined the displace headers in the final ICD-10-MS-DRG Definitions Manual, Version 41 to reflect this clarification. CMS does agree with commenters that there are other valve procedures listed under the ”Concomitant Procedure” logic list and will address any proposed modifications to the logic in future rulemaking.

CMS agrees with commenters that CMS needs to consider evaluation of additional concomitant procedures; a commenter suggested CMS conduct a comprehensive analysis of all concomitant procedures. **CMS is interested in additional feedback on how it can mitigate any unintended negative payment impacts to providers providing concomitant procedures.** Commenters can submit their recommendation via the MEARIS. CMS will consider these comments in future rulemaking.

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 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 discussed 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 summarized its review of this request. CMS agreed 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 in 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 supported that the resulting MS-DRG assignments would be more clinically homogenous and better reflect resource use.

For FY 2024, CMS finalizes its proposal 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-MDC MS-DRG 001 and 002 when reported as a standalone procedure. Procedure code 02HA0RZ will no longer need to be reported as part of the procedure code combination or procedure code "cluster" to satisfy the logic for assignment to MS-DRGs 001 and 002.

Commenters supported this proposal.

Effective October 1, 2023, procedure codes X2HL0F9, X2HM0F9, and X2HM0F9 will replace procedure code 03HY0YZ (see table in the final rule). CMS used 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 (MS-DRGs 252-254). CMS notes that although the new procedure codes are being assigned to the same MS-DRG as the predecessor code, this does not automatically result in the new procedure codes being assigned to the same MS-DRG or to have the same designation (O.R. vs. Non-O.R.) as the predecessor code. A table in the final rule lists the procedure code combinations assigned to MS-DRGs 001 and 002 for short-term external heart assist.

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 these MS-DRGs.

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 summarized its review of this request. For this analysis, CMS did 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. 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 analyses, CMS agreed that the differences in resource consumption warrants reassignment of these cases. CMS did 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 concluded 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 concluded that a two-way split of the base-MSG met all five criteria.

For FY 2024, CMS finalizes its proposal 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 defines the logic for this MS-DRG using the previously diagnosis codes for USAT and CDT listed in the proposed rule. CMS will continue to monitor the claims data for these new MS-DRGs to determine if additional refinements are needed.

Commenters supported this proposal; a few commenters supported the proposal but suggested the proposal should be delayed until more data could be collected. CMS believes it is not premature to propose the creation of a new MS-DRG based on our review and claims data analysis. CMS disagrees with comments that inclusion of both conventional CDT and USAT in the proposed MS-DRGs disregards fundamental clinical differences between the procedures. CMS acknowledges that USAT procedures performed utilizing the EKOS device employ ultrasound but the objective of both CDT and USAT is to effectuate thrombolysis and reduce clot burden. CMS reiterates that based on its analysis, USAT and CDT procedures performed on peripheral vascular structures are clinically distinct and utilize a different pattern of resources than other procedures in MS-DRGs 252-254.

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, percutaneous coronary interventions (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 noted 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 finalized its proposal to discontinue this new technology add-on payments A table in the proposed rule listed the four ICD-10-PCS procedure codes that describe percutaneous coronary IVL.

CMS summarized its review of this request. CMS noted 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 analysis showed 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 showed that average costs are generally similar without regard as to whether a drug-eluting or non-drug-eluting intraluminal device was placed.

CMS agreed that percutaneous coronary IVL contributed 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 proposed to create new MS-DRGs for percutaneous coronary IVL involving the insertion of an intraluminal device. Based on its analysis, CMS concluded that a two-way split of the base MS-DRG 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 proposed 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 concluded 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 concluded that a two-way split of the base-MSG met all five criteria.

For FY 2024, CMS finalizes its proposal 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 defines the logic for this MS-DRG using the previously diagnosis codes for USAT and CDT listed in the proposed rule. CMS will continue to monitor the claims data for these new MS-DRGs to determine if additional refinements are needed.

Many commenters supported this proposal. Some commenters suggested that new MS-DRG 325 should be split into two severity levels; another commenter suggested CMS delay application of the NonCC subgroup criteria. In response, CMS notes that based on the analysis there were insufficient cases in each subgroup to split the DRG. CMS also reiterates that it finalized the expansion of the criteria to include the NonCC subgroup criteria to new MS-DRGs and the delay only applies to existing MS-DRGs.

In response to commenters expressing concern with the proposal, CMS states the analysis clearly show that cases reporting percutaneous coronary IVL, with or without involving the insertion of intraluminal device, have higher average costs and generally longer lengths of stay compared to all the cases in their assigned MS-DRG. CMS believes that continued monitoring of the data is needed prior to proposing any modifications to the proposed new MS-DRGs for percutaneous IVL.

MS-DRG assignments for insertion of coronary stents in PCIs. In the proposed rule, CMS discussed the above analysis also showed 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 noted 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 discussed 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 summarized its analysis of this proposal and concluded 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 finalizes its proposal 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 also finalizes its proposal to add the procedure codes from MS-DRGs 246-249 to the new proposed MS-DRGs 250 and 251.

Commenters supported CMS' proposal. Some commenters supported the proposal but requested CMS review the proposed weights for these MS-DRGs because the decline in the relative weights would cause inadequate payment for these new MS-DRGs. CMS responds that when MS-DRGs are restructured and there is a different case-mix within the MS-DRGs, the relative weights will change.

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 summarized 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 did 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.

In the proposed rule, CMS also discussed its 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 demonstrated that the average length of stay and average costs for all cases are similar for each of the "without MCC" subgroups. CMS believed that it is no longer necessary to subdivide these MS-DRGs based on the diagnosis codes reported.

For FY 2024, CMS finalizes its proposal 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 finalizing its proposal to create two new MS-DRGS with a 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 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 and 6P.7b contain the list of procedure codes used to define the logic for each the new MS-DRGs.

Most commenters supported these proposals. While supporting the proposal, other commenters recommended an additional MS-DRG should be created for cardiac defibrillator implant with cardiac catheterization without MCC. CMS responds the data clearly showed that the cases reporting secondary diagnoses designated as MCCs are more resource intensive as compared to other cases reporting cardiac defibrillator implant. Based on this information, CMS proposed creating one base MS-DERG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated 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 continues to believe the resulting proposed MS-DRG assignment is more clinically homogeneous and better reflects hospital resource use. In response to comments about the NonCC subgroup criteria, CMS reiterates that it finalized the expansion of the criteria

to include the NonCC subgroup criteria to new MS-DRGs; it only finalized a delay in applying this criterion to existing MS-DRGs.

In response to a comment suggesting CMS maintain MS-DRGs 226 and 227 because the proposed MS-DRG 276 has the same GROUPER logic as current MS-DRG 226, CMS notes it prefers new MS-DRG numbers because it allows individuals, payers, and organization to be aware of changes to base MS-DRGs and minimizes any confusion and unintended consequences. Effective October 1, 2023, 22 new procedure codes will identify procedures involving extravascular (EV) ICD leads. CMS used its established process for MS-DRG assignment which examines the MS-DRG assignment for the predecessor codes to determine the most appropriate MS-DRG assignments. A table in the final rule lists these assignments. CMS notes that although the new procedure codes are being assigned to the same MS-DRG as the predecessor code, this does not automatically result in the new procedure codes being assigned to the same MS-DRG or to have the same designation (O.R. vs. Non-O.R.) as the predecessor code.

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.[2] 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 believed it was appropriate to address the prior MS-DRG request for diagnosis code K35.20. CMS analyses included MS-DRGs 371-373, MS-DRGs 338-340 (Appendectomy with Complicated Principal Diagnosis) and MS-DRGs 340-343 (Appendectomy without Complicated Principal Diagnosis). The analyses showed 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 believed its 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 MS-DRGs.

CMS finalizes its proposal to delete MS-DRGs 338-343 and create 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)

[2] 83 FR 41230, 85 FR 32500 through 32503, and 85 FR 58484 through 58488.

These new MS-DRGs will no longer require a diagnosis in the definition of the logic for case assignment. CMS includes the current list of appendectomy procedures in the logic for case assignment of appendix procedures for the new MS-DRGs.

Several commenters supported these proposals. Commenters who opposed these proposals were concerned that about the potential decrease in case weight, the failure to incorporate clinical best practices for treatment of patients with complicated disease, and differences between uncomplicated and complicated appendicitis. In response to the concern about the potential decrease in case weight, in a table in the final rule, CMS shows that the relative weights and geometric mean length of stay for the existing MS-DRGs has been trending over the past few years. CMS also acknowledges that tertiary care centers may provide care for more complicated appendicitis but it does not propose MS-DRG modifications based on provider types. CMS also states that MS-DRGs classifications are based on a combination of data analysis and clinical judgement.

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

For FY 2024, CMS finalizes its proposal 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.

The majority of commenters supported this proposal. The requestor disagreed with the proposal and raised concerns about CMS' analysis. CMS discusses its analysis and provides a summary table for cases reporting alcoholic hepatitis and non-alcoholic hepatitis in the final rule.

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 noted 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 continues the new technology add-on payments. A table in the proposed rule listed 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 summarized 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 agreed 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 was concerned about the reliability of the claims data and it believes further review is warranted. CMS also noted 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 finalizes its proposal to maintain the current structure of MS-DRGs 453-460.

Commenters supported this proposal. Several commenters (orthopedic surgeons) who expressed support for the request stated that without assignment to their higher severity MS-DRGs their facilities would not allow use of the technology for Medicare populations. CMS agrees that the findings appear to indicate that cases utilizing an aprevo customized interbody spinal fusion device reflect a higher consumption of resources. CMS anticipates that the revision to the code title for the aprevo devise will encourage more accurate reporting of procedures and improve the quality and reliability of the data.

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 with codes describing the insertion of TIVADs or tunneled vascular access devices.

CMS summarized its review of this request, including reviewing the GROUPER logic for MS-DRGs 673-675 and 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 believed these eight diagnosis codes are more clinically aligned with the diagnosis codes assigned to MDC 05.

CMS finalizes its proposal 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.

Commenters supported this proposal.

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 final 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 PHE, CMS believed it was appropriate to allow additional time for the claims data to stabilize before selecting the timeframe for this analysis.

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 will consider the comments it received about this topic as it develops its methodology.

CMS received several requests to change the O.R. designation of specific ICD-10-PCS procedure codes. Most of the requests were not discussed in the proposed rule; CMS will consider these requests as part of its comprehensive review of procedure codes. CMS notes that there are over 19,000 ICD-10-PCS codes that describe diagnostic and therapeutic endoscopic procedures performed on thoracic and abdominal organs and it will include these codes in the planed comprehensive review.

The reader is referred to the final rule for a discussion of the request to change the designation of procedures for open drainage of subcutaneous tissue and fascia. For FY 2024, CMS finalizes its proposal to maintain the designation of the 22 codes that describe these procedures.

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[3], 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.[4] 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.

[3]72 FR 47152 through 47171
[4]84 FR 42150 through 42152

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

CMS plans to continue comprehensive CC/MC analyses using a combination of the prior mathematical analysis of claims data in combination with the guiding principles. CMS 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.[5]

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 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 suggested that when the three SDOH Z codes are 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 finalizes its proposal 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.

Commenters expressed overwhelming support for this proposal. Some commenters requested CMS explore other SDOH diagnosis codes that could impact hospital resource use. Many commenters supported this proposal but raised operational concerns related to the limit of 25 diagnoses on the institutional claim form. Commenters stated that SDOH Z codes could limit the use of other diagnosis codes that need to be captured on the claim form for both payment and

[5] These files are available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payments/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

quality measures. CMS appreciates these comments and it will examine if other diagnoses codes, including those recommended by commenters, impact hospital resource use. CMS notes that any changes to the institutional claim form would need to be submitted to the National Uniform Billing Committee (NUBC).

Some commenters discussed challenges for clinicians in documenting SDOHs. In response, CMS notes that the ICD-10-CM Office Guidelines for Coding and Reporting have been updated to provide additional guidance for diagnosis codes describing SDOHs. In addition, HHS has had discussions with electronic health records (EHRs) vendors about the need to integrate SHOH data into the EHR. On April 18, 2023, the Office of the National Coordinator proposed updated certification standards (USCDI v3) that would, if finalized, require certified EHR vendors to include four SDOH data elements: SDOH Assessment, Goals, Interventions, Problems/Health Concerns.[6]

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.

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

c. CC Exclusions List for FY 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. This list includes 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.

[6] 88 FR 23746

The following tables identify the additions and deletions to the CC Exclusion list:

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

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 associated with the proposed rule: Table 6H.3 – Principal Diagnosis Codes for Removal from CC Exclusion List

13. 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 2024:

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

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

In the final rule, CMS summarizes the comments it received for Tables 6A and Table 6B and provides its responses.

14. 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 finalized proposals based on CMS' internal review and analysis are discussed below. The interested reader is referred to the final rule for discussion of the following edits:

- External causes of morbidity codes as principal diagnosis
- Age conflict edit.
- Sex conflict edit.
- Manifestation code as a 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. 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 finalizes its proposal 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 changes are summarized below in tables reproduced from the final rule.

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

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

Surgical Hierarchy: MDC 05	
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

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

Surgical Hierarchy: MDC 16	
Proposed New Title MS-DRGs 799-801	Splenic Procedures
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 final rule).

CMS notes that for FY 2024, there are 74,044 diagnosis codes and 78,603 procedure codes.

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.

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 final rule, lists the existing MS-DRGs subject to this policy, effective October 1, 2023.

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

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

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	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	275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
MDC 5	276	Cardiac Defibrillator Implant with MCC
MDC 5	277	Cardiac Defibrillator Implant without 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 the MedPAR file (fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year) from the 2nd year preceding the ratesetting year (e.g., FY 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 the FY 2024 final rule, CMS used:

- FY 2022 MedPAR data: Bills received through March 31, 2023 from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which are 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 6,991,373 million Medicare discharges regrouped using the FY 2024 final MS-DRG classifications.
- FY 2021 Medicare Cost Reports: Medicare cost report data files, principally for FY 2021 cost reporting periods, using the March 31, 2023 update of the FY 2021 HCRIS.

For FY 2024, CMS did not propose any changes to its methodology and calculated MS-DRG weights using national averages for the 19 CCRs. Accompanying the final rule, CMS posted the version of HCRIS cost report data file which it used to calculate the 19 CCRs for FY 2024, available at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page#Data. (Select file #4 under FY 2024 Final Rule Data files, "FY 2024 Final 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 final 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	0.417
Intensive Days	0.341	0.351
Drugs	0.184	0.18
Supplies & Equipment	0.311	0.303
Implantable Devices	0.281	0.269
Inhalation Therapy	0.150	0.153
Therapy Services	0.283	0.268
Anesthesia	0.072	0.072
Labor & Delivery	0.366	0.406
Operating Room	0.165	0.16
Cardiology	0.094	0.086
Cardiac Catheterization	0.104	0.102
Laboratory	0.107	0.102
Radiology	0.137	0.128
MRIs	0.071	0.067
CT Scans	0.034	0.033
Emergency Room	0.155	0.153
Blood and Blood Products	0.255	0.245
Other Services	0.359	0.34

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 proposed to continue eliminating clinical trial cases from the standardized amount calculation but no longer use drug costs of less than $373,000 as a proxy for the case being a clinical trial case. The proposed rule indicated 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 proposed 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 proposed to use this indicator to retain these types of cases in the relative weight calculation.

Public commenters both supported and opposed CMS no longer eliminating cases with less than $373,000 in drugs costs from the MS-DRG 018 calculation. These commenters expressed concern that some providers have limited experience properly reporting claims for clinical trial and expanded access use cases and some providers do not appear to have fully complied with CMS guidance. Also, inclusion of 4 percent of the cases with low drug costs will continue to lower the relative weight for MS-DRG 018 when these cases are likely clinical trial cases.

CMS responded that while there continues to be a small percentage of claims that report standardized drug charges of less than $373,000 and do not report ICD–10–CM code Z00.6, it does not believe that it is necessary to continue using the proxy until there are no more of these claims. Further, CMS indicates that the variation in the relative weight with and without the proxy is small percentage, unlike in prior years. CMS is finalizing its proposal without change.

For FY 2024, CMS estimated that the average costs of CAR-T clinical trial cases ($84,883) were 27 percent of those where the hospital has a cost for the CAR-T product ($314,862). Accordingly, CMS is proposing to adjust the transfer-adjusted case count for MS-DRG 018 by 0.27 for 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 applied this same adjustor for the applicable cases that group to MS-DRG 018 for purposes of payment, budget neutrality and outlier simulations.

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 continuing the same policy for FY 2024. This cap necessitates a budget neutrality adjustment of -0.01 percent to the standardized amounts.

Other Issues. CMS is normalizing the relative weights by an adjustment factor of 1.941198 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself does not increase or decrease total payments under the IPPS.

For very low volume MS-DRGs (less than 10 cases, generally those for newborns), CMS maintains the prior year relative weight and adjusts it by the average change in the relative weight for all MS-DRGs.

D. 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.[9] 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[10]; 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.[11] 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.[12]

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[13]:

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

If a technology meets all three of the criteria, CMS considers it substantially similar to an existing technology and for purposes of the new technology add-on payments, CMS will not consider the medical service or technology "new". CMS first determines whether a medical

[9] Section 1886(d)(5)(K)(vi) of the Act
[10] 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).
[11] 84 FR 42292 through 42297; regulations at §412.87(c) and (d)
[12] 85 FR 58736
[13] 74 FR 43813 and 43814

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.

CMS finalizes its proposal to use the FY 2022 MedPAR claims data for FY 2024 rate setting. For the FY 2025 threshold values, CMS uses the FY 2022 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2025. The MS-DRG thresholds applicable to FY 2025 are included in the data files associated with the FY 2024 proposed rule on the CMS website.[14]

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[15], CMS codified at §412.87(b) the following aspects of how it evaluates substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

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

[14] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

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 still needs 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 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[16], 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.[17]

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.[18] 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.

As discussed below in section 9, beginning with new technology add-on payment applications for FY 2025, CMS finalizes its proposal 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 finalizes, beginning with FY 2025 applications, the new technology must have received FDA 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

[17] 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.

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 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.

Beginning with the application cycle for FY 2024, CMS publicly posts online new technology add-on payment applications including 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.[19] On December 14, 2022, CMS held a town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" related to pending new technology applications.[20] In their evaluation of individual applications, CMS considered the presentations made at the town hall meeting and written comments received by December 22, 2022. Where applicable, CMS summarized comments at the end of each discussion of the individual applications in the proposed rule. Comments that were unrelated to the "substantial clinical improvement" criterion were not summarized; commenters could resubmit their comments in response to proposals in the 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

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

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.[21] 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, the NCTAP would 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 would 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.

Since the PHE ended on May 11, 2023, discharges involving eligible products will continue to be eligible for the NCTAP through September 30, 2023 (through the end of FY 2023). The NCTAP expires 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).

In response to comments recommending that CMS continue NCTAP, CMS notes that in the FY 2022 IPPS final rule, it finalized extending NCTAP through the end of the FY in which the PHE ends to mitigate the potential financial disincentives for hospitals to provide these new treatments. CMS agrees with the recommendations to monitor Medicare beneficiaries' access to COVID-19 treatments.

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

CMS discusses the 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 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

[21] 85 FR 71155

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. Because DefenCath did not receive FDA approval by July 1, 2023 no new technology add-on payments will be made for cases involving the use of DefenCath for FY 2023 and it will not be eligible for add-on payments for FY 2024.

CMS notes that the applicant for DefenCath submitted a new technology add-on payment application for DefenCath (discussed below in alternate pathways for QIDPs as the taurolidine/heparin application).

Continuation of Technologies. Table II.F.-01 in the final rule (see table extract below) lists the 11 technologies CMS approved for continuation of 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 final rule also includes the maximum NTAP amount for FY 2024, codes used to identify cases eligible for NTAP, and previous related final rule citations.

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)
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 finalizes its proposal to discontinue new technology add-on payments for COVID-19 Hemolung RAS cases.

Discontinuation of Technologies. Table II.F.-02 in the final rule (see table extract below) lists the 15 technologies that have new technology add-on payments discontinued 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 final rule also includes previous related final rule citations.

Technologies Approved for FY 2023 New Technology Add-On Payments But 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
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 on the date of the EUA issuance and prior to receiving FDA approval or clearance. CMS continued 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.

CMS finalizes its proposal 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.F.-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).

A commenter requested that CMS continue new technology add-on payments in FY 2024 for both ABECMA and CARVYKIT because the newness start date is extremely close to April 1 and the commenter believed the first commercial shipment for these products would have been after April 1 due to the time needed to manufacture CAR T-cell products. The commenter also requested CMS consider a standard third-year extension of new technology add-on payments for cell and gene therapies due to the unique manufacturing process and low volume. CMS states that consistent with the statute, a technology no longer qualifies as new once it is more than 2 to 3 years old, irrespective of how frequently it is used in the Medicare population. CMS may consider a documented delay in the technology's market availability. CMS notes that as discussed in the FY 2023 IPPS final rule, in response to a comment from the applicant for ABECMA, CMS requested additional information on when the technology first became available for sale. The applicant did not provide this information and CMS considers March 26, 2021, to be the beginning of the newness period for ABECMA.

A commenter requested that CMS continue new technology add-on payments for aprevo for ALIF and LLIF indications because many surgeries were not performed in 2020 due to the PHE. CMS reiterates the policies related to the two to 3 years newness duration. CMS notes that it is renewing the TLIF indication for aprevo, which has a newness start date of June 30, 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 2024; eight applicants withdrew their applications prior to the issuance of the proposed rule. Four applicants withdrew their applications prior to the issuance of this final rule: sabizabulin, DuraGraft, VEST, and omidubicel. Two applicants did not receive FDA approval for their technologies by July 1, 2023 and are not eligible for FY 2024 new technology add-on payments: Vanflyta and elranatamab. Of the remaining 13 applications, CMS approves 10 applications with 4 of the applications considered as 2 technologies due to substantial similarity, for a total of 8 new approvals for FY 2024 new technology add-on payments.

The following applications were approved: CYTALUX® for ovarian cancer; CYTALUX® for lung cancer; EPKINLY™ and COLUMVI™; Lunsumio™; REBYOTA™ and VOWST™; SPEVIGO®; TECVAYLI™; and TERLIVAZ®.

The summary below provides a high-level discussion of the remaining 13 new technology assessment; readers are advised to review the final 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 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.[22]

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

Newness. 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 and effective October 1, 2023 five ICD-10-PCS procedure codes are approved for use with CYTALUX.

As summarized in a table in the final rule, for the first criterion, 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, the applicant stated no other drugs marketed under the same ingredient category. For the third criterion, the applicant stated there are no existing drugs/biologicals used as an adjunct for intraoperative identification of ovarian cancer.

CMS concludes that CYTALUX meets the newness criterion. The beginning of the newness period will commence when CYTALUX became commercially available on April 15, 2022.

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

[22] 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

In the proposed rule, CMS discussed several concerns regarding whether CYTALUX meets the substantial clinical improvement criterion. CMS was concerned that in the Phase 3 study, CYTALUX showed a false positive rate of 24.8% and was concerned that removing additional tissues that were false positives could impact patient outcomes. 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 was interested in data demonstrating that CYTALUX resulted in improved outcomes.

The applicant responded to CMS' concerns and discussed results from the Phase 3 trial, including that using CYTALUX led to a revision of the surgical plan for 56 percent of patients and more complete debulking was achieved in 51 percent of patients. The applicant stressed that extensive clinical literature demonstrates that complete resections are associated with improved survival in ovarian cancer. The applicant also stated that CYTALUX is not a therapeutic agent, and therefore it believed long-term survival studies are not necessary to demonstrate clinical improvement. With regard to the false positive rate, the applicant did not believe this alters CYTALUX's significant clinical improvement analysis as the presence of false positive results did not cause negative patient outcomes or additional unnecessary treatments.

Several commenters supported the application and discussed the importance of CYTALUX for removal of additional malignant tissue that would not be removed using standard methodologies.

Based on this additional information, CMS concludes that CYTALUX represents a substantial clinical improvement because it can detect ovarian cancer that is currently undetectable during surgery.

CMS finalizes CYTALUX meets all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving the use of CYTALUX will be identified by five new ICD-10-PCS codes effective October 1, 2023. Based on information provided by the applicant, the estimated cost per patient is $4,250. For 2024, the maximum new technology add-on payment for a case involving the use of CYTALUX is $2,762.50.

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: 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. The applicant submitted a request for a unique ICD-10-PCS procedure code for CYTALUX and effective October 1, 2023, five ICD-10-PCS procedure codes were approved for use with CYTALUX.

In response to CMS' request for additional information about the longer delay for the market availability for CYTALUX for lung cancer, the applicant explained that CYTALUX for ovarian cancer was only briefly available on the market for a small, limited pilot of 20 cases from April through June 2022. The technology was subsequently taken off the market due to the withdrawal of the necessary imaging system and a commercial lot of CYTALUX was not initiated again until there was evidence of FDA approval for use in lung cancer. The applicant stated that the first commercial lot of CYTALUX became available for use in lung cancer on June 5, 2023.

As summarized in a table in the final rule, for the first criterion, 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, the applicant stated that are no other drugs marketed under the same ingredient category. For the third criterion, the applicant stated no other existing drugs/biologicals are used as an adjunct for intraoperative identification of ovarian cancer.

CMS concludes that CYTALUX meets the newness criterion. The beginning of the newness period will commence when CYTALUX for lung cancer became commercially available on June 5, 2023.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion and concludes 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discussed several concerns regarding whether CYTALUX meets the substantial clinical improvement criterion. As with the use of CYTALUX for ovarian cancer, CMS was concerned that in the Phase 3 study, CYTALUX showed a false positive rate of 25.7% and was concerned that removing additional tissues that were false positives could impact patient outcomes. CMS noted 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 wondered if the authors were referring to fewer resections or reduced mortality. CMS was interested in data demonstrating that CYTALUX resulted in improved outcomes.

The applicant responded to CMS' concerns and discussed results from the Phase 3 trial, including that the use of CYTALUX allowed surgeons to localize the primary lesions in 19 percent of patients whose lesions were not identified by standard techniques. In addition,

CYTALUX reduced the time to identify lesions which reduced anesthesia time for the patient. CYTALUX also detected additional synchronous malignant lesions not identified on preoperative imaging. The applicant stated that CYTALUX improves surgeons' ability to treat the disease more completely via resection which may reduce the risk of recurrence. In response to CMS question about decreased rate of subsequent diagnostic intervention, the applicant stated that trials were not designed to follow patients' long term to determine the frequency of additional procedures, oncologic outcomes, or mortality rates. The applicant believes that the ability to perform a more complete resection during the initial procedure has the potential to reduce the need for future intervention.

Several commenters supported the application and discussed the importance of CYTALUX for removal of additional lesions that was not identified by standard methodologies, including CT scans.

Based on this additional information, CMS concludes that CYTALUX represents a substantial clinical improvement because it can identify lung cancer that is currently undetectable using standard methods.

CMS finalizes CYTALUX meets all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving the use of CYTALUX will be identified by five new ICD-10-PCS codes effective October 1, 2023. Based on information provided by the applicant, the estimated cost per patient is $4,250. For 2024, the maximum new technology add-on payment for a case involving the use of CYTALUX is $2,762.50.

c. EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm)

Two manufacturers, Genmab US and Genetech Inc., submitted separate applications for new technology add-on payments for FY 2024 for EPKINLY and COLUMVI, respectively. CMS notes that both of these technologies are bispecific antibodies used for the treatment of patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) after two or more prior therapies. COLUMVI specifically target diffuse LBCL (DLBCL), the largest subset of LBCL. The bispecific antibodies directly bind to CD20 expressing B cells and CD3 expressing T cells which induces activation, proliferation, and cytotoxic activity of the T cells against malignant B cells.

In the proposed rule, CMS discussed these two applications as two separate technologies but raised concerns that these applications are substantially similar. After further consideration, including comments received, CMS concludes that EPKINLY and COLUMVI are substantially similar and evaluates both technologies as one application for new technology add-on payments.

The online application posting for EPKINLY is available at https://mearis.cms.gov/public/publications/ntap/NTP221012JQM0G. The online application posting for COLUMVI is available at https://mearis.cms.gov/public/publications/ntap/NTP221017RK2RD.

Newness. EPKINLY received BLA approval from FDA on May 19, 2023, for treatment of adult patients with R/R DLBCL and high-grade B cell lymphoma 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 EPKINLY. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code for EPKINLY and was granted a code effective October 1, 2023 (XW013S9).

COLUMVI received BLA approval from FDA on June 15, 2023 for treatment of adult patients with R/R DLBCL, not otherwise specified, including DLBCl arising from follicular lymphoma after two or more lines of systemic therapy. According to the applicant, the administration of COLUMVI 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 and was granted a code effective October 1, 2023 (XW043P9).

As summarized in tables in the final rule, both applicants asserted that EPKINLY and COLUMVI meet the newness criterion. In the proposed rule, CMS noted that EPKINLY and COLUMVI may have a similar mechanism of action for treatment of adult patients with RR LBCL/DLBCL after three or more prior lines of therapy. CMS thought that COLUMVI may treat the same or similar patient populations as existing FDA-approved treatments, including CAR T-cell therapies and non-CAR T-cell therapies such as POLIVY, SPOVIO, and ZYNLONTA. CMS also believed that EPKINLY and COLUMVI may treat the same or similar disease (LBCL/DLBCL) in the same or similar population (R/R patients who received existing treatments for R/R LBCL). CMS stated 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 was interested in information on how these two technologies may differ with respect to the newness criterion.

The applicant for EPKINLY submitted a comment maintaining that EPKINLY meets the newness criterion. CMS notes the applicant did not discuss whether or not EPINLY is substantially similar to COLUMVI. The applicant for COLUMVI also submitted a comment maintaining that COLUMVI meets the newness criterion. The applicant recognized the similarities between the two treatments, but discussed key distinctions between the two bispecific antibodies and compared the two CD20 binding domains in COLUMVI as substantially different from a single CD20 binding domain in EPKINLY. The applicant also stated COLUMVI elicits a complete response faster than EPKINLY and also requires fewer total treatment visits for patients compared with EPKINLY. In addition, the applicant for COLUMVI discussed the differences between COLUMVI and other available treatments.

After consideration of comments, CMS acknowledges that there may be slight molecular difference, but it believes that both EPKINLY and COLUMVI fall into the same class of IG1 bispecific antibodies and are substantially similar to one another. As discussed in prior rulemaking (87 FR 48924), CMS does not believe the number of domains meaningfully differentiate the mechanism of action. CMS is not convinced that the differences in response rate and treatment schedule are due to a difference in the mechanism of action. In addition, these technologies are intended to treat the same or similar disease in the same or similar population and that potential cases representing patients who may be eligible for treatment would be assigned to the same MS-DRGs. CMS also believes EPKINLY and COLUMVI are not substantially similar to any other existing technologies.

CMS concludes that EPKINLY and COLUMVI meet the newness criterion. Because these technologies are substantially similar to each other, CMS uses the earliest market availability date submitted as the beginning of the newness period for both technologies. The newness period for EPKINLY and COLUMVI would begin on the date EPKINLY received FDA approval, May 19, 2023.

CMS notes that if substantially similar technologies are submitted for review in different (and subsequent) years, it evaluates and makes a determination on the first application and applies that same determination to the second application. For technologies submitted for review in the same year that CMS determines are substantially similar, it considers both sets of cost data and clinical data in making a new technology add-on payment determination.

Cost. CMS summarizes the analysis provided by both applicants demonstrating the technologies meets the cost criterion. CMS concludes that both EPKINLY and COLUMVI meet the cost criterion.

Substantial Clinical Improvement. For EPKINLY, the applicant stated that EPKINLY 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS was concerned that the applicant did not provide the complete study of EPKINLY (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 stated this limits its ability to fully evaluate and assess the supporting evidence. In addition, CMS was concerned that the evidence comparing differences between trials did not indicate that EPKINLY has a better safety profile and efficacy than existing therapies. CMS requested additional information to support these assertions.

For COLUMVI, the applicant stated that COLUMVI 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discussed concerns with the information provided. CMS was concerned that the evidence presented did not support that COLUMVI is a treatment option for patients who are ineligible for other treatments available for RR DLBCL patients who have progressed after other treatments. CMS was concerned that the statement that COLUMVI reduced mortality of patients who have progressed after autologous stem cell transplant (ASCT) or CAR T-cell therapies was based on comparison between independent studies. Similarly, CMS was concerned that the evidence did not support a difference in safety or efficacy between COLUMVI and other treatments. CMS also questioned if COLUMVI is the only off-the shelf treatment options. CMS noted that no information was presented to support the claim that COLUMVI is a fixed-treatment duration therapy and improves a patient's quality of life.

Both applicants submitted comments and provided responses to concerns raised in the proposed rule. The applicant for EPKINLY acknowledged that direct treatment comparisons with other

treatments has not been done but that real world indirect comparisons have shown that compared to chemotherapy, EPKINLY offers a substantially higher chance of response and significantly lower risks of progression and mortality. The applicant also stated that EPKINLY is an off-the-shelf therapy that may be effective for patients who cannot easily access CAR T-cell therapy, who are ineligible for CAR T-cell therapy, or have progressed after receiving CAR T-cell therapy. The applicant for COLUMVI stated that COLUMVI expands treatment options for three key subsets of patients with R/R DLBCL: patients ineligible or who cannot access ASCT or CAR T-cell therapy, patients who have progressed after ASCT or CAR T-cell therapy, and patients who have progressed after two or more other lines of approved therapies. Another commenter discussed limitations of obtaining CAR T-cell therapy because the treatment is only offered at approximately 200 centers that are concentrated in major metropolitan areas.

CMS concludes that EPKINLY and COLUMVI represent a substantial clinical improvement over existing technologies for treatment of patient with R/R DLBCL, after two or more prior therapies who are unresponsive to, or ineligible for, currently available treatments, who are ineligible due to factors such as organ dysfunction, or prior stem cell transplantation, or for whom CAR T-cell therapy is not an available treatment option.

CMS finalizes that EPKINLY and COLUMVI meets all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving EPKINLY will be identified by XW013S9 and cases involving COLUMVI will be identified by XW033P9. The manufacturer of EPKINLY stated the cost of the technology is $11,463.61 per patient and projected 117 cases in 2024. The manufacturer of COLUMVI stated that the cost of the technology is $5,748.53 and projected 40 cases in 202. Using a weighted average of the cost of EPKINLY and COLUMVI based on the projected number of cases, the case-weighted average cost is $10,006.26 for these technologies. The maximum new technology add-on payment for a case involving the use of EPKINLY or COLUMVI is $6,504.07 for FY 2024.

d. Lunsumio™ (mosunetuzumab)

Genetech submitted an application for new technology add-on payment 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 R/R follicular lymphoma (FL) who have received at least 2 prior systemic therapies (also referred to as 3L+FL).[23] 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 treatment of adult patients with R/R 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 noted 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

[23] An application was submitted and summarized in the FY 2023 IPPS proposed rule (87 FR 28261-28274) and was withdrawn prior to the issuance of the final rule.

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 final rule, for the first criterion, the applicant stated that Lunsumio's mechanism of action is different from other therapies approved for the treatment of 3L+ R/R FL. The applicant stated that Lunsumio might be assigned to the same MS-DRG as existing technologies but does not involve the treatment of the same or similar population as existing therapies. CMS noted that there are other FDA approved therapies for treatment of patients with R/R FL after two or more lines of systemic therapy and that CAR T-cell therapies, such as Yescarta, are FDA approved therapies. CMS believed that Lunsumio would be used for the same disease and same population when compared to other therapies approved to treat 3L+ R/R FL.

The applicant submitted a comment addressing the newness criterion and reiterated that although several treatment options have been developed and approved for R/R FL there are no preferred treatment options for treating 3L+ R/R FL. The applicant also discussed distinctions between Lunsumio and copanlisib, tazemetosib, and CAR T-cell therapies. The applicant highlighted the limited access to CAR T-cell therapy and noted that twelve states have no available CAR T-cell therapy sites. Another commenter supported the newness of Lunsumio in the treatment of multiple relapsed FL, as the first approved CD20xCD3 bispecific antibody.

After reviewing the comments, CMS continues to believe that Lunsumio would be used for the same disease in a similar population when compared to other therapies approved to treat 3L+ R/R FL but that these limitations are more relevant for the substantial clinical improvement criterion. CMS agrees that Lunsumio has a unique mechanism of action as a bispecific antibody for the treatment of 3L+ FL. CMS notes the applicant did not provide additional information about the date of first sale.

CMS concludes that Lunsumio meets the newness criterion and considers the newness period to commence on December 22, 2022.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS concludes 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS was concerned that the primary support comes from a single-arm, Phase II trial of 90 patients 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 was also concerned that comparison to other technologies was based on historical rates found in other clinical trials and no direct comparison of therapies was provided.

The applicant provided comments discussing the benefits of single-arm trials to facilitate faster access to novel therapies for patients who have an unmet need. Benefits included smaller sample size requirements, shorter completion time, and the ability to identify signs of efficacy earlier in drug development. The applicant acknowledged that single-arm studies lack a comparator arm and certain endpoints, such as progression-free survival and overall survival, can only be evaluated against a historical control. The applicant provided comparisons between Lunsumio and pivotal clinical trials for other therapies.

Based on this information, CMS concludes that Lunsumio represents a substantial clinical improvement over existing therapies for the treatment of patients with 3L+ FL.

CMS finalizes that Lunsumio meets all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving Lunsumio will be identified by XW03358 and XW04358. The applicant stated that Lunsumio is sold in a 1 mg and 30 mg single dose vial priced at $593.06 per mg. According to the applicant, most of the inpatient usage occurs as the result of adverse events that developed in clinical trials when Grade 2, 3, or 4 CRS developed. The adverse events occurred 75 percent after a 60 mg dose, 20 percent after a 1 mg dose, and 5 percent after a 2 mg dose. Based on this information, CMS determined a weighted inpatient dose of 45.3 mg; the average cost per patient for Lunsumio is $26,910.92. The maximum new technology add-on payment for a case involving Lunsumio is $17,492.10 for FY 2024.

e. 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.[24] 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 stated 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 final rule, for the first criterion, 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 stated 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

[24]An application was submitted and summarized in the FY 2022 IPPS proposed rule (86 FR 25286-25291) and was withdrawn prior to the issuance of the final rule.

not be assigned to the same MS-DRG as existing technologies because there are no similar existing technologies.

CMS stated 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 was concerned that the proteolytic enzyme is a type of collagenase similar to existing collagenase based enzymatic debridement products. CMS also believed that patients using NexoBrid™ would be assigned to the same MS-DRGs as patients treated for burns.

The applicant submitted a comment reiterating that NexoBrid has a novel mechanism of action and provided additional information about how NexoBrid degrades collagen by bromelain via a combination of endopeptidases and other enzymes. The applicant also explained how NexoBrid differs significantly from collagenase-based debridement agents and discussed that the payment associated with existing burn MS-DRGs would not adequately account for NexoBrid's cost.

Another commenter stated that NexoBrid does not meet the newness criterion because it has been commercially available in the European Union for over a decade. The commenter also noted that other fruit-based enzymatic debridement products have been utilized for decades, including the FDA approved SANTYL® Collagenase Ointment.

In response to comments, CMS notes availability of a product for decades in the European Union does not eliminate a product being considered "new" for new technology add-on payments because the available data for the cost of the technology would not be available in Medicare data. CMS also notes that the evaluation of a technology as being substantially similar to another technology is based on comparing FDA approved products. CMS believes that technologies that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and efficacy.

CMS believes that NexoBrid is substantially similar to an existing collagenase-based debridement agent, SANTYL Collagenase Ointment. CMS believes that both technologies use a similar mechanism of active to achieve the same therapeutic outcome. NexoBrid would be assigned to the same burn MS-DRGs as other enzymatic and surgical debridement technologies used in the treatment of burns. CMS notes that inadequate payment relates to the cost criterion and is not the basis for the assessment of substantial similarity. CMS agrees with the applicant that the use of NexoBrid would involve treatment of a similar disease and similar patient population when compared to existing treatment approaches. CMS considers the beginning of the newness period for NexoBrid to begin on the date SANTYL Collagenase Ointment received FDA approval; the 3-year anniversary date of its entry onto the US marker occurred prior to FY 2024.

CMS finalizes NexoBrid does not meet the criteria for new technology add-on payments for FY 2024.

f. REBYOTA™ (fecal microbiota, live-jslm) and VOWST™ (fecal microbiota spores, live-brpk, referred to as 'SER-109' in the proposed rule)

Two manufacturers, Ferrin Pharmaceuticals and Seres Therapeutics, submitted separated applications for new technology add-on payments for FY 2024 for REBYOTA and VOWST,

respectively. CMS notes that both technologies are microbiota-based treatments indicated for the reduction or prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI (rCDI).

In the proposed rule, CMS discussed these two applications as two separate technologies but raised concerns that these applications are substantially similar. After further consideration, including comments received, CMS concludes that REBYOTA and VOWST are substantially similar and evaluates both technologies as one application for new technology add-on payments.

The online application posting for REBYOTA is available at: https://mearis.cms.gov/public/publications/ntap/NTP221017WUDXM. The online application posting for VOWST is available at https://mearis.cms.gov/public/publications/ntap/NTP221016VHL8B.

Newness. 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 stated 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).

VOWST received BLA approval from FDA on April 26, 2023 for the prevention of the recurrence of CDI in patients 18 years of age and older following antibacterial treatment for rCDI. The applicant submitted a request for approval for a unique ICD-10-PCS code for SER-109 and was granted a code effective October 1, 2023 (XW0DXN9).

As summarized in tables in the final rule, both applicants asserted that REBYOTA and VOWST meet the newness criterion. In the proposed rule, CMS noted that although the exact mechanism of action for each biologic is not known, both appear to act on the gut microbiome to suppress CDI and prevent rCDI. CMS also stated that both technologies appeared to map to the same MS-DRGs and were used to treat the same or similar disease (rCDI) in the same or similar population (patients who have previously received standard or care antibiotics for CDI or rCDI). CMS was interested in information on how these two technologies may differ with respect to the newness criterion.

In comments, the applicant for REBYOTA discussed the differences between REBYOTA and VOWST; VOWST is an oral microbiome therapeutic consisting of gram-positive Firmicutes and has a more burdensome administration than REBYOTA. The applicant for VOWST stated that CMS should not evaluate VOWST and REBYOTA as a single applicant because the mechanism of action for both therapies is unknown and therefore it is not possible to conclude the technologies have the same mechanism of action. The applicant also provided additional information about the differences in therapeutic composition, manufacturing process, and route of administration.

After consideration of comments, CMS acknowledges that the exact mechanism of action for each technology is not fully defined but it is not convinced that difference in their manufacturing process, route of administration, dosage and storage result in a substantially different therapeutic mechanism of action. Both applicants provide sufficient data to suggest that their mechanisms of action relate to repopulation of the gastrointestinal microbiome. With regard to differences in therapeutic composition, since both technologies are derived from human stool, it believes there

is overlap between the microorganisms contained in both preparations. Finally, both technologies treat the same disease in the same patient population and are assigned to the same MS-DRGs.

CMS concludes that REBYOTA and VOWST meet the newness criterion. Because these technologies are substantially similar to each other, CMS uses the earliest market availability date submitted as the beginning of the newness period for both technologies. The newness period for REBYOTA and VOWST would begin on the date REBYOTA became commercially available, January 23, 2023.

Cost. CMS summarizes the analysis provided by both applicants demonstrating the technologies meets the cost criterion. CMS concludes that both meet the cost criterion.

Substantial Clinical Improvement. For REBYOTA, the applicant asserted 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS believed additional information was 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 existing technologies.

For VOWST, the applicant asserted that VOWST 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 asserted VOWST improved 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS was concerned that the phase II and phase III trials excluded patients who received ZINPLAVA in the prior 3 months and there was no data comparing the treatment of rCDI utilizing antibiotics plus ZINPLAVA. CMS believed that without a comparison to currently available therapies, there was insufficient evidence to support the applicant's statements that VOWST 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 VOWST to other available treatments.

Both applicants submitted comments and provided responses to concerns raised in the proposed rule. Both applicants provided additional information supporting the use of REBOYTA and VOWST in patients with CHF, a contraindication for ZINPLAVA.

CMS concludes that REBOYTA and VOWST represent a substantial clinical improvement over existing technologies because the technologies improve clinical outcomes by increasing resolution of the disease process over placebo without serious adverse effects for patients who have previously received standard of care antibiotics for rCDI. In addition, CMS believes these technologies restore the gut microbiome and resolve dysbiosis to prevent the recurrence of CDI in patients following antibacterial treatment for rCDI.

CMS finalizes that REBOYTA and VOWST meet all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving REBOYTA will be identified by XW0H7X8 and cases involving VOWST will be identified by XW0DXN9. The manufacturer of REBYOTA stated the cost of the technology is $9,000.00 per patient and projected 2,180 cases in FY 2024. The manufacturer of VOWST stated the cost of the technology is $17,5000.00 and projected 448 cases in FY 2024. Using a weighted average of the cost of REBYOTA and VOWST based on the projected number of cases, the case-weighted average cost is $10,445 for these technologies. The maximum new technology add-on payment for a case involving the use of REBYOTA or VOWST is $6,789.25 for FY 2024.

g. 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 stated 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, 2017. 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 final 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 from 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 stated 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 was 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.[25] CMS noted that the applicant also submitted studies conducted using the SeptiCyte LAB to demonstrate substantial clinical improvement. If SeptiCyte RAPID was substantially similar to SeptiCyte LAB, CMS believed the newness period for this technology would begin on April 6, 2017 and the technology would no longer be considered new and would not be eligible for new technology add-on payments.

CMS also noted 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.

In comments, the applicant clarified that SeptiCyte LAB, the predicate device to SeptiCyte RAPID, was never manufactured, commercialized, or sold in the U.S. The applicant explained that FDA cleared SeptiCyte LAB on April 6, 2017, but Immunoexpress never manufactured or sold the devise in the U.S. The applicant also indicated the devices first sale was on April 20, 2022.

After consideration of comments, CMS believes that SeptiCyte RAPID is not substantially similar to existing diagnostic options and meets the newness criterion. CMS discusses how SeptiCyte RAPID is similar to SeptiCyte Lab and does not represent a new mechanism of action (first criterion); that the technologies map to the same MS-DRGs (second criterion); and treat the same disease and same patient populations (third criterion). CMS concludes that SeptiCyte Rapid is substantially similar to the predicate technology, SeptiCyte Lab.

Because SeptiCyte Lab and SeptiCyte RAPID are substantially similar to each other, CMS uses the earliest market availability date submitted as the beginning of the newness technology for both technologies. Because SeptiCyte LAB has not been available for sale of the U.S. market, CMS is unable to establish the beginning of the newness period for SeptiCyte Lab. Therefore, CMS concludes it is appropriate to use the earliest market availability date submitted for SeptiCyte RAPID as the beginning of the newness period for both technologies. CMS notes that absent additional information from the applicant, it cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market.

CMS concludes that SeptiCyte RAPID meets the newness criterion and the beginning of the newness period is November 29, 2021.

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

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

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

CMS discussed concerns with the information provided. CMS noted 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 was 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 did not provide any evidence demonstrating that SeptiCyte RAPID affects the management of the patient or improves clinical outcomes.

The applicant responded to CMS' concerns and provided eight case studies demonstrating the use of SeptiCyte RAPID. Several commenters also discussed how SeptiCyte RAPID has the potential to improve patient care.

After review of the application and the additional information, CMS remains concerned that SeptiCyte RAPID does meets the substantial clinical improvement criterion by either diagnosing a medical condition earlier or by changing patient management. CMS states the applicant has not demonstrated that SeptiCyte RAPID actually leads to changes in the management of patients by initiating or discontinuing antibiotics. CMS concludes it is unable to determine that SeptiCyte RAPID meets the substantial clinical improvement criterion.

CMS finalizes that SeptiCyte RAPID does not meet the criteria for new technology add-on payments for FY 2024.

h. 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).The applicant submitted an application for FY 2023 but did not meet the July 1, 2022 deadline for FDA approval.[26]

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 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 final rule, for the first criterion, 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, the applicant stated there is no MS-DRG specific for SPEVIGO but indicated that it

[26]An application was submitted and summarized in the FY 2023 IPPS proposed rule (87 FR 28108-28746).

maps to four MS-DRGs. For the third criterion, 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 requested 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 noted 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.

The applicant provided additional information on currently available treatments and how they compare to SPEVIGO. The applicant explained the difference between GPP and plaque psoriasis (PSO) and that despite treatment with PSO agents, many patients with GPP had residual symptoms. The applicant also discussed how GPP results from dysregulation of the innate system involving disruption of interleukin (IL)-36 and PSO has a dysregulation of the IL-17/IL-23 pathway. With regard to whether SPEVIGO may map to the same MS-DRGs as other current treatment for GPP, the applicant maintained that since SPEVIGO is the only FDA approved treatment for GPP flares, it would be the only therapy to be used for patients with GPP flares once it was approved.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS was interested in the applicant providing details about why it decided not to remove charges for prior technology from the cost analysis. The applicant provided an updated cost analysis in which they removed all drug cost center charges. CMS concludes that SPEVIGO meets the cost criterion.

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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS was concerned that the Effisayil-1 study compared 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 and complete clearance was not always achieved with SPEVIGO. CMS was concerned that the results of the trial are not generalizable to the Medicare population; the mean age in the study was 43.2 years for the treatment arm and the study population did not have significant comorbidities. CMS also discussed other concerns about the study design including the short duration and lack of comparative data to existing technologies. CMS stated additional information would be helpful to support the applicant's assertion of superiority over existing technologies.

The applicant provided additional information addressing these concerns. The applicant reiterated that other treatments approved for PSO have been tested in trials with patients with GPP flares that were small, single-arm, uncontrolled studies that did not evaluate endpoints specific to GPP. In addition, due to the lack of FDA-approved treatments as well as consensus on standard of care for GPP flares, placebo can be considered an appropriate comparator. The

applicant noted the FDA requested the inclusion of the placebo arm. The applicant provided additional information about systemic inflammation and provided evidence that systemic inflammation was reduced in conjunction with skin clearance. The applicant believes the study results are generalizable to the Medicare population, because patients with GPP often have multiple comorbidities that make them similar to the Medicare population; patients with comorbidities were not excluded from the Effisayil-1 trial.

Based on the additional information, CMS agrees that SPEVIGO represents a substantial clinical improvement as a treatment option for GPP flares in adult patients.

CMS finalizes that SPEVIGO meets all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving SPEVIGO will be identified by XW03308. The applicant estimated that the average inpatient cost of SPEVIGO is $51,133. The maximum new technology add-on payment for a case involving SPEVIGOR is $33,236.45 for FY 2024.

i. 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.[27] 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.

As summarized in a table in the final rule, for the first criterion, 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, the applicant stated that TECVAYKI will use the same DRG assignments as other treatments for MM. For the third criterion, the applicant stated that the proposed FDA indication is similar to other treatments approved for MM patients.

In the proposed rule, CMS questioned whether or not TECVAYLI was substantially similar to another new technology add-on payment applicant, elranatamab. As of the July 1 deadline,

[27] 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.

elranatamab had not received FDA approval and is therefore no longer eligible for consideration for new technology add-on payments for FY 2024. CMS concludes that TECVAYLI meets the newness criterion. The beginning of the newness period is when the product became commercially available, on November 9, 2022.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS concludes 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. This information is summarized in a table in the final rule.

CMS discussed concerns with the information provided. CMS was concerned that the evidence supporting the claim that TECVAYLI provides a treatment option for patients that cannot receive other treatment options did not include CAR T-cell therapies. In addition, CMS noted 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 questioned the applicable of this information to RRMM. CMS was also concerned that the evidence supporting improved safety focused on only a single metric (CRS grade 3 or higher) and was not based on a comparative study. CMS questioned whether there is significant clinical improvement compared to CAR T-cell therapies.

The applicant provided additional information addressing these concerns. The applicant reiterated that TECVAYLI improved clinical outcomes for patients with RRMM and plays an important role in addressing unmet need for patients, including Medicare beneficiaries, who are otherwise ineligible for, or unable to access, other treatments for RRMM. The applicant stated there is no direct comparison data available but compared the safety profile for TECVAYLI to CAR T-cell therapies. Another commenter stated that BCMA-directed bispecific antibody therapies for RRMM represent a substantial clinical improvement over existing treatment options and discussed how many patients do not have access to CAR T-cell therapies.

CMS concludes that TECVAYLI represents a substantial clinical improvement as a treatment option for a patient population unresponsive to, or ineligible for, currently available treatment. CMS agrees that TECVAYLI offers a treatment option for patients ineligible for CAR T-cell therapy or for who CAR T-cell therapy is not an available therapy and who are not ineligible for XPOVIO.

CMS finalizes that TECVAYLI meets all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving TECVAYLI will be identified by XW01348. The applicant estimated that the average inpatient cost of TECVAYLI is $13,754.67. The maximum new technology add-on payment for a case involving TECVAYLI is $8,940.54 for FY 2024.

j. 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).[28] 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 October 14, 2022; they 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 final rule, for the first criterion, 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, 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, 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 remained concerned that although TERLIVAZ might be the first treatment specifically indicated for the treatment of HRS, it did 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 stated 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.

In response, the applicant stated that TERLIVAZ offers an effective treatment for patients with HRS with rapid reduction in kidney function who are unresponsive to existing off-label therapies. The applicant noted that a large portion of patients in the CONFIRM trial failed prior therapy for HRS and in this subgroup of patients, treatment with TERLIVAZ was associated with a greater rate of verified HRS reversal compared to placebo. In addition, TERLIVAZ is listed as the preferred therapy for HRS by several U.S. and international guidelines. Several

[28] 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.

commenters also provided support for TERLIVAZ's eligibility for new technology add-on payments.

Based on review of comments, CMS concludes that TERLIVAZ has a unique mechanism of action and concludes that it meets the newness criterion. The beginning of the newness period is the date TERLIVAZ became commercially available, October 14, 2022.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS concludes 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 final rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS had several concerns with the information presented in support of substantial clinical improvement. CMS was concerned about the use of verified HRS reversal as the primary endpoint in the CONFIRM study (Phase 3 trial). CMS questioned whether this is a clinically significant and appropriate measure of improvement in renal function. CMS noted 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 noted 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 believed it did not appropriate to draw conclusions form post-hoc analyses alone without additional outcome data.

The applicant provided additional information addressing these comments. The applicant explained that the data from the post hoc analysis was derived from the largest, double-blind, randomized, placebo-controlled clinical trial of TERLIVAZ to date. The applicant also stated that the endpoint of durability of HRS reversal is a more objective measure of sustained improvements in renal function than verified HRS reversal without HRS recurrence because HRS that develops due to the hemodynamic alterations from portal hypertension and cirrhosis can recur. The applicant stated that although the CONFIRM trial was not powered to detect a difference between therapies in patients aged 65 years and older, the mean age in the trial was 54 years, and approximately 18 percent of patients in each treatment group was aged 65 years and older. In addition, the applicant provided a manuscript that has been accepted for publication, that provided additional analysis in patients aged 65 years or older with HRS. Several commenters also indicated that the CONFRIM trial demonstrated the substantial clinical improvement of TERLIVAZ as compared with placebo on multiple outcomes.

CMS agrees that TERLIVAZ represents a substantial clinical improvement over existing technologies because it is the only FDA-approved treatment for HRS patients and significantly improves clinical outcomes among HRS patients.

CMS finalizes that TERLIVAZ meets all three criteria for new technology add-on payments and approves add-on payments for FY 2024. Cases involving TERLIVAZ will be identified by XW03367 and XW04367. The applicant stated the WAC of TERLIVAZ is $950 per vial and the mean treatment duration in the CONFIRM trial was 6.2 days using 27 vials. The applicant estimated that the average inpatient cost of TERLIVAZ is $25,650. The maximum new technology add-on payment for a case involving TERLIVAZ is $16,672.50 for FY 2024.

k. 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.[29] 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 final, for the first criterion, 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, the applicant stated that lung imaging ICD-10-PCS codes do not determine the MS-DRG assignment upon discharge. For the third criterion, the applicant discussed how the use of XENOVIEW would not be for a distinct disease or patient population. CMS stated 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.

The applicant submitted a comment reiterating that XENOVIEW is FDA-approved as a new chemical entity and that no conventional existing imaging or pulmonary function testing can report regional specific quantified ventilation defect percentage (VDP). The applicant also discussed why cases involving XENOVIEW would be assigned to different MS-DRGs than cases involving the use of other MRIs and imaging modalities for pulmonary function and imaging of the lungs.

CMS continues to believe that cases involving the use of XENOVIEW or other MRIs and imaging modalities for pulmonary function and imaging of the lungs have the same primary diagnosis codes and would be assigned to the same MS-DRGs. CMS does agree that

[29] 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.

XENOVIEW uses a new mechanism of action to provide a detailed, quantifiable image of gas distributions in regions of the lung. CMS concludes that XENOVIEW meets the newness criterion. The newness period began on the date of FDA approval, December 23, 2022.

Cost. In the proposed rule, CMS noted that the applicant limited its analysis to eight MS-DRGs and was 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. The applicant revised its cost analysis to include MS-DRGs 204-206. Based on this analysis, CMS concludes that XENOVIEW meets the cost criterion.

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 was concerned 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 questioned 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.

In response to these concerns, the applicant provided additional information supporting its assertion that the technology provides information on lung ventilation defects that impact treatment decisions and patient outcomes. The applicant states that as a diagnostic test, XENOVIEW MRI would not be expected to directly change health outcomes; rather, a diagnostic test affects health outcomes through changes in disease management. Several additional commenters supported the use of XENOVIEW to aid in the characterization of the patient's disease and described how the information impacted patient management.

Based on review of the comments and additional information, CMS continues to have concerns about how this technology influences patient management. CMS notes that although commenters provided statements as to how XENOVIEW could be used, these testimonials appear to consist of hypothetical use cases, and it is uncertain how this reflects the actual use of XENOVIEW in the inpatient Medicare population. In addition, there was no evidence submitted demonstrating the use of XENOVIEW actually affects the management of patients, such as a change in diagnosis, a change in treatment planning, or discontinuation of or intensification of treatment regimens. CMS concludes it cannot determine whether XENOVIEW meets the substantial clinical improvement criterion.

CMS finalizes that XENOVIEW does not meet the criteria for new technology add-on payments for FY 2024.

7. 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 existing technologies.

Applications for new technology add-on payments must have FDA market authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS final rule, CMS provided for conditional approval for a technology submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) that did not receive FDA marketing authorization by the July 1 deadline for the particular fiscal year for which the applicant applied for add-on payments.[30] 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 prior to the issuance of the proposed rule. Prior to the issuance of the final rule, seven additional applicants withdrew their respective applications for the Selux NGP System, Total Ankle Talar Replacement, Transdermal GFR Measurement System, Ceribell Delirium Monitor, NUsurface, 4WEB Ankle Truss System and the Nelli Seizure Monitoring System. One applicant, Lim Flow did not meet the July 1 deadline for FDA approval or clearance. Of the remaining 12 applications, CMS approved 11 and conditionally approving 1 for new technology add-on payments for FY 2024. These 12 applications include 9 technologies that received Breakthrough Device designation and 3 were designated as a QIDP.

The following applications were approved: Aveir™ AR Leadless Pacemaker; Aveir™ Dual-Chamber Leadless Pacemaker; Canary Tibial Extension with Canary Health Implanted Reporting Processor System; Ceribell Status Epilepticus Monitor; DETOUR System; EchoGo Heart Failure 1.0; Phagenyx® System; SAINT Neuromodulation System; TOPS™ System; taurolidine/heparin (conditional approval); REZZAYO™; and XACDURO®.

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 technology add-on payment is the less of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS-DRG payment for the case.

The 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 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

[30] 85 FR 58737 through 58742

cost criterion for certain applications are available in Table 10 associated with the information posted on the CMS website.[31]

a. Alternative Pathway for Breakthrough Devices

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.

(1) 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 below, 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 received FDA approval on June 29, 2023 for the same indications as the Breakthrough Device designation. The Aveir AR Leadless Pacemaker was granted approval for procedure code X2H63V9, effective October 1, 2023.

CMS noted 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 believed 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 stated 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 believed the only eligible use of the AR Leadless Pacemaker would be included under the new technology add-on payment application for the Dual-Chamber Leadless Pacemaker.

In response, the applicant stated the Aveir system is modular, which allows a single device to be implanted initially in a heart chamber and the second pacemaker added when the clinical need arises. The applicant asserted that the Aveir AR Leadless Pacemaker is a Breakthrough Device

[31] 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.

for atrial pacing. The applicant also provided a list of clinical scenarios and procedure codes for which it believed either the Aveir AR Leadless Pacemaker or the Aveir Dual-Chamber Leadless Pacemaker qualified for the Breakthrough Device designation; procedure code X2H63V9 could be used for de novo insertion of atrial only single chamber leadless pacemaker, or removal and replacement of right single chamber leadless pacemaker. Another commenter requested CMS clarify the clinical scenarios for which the new technology add-on payment would apply.

CMS concludes that only the of the Aveir AR Leadless Pacemaker as part of an upgrade procedure to dual chamber pacemaker, or as part of a De Novo insertion of the Aveir Dual Chamber Leadless Pacemaker, are consistent with the Breakthrough Designation and eligible for new technology add-on payments. CMS notes that procedure code X2H63V9 (Insertion of dual-chamber intracardiac pacemaker into right atrium, percutaneous approach, new technology group 9) describes upgrade procedures to dual-chamber pacing by implanting a leadless pacemaker into the atrium only where the patient already has a ventricular leadless pacemaker.

Cost. In the proposed rule, CMS questioned whether searching for cases utilizing standard pacemakers instead of leadless pacemakers would better reflect the technology the AR Leadless Pacemaker will be replacing. In response, the applicant revised its cost analysis. Based on this analysis, CMS concludes that the technology meets the cost criterion.
CMS finalizes its proposal to approve new technology add-on payments for Aveir AR Leadless Pacemakers for FY 2024. CMS reiterates that only the use of the technology in the insertion of a dual chamber system is relevant for the purposes of new technology add-on payments. Cases eligible for the add-on payment will be identified by procedure code X2H63V9. The beginning of the newness period is June 29, 2023, the date of FDA marketing authorization for the indications covered by the Breakthrough Device designation. Based on information provided by the applicant, the cost per case of Aveir AR Leadless Pacemaker is $16,500. The maximum new technology add-on payment for a case involving the technology is $10,725.

(2) *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 received FDA approval on June 29, 2023 for the same indications as the Breakthrough Device designation. The Aveir Dual-Chamber Leadless Pacemaker was granted approval for procedure codes X2H63V9 and X2HK3V9, effective October 1, 2023.

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. *Cost*. In the proposed rule, CMS questioned whether searching for cases utilizing standard pacemakers instead of leadless pacemakers would better reflect the technology the AR Dual-Chamber Leadless Pacemaker will be replacing. In response, the applicant revised its cost analysis. Based on this analysis, CMS concludes that the technology meets the cost criterion.

CMS finalizes its proposal to approve new technology add-on payments for Aveir Dual-Chamber Leadless Pacemakers for FY 2024. The beginning of the newness period is June 29, 2023, the date of FDA marketing authorization for the indications covered by the Breakthrough Device designation. Cases eligible for the add-on payment will be identified by procedure code X2H63V9 in combination with X2HK3V9. Based on information provided by the applicant, the cost per case of Aveir Dual-Chamber Leadless Pacemaker is $24,000. The maximum new technology add-on payment for a case involving the technology is $15,600.
(3) 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 was approved ICD-10-PCS procedure codes XNHG0F9 and XNHH0F9.

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

Based on preliminary information provided by the applicant the cost of CTE with CHIRP System is approximately $1,654 per knee. This included $1,309 for the CTE and $345 for the Canary Medical Home Base Station. Because the Home Base Station is provided to the patient to set up and connect to their home Wi-Fi prior to surgery, CMS believed this cost would not be relevant to inpatient costs. CMS proposed 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.

The applicant stated that the CTE with CHIRP is a system requiring both the CTE and the Home Base Station components for the system to function. CMS responds that the Home Base Station is not an item that the patient takes home when discharged from the hospital. CMS excludes the Home Base Station from the add-on payment and concludes the add-on payment would include only the cost of the CTE. CMS welcomes additional information from the applicant for future consideration.

CMS finalizes its proposal to approve new technology add-on payments for CTE with CHIRP System for FY 2024. The beginning of the newness period is October 4, 2021, the date the product was commercially available. Cases eligible for the add-on payment will be identified by procedure code XNHG0D9 or XNHH0D9. Based on information provided by the applicant, the cost per case of Aveir Dual-Chamber Leadless Pacemaker is $1,309 per knee. The maximum new technology add-on payment for a case involving the technology is $850.85 per knee.

(4) Ceribell Status Epilepticus Monitor

Ceribell submitted an 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 technology received 510(k) clearance on May 23, 2023 for the Breakthrough Device designation. The applicant was approved ICD-10-PCS procedure code XX20X89, effective October 1, 2023.

In the proposed rule, CMS noted that the Ceribell EEG Headband and Pocket EEG are not included on the Breakthrough Device designation. CMS stated that only the software would be eligible for new technology add-on payments under the alternative pathway.

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

The applicant submitted a revised cost analysis because they updated their pricing structure to commercialize the technology through a subscription-based pricing model. Under this model, a hospital will pay a fixed monthly subscription for use of the software that allows the hospital to

utilize the technology without limitations on volume. CMS summarizes this updated analysis and concludes the technology still meets the cost criterion.

CMS finalizes its proposal to approve the Ceribell Status Epilepticus Monitor for new technology add-on payments for FY 2024. The beginning of the newness period is May 23, 2023, the date the device received 510(k) clearance by the FDA. Cases will be identified by procedure code XX20X89. Based on the updated information provided by the applicant the cost per case of the Ceribell Status Epilepticus Monitor is $1,406 based on the cost of only the software. The maximum new technology add-on payment will be $913.90 for FY 2024.

(5) 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 received FDA premarket approval on June 7, 2023, for the same indication. The applicant was granted an approval for four procedure codes effective October 1, 2023.

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

CMS finalizes its proposal to approve the DETOUR System for new technology add-on payments for FY 2024. The beginning of the newness period is June 7, 2023. Cases will be identified by the four approved procedure codes. Based on information provided by the applicant the cost per case of the DETOUR System is $25,000. The maximum new technology add-on payment will be $16,250 for FY 2024.

(6) 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. EchoGo 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 was granted approval for procedure code XXE2X19, effective October 1, 2023.

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

CMS finalizes its proposal to approve the EchoGo Heart Failure 1.0 for new technology add-on payments for FY 2024. The beginning of the newness period is November 23, 2022. Cases will be identified by procedure code XXE2X19. Based on the information provided by the applicant the cost per case of the EchoGo Heart Failure 1.0 is $1,575. The maximum new technology add-on payment will be $1,023.75 for FY 2024.

(7) Phagenyx® System

Phagenesis Ltd. Submitted an application for the Phagenyx System, a neurostimulation device for the treatment of neurogenic dysphagia.[32]

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 procedure code (XWHD7Q7). In a comment, the applicant provided an update on the availability of the device, stating the actual commercial availability of the device was established when FDA cleared the product from U.S. customs on April 12, 2023.

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

CMS finalizes its proposal to approve the Phagenyx System for new technology add-on payments for FY 2024. The beginning of the newness period is April 12, 2023, the date the technology became commercially available. Cases will be identified by procedure code XWHD7Q7. Based on the information provided by the applicant the cost per case of the Phagenyx System is $5,000. The maximum new technology add-on payment will be $3,250 for FY 2024.

[32] 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.

(8) 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).[33]

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 describe procedures using the technology.

CMS noted 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 was interested in additional information regarding the Breakthrough Device status of the integrated, single unit system as it becomes available.

In comments, the applicant stated they will commercially launch the SAINT Neuromodulation System on April 15, 2024. The applicant also stated that the company is also continuing to develop future versions of the technology but intends that these modifications to the hardware system will be substantially equivalent to the hardware components in the current system. In response, CMS states it is unclear whether the technology would be available for sale prior to April 15, 2024 and it considers the newness date for this technology to be September 1, 2022. CMS welcomes additional information for future rulemaking.

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

CMS finalizes its proposal to approve the SAINT Neuromodulation System for new technology add-on payments for FY 2024. The beginning of the newness period is September 1, 2022, the date the device received FDA marketing authorization for the Breakthrough Device designation indications. Cases will be identified by procedure code X0Z0X18. Based on the

[33] An application for this technology was submitted for new technology add-on payments 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.

information provided by the applicant the cost per case of the SAINT Neuromodulation System is $19,500. The maximum new technology add-on payment will be $12,675 for FY 2024.

(9) 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 from 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 noted 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 describe procedures using this technology.

The TOPS System received premarket approval from FDA on June 15, 2023 for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5.

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

CMS finalizes its proposal to approve the TOPS System for new technology add-on payments for FY 2024. The beginning of the newness period is June 15, 2023. CMS notes that only the use for patients suffering from neurogenic claudication resulting from degenerative spondylolisthesis, and the FDA Breakthrough Device designation, are relevant for new technology add-on payment eligibility. Cases will be identified by procedure code X0Z0X18 in combination with ICD-10-CM code M48.062. Based on the information provided by the applicant the cost per case of the SAINT Neuromodulation System is $19,500. The maximum new technology add-on payment will be $11,375 for FY 2024.

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).

In the proposed rule, CMS noted 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). DefenCath did not receive FDA marketing authorization by July 1, 2023 and therefore no new technology add-on payments with be made for cases involving the use of DefenCath for FY 2023. The applicant submitted a second application in the event that it did 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 procedure code XY0YX28 may be used to procedures using this technology.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS concluded that the taurolidine/heparin meets the cost criterion.

CMS grants conditional approval for new technology add-on payments for FY 2024, subject to the technology receiving FDFA marketing authorization by July 1, 2024. CMS states the following options apply to the application:

- If taurolidine/heparin 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 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 information from the applicant, the cost per case of taurolidine/heparin is $22,815. The maximum new technology add-on payment for a case involving the use of taurolidine/heparin would be $17,111.25 (75% of the average cost of the technology) for FY 2024.

(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. The applicant stated that REZZAYO would not be commercially available until July 2023; a rationale for the delay was not provided. The applicant was granted approval for procedure codes XW033R9 and XW043R9, effective October 1, 2023.

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

CMS finalizes its proposal to approve REZZAYO for new technology add-on payments for FY 2024. The beginning of the newness period is March 22, 2023. CMS notes the applicant did not provide information explaining a documented delay in market availability. Cases will be identified by procedure XW033R9 and XW043R9. Based on the information provided by the applicant the cost per case of REZZAYO is $5,850. The maximum new technology add-on payment will be $4,386.50 (75% of the average cost of the technology) for FY 2024.

(3) XACDURO® (sulbactam/durlobactam)

Entasis Therapeutics submitted an application for XACDURO, 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). XACDURO 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.

XACDURO received QIDP designation for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii. The applicant stated it was 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 noted that under the alternative pathway, only the FDA QIDP designation, the use of XACDURO for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii, is eligible for new technology add-on payments. The applicant was granted approval for procedure codes XW033K9 and XW043K9, effective October 1, 2023.

XACDURO received FDA approval on May 23, 2023, with an indication for use in patients 18 years of age and older for the treatment of HABP/VABP caused by susceptible isolates of ACtinetobacter baumanni-calcoaceticus complex; an indication within the scope of the QIDPP designation.

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

CMS finalizes its proposal to approve XACDURO for new technology add-on payments for FY 2024. The beginning of the newness period is May 23, 2023. Cases will be identified by procedure XW033K9 and XW043K9 in combination with ICD-10-CM codes Y95 and J15.6. Based on updated information provided by the applicant the cost per case of XACDURO is $18,240. The maximum new technology add-on payment will be $13,680 (75% of the average cost of the technology) for FY 2024.

8. Other Comments

CMS notes it received several comments that are outside the scope of the proposals included in the proposed rule and it is not addressing them in this final rule. Comments included recommendations for changes to the new technology add-on payment policies including increasing the payment amount to 85 percent or more, expanding the alternative pathway to include additional FDA designations, and expand the conditional approval process to additional designations. CMS may consider these recommendations for possible proposals in future rulemaking.

9. Modification of New Technology Add-On Payment Application Eligibility Requirements Related to FDA Application Status and Moving the FDA Marketing Authorization Deadline from July 1 to May 1 for Technologies that Are Not Already FDA Market Authorized

In the proposed rule, CMS discussed the information submitted and the process it uses for determining whether a 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 noted 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. 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 finalizes its proposal 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 it is not in an inactive status such as withdrawn, the subject of a Complete Response Letter or a final decision from FDA refusing to approve the application, or on hold).

- An applicant must provide documentation of the market authorization request when the application is submitted to CMS. CMS finalizes 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 or filing letter.

CMS finalizes its proposal 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.

In the proposed rule, CMS also discussed 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.

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

As discussed below, CMS noted commenters' concerns regarding the potential impact of the shortened time period between April 1 and May 1, and it anticipates considering potential changes to the April 1 cut-off for the third year of new technology add-on payments to allow for a longer window of eligibility in future rulemaking.

A few commenters supported the proposals. Many commenters stated they understood the policy goals behind the proposal, but provided alternatives to achieve those goals or asked for a delay in implementation. Other commenters disagreed that the proposals would improve transparency, facilitate public input or improve the review process.

In response to commenters who did not believe the proposals would achieve CMS' policy goals and thought the proposals were designed to reduce the number of applications or decrease CMS' workload, CMS reiterates the intent of the proposals is to address the ever-increasing complexity and number of applications lacking critical information needed to evaluate the new technology add-on payment criteria. Applications that have not yet received FDA marketing authorization often have incomplete information about the indication, lack cost information, and provide

limited clinical information and supporting data. CMS notes that public commenters in previous final rules have stated they cannot meaningfully comment on a product that has not yet been FDA approved. CMS believes more comprehensive applications will allow CMS to better identify critical questions in the proposed rule and will enable more informed public comments.

CMS recognizes that some applicants submit prior to submitting applications for FDA marketing authorization to strategically identify concerns CMS may have with the new technology. CMS acknowledges this could be advantageous for an applicant, but it does not believe it is an appropriate use of resources to evaluate applications for technologies that will not be eligible in time for the particular rulemaking cycle. CMS notes that over the last 4 years, 50 to 75 percent of applications did not meet the July 1 deadline for obtaining marketing authorization.

CMS disagrees with commenters' assertions that the proposals would not improve transparency and impact the volume or complexity of Breakthrough Device applications. CMS believes that requiring an FDA marketing authorization request to have been submitted and in active status at the time of applicants submitting information will provide critical information needed to determine eligibility and the interrelationship between the intended indications and the FDA Breakthrough Device designation.

CMS disagrees with commenters' assertions that the proposals would create a barrier to accessing innovative technologies. CMS notes that patient access to new technologies should not be adversely affected if a technology does not qualify to receive new technology add-on payments, because it continues to pay for new technologies through the regular payment mechanism established by the MS-DRG methodology. In addition, a determination of a new technology add-on payment does not affect coverage of the technology or the ability of a hospital to provide a technology to patients when appropriate.

CMS maintains the proposed process does not eliminate flexibilities in the process. CMS notes that applicants can continue to provide information as it becomes available according to its current processes, such as the December supplemental deadline and the public comment period. In addition, the FDA marketing authorization is not required at the time of application. CMS does not anticipate the proposals will discourage applicants from applying for new technology add-on payments.

Several commenters recommended that if CMS finalizes the aspect of its proposal to move the FDA approval date to May, it also adjusts its regulations to provide all devices would be granted 3 fiscal years from the time of the new technology add-on payment approval, independent of the timing of the FDA approval. A few commenters noted that the proposal could mean CMS has less claims data to determine the MS-DRG payment rate. CMS responds that it anticipates considering for future rulemaking changes to how to assess new technology add-on payment eligibility in the third year of newness, such as consideration of adjusting the April 1 cut-off to allow for a longer window of eligibility.

Some commenters performed analysis to demonstrate the potential impact of the proposed May 1 deadline policy. In response, CMS notes that many of the commenters may have conflated FDA approval dates with the newness period start date. CMS notes that in certain circumstances, the

newness start date may occur after the FDA marketing authorization date. CMS notes that its data analysis over the last 3 years demonstrates that nearly all applicants who submit new technology add-on payments applications prior to FDA submission do not receive FDA approval by the July 1 deadline. Between FY 2021 and FY 2023, only 3.8 percent of applications submitted prior to submission of the marketing authorization application to FDA received FDA marketing authorization prior to the July 1 deadline. During this same time period, only 4 out of 107 applications received FDA marketing authorization between May 1 and July 1 and were approved for new technology add-on payments. CMS concludes that changing the FDA approval date from July 1 to May 1 would affect only a small number of applications.

In response to comments requesting clarification about the requirement to demonstrate that a product was submitted to FDA for marketing authorization, CMS notes that it collaborated with the FDA for developing the terminology in the proposal. CMS states that for the purpose of new technology add-on payment applications, an FDA marketing authorization application is "complete" when the full application has been submitted to the FDA. A full application includes all modules or all information following a rolling review or Real-Time Oncology Review (RTOR). CMS will only accept applications once FDA has received all of the information to determine whether it will accept (such as in the case of a 510k application or De Novo Classification request) or file (such as in the case of a PMA, NDA, or BLA) the application, as demonstrated by the acceptance/filing letter that is provided by FDA to indicate it has determined the application is sufficiently complete to allow for substantive FDA review. CMS considers an FDA marketing authorization application to be in an "active" status when it has been determined to be sufficiently complete to permit substantive review by FDA, and when it is still under review at the time the application is submitted (this means it is not in an inactive status such as withdrawn, the subject of a Complete Response Letter or final decision from FDA to refuse to approve the application, or on hold).

CMS will require applicants to provide the initial acceptance or filling letter that is provided by FDA after its initial administrative review. CMS will not require specific documentation from FDA to demonstrate continued "active status" after initial acceptance or filing. CMS acknowledges that the FDA application process is dynamic and could switch from "active" to "on hold" at any time for various reasons. CMS notes that when FDA provides applicants with a "Refuse to File" (RTF) or "Refusal to Accept" (RTA) letter, this specifically indicates that FDA has determined the application is not complete.

Commenters recommended a wide range of changes to the process, including more frequent application cycles, requiring proof of active FDA review by the December supplemental information deadline, expand eligibility for conditional implementation, delay implementation, and solicit input from stakeholders instead of implementing the proposed policy. CMS notes there are a number of complexities, both legal and operational, that CMS would need to consider before increasing the frequency of new technology add-on payment application review cycles. CMS continues to believe that the appropriate deadline for submission of a request for FDA marketing authorization is at the time the application is submitted to CMS. CMS notes it does not have sufficient experience with the conditional approval process to expand eligibility. It also does not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement before FDA approval.

Regulatory Impact Analysis
For FY 2024, continues 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 will be approximately $131 million.

CMS approves 10 technologies for 8 new technologies under the traditional pathway for FY 2024 new technology add-on payments. CMS estimates the aggregate total FY 2024 payments for these new technology add-on payments will be approximately $59 million.

CMS approves 12 technologies (3 designated as A QIDP) under the alternative pathway for FY 2024 new technology add-on payments. CMS estimates that the total payment for these technologies will be approximately $305 million. Total estimated FY 2024 payments for QIDP designated new technologies are approximately $218 million and the total estimated FY 2024 payments for new technologies that are part of the Breakthrough Device program are approximately $87 million.

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

CMS adjusts a portion of IPPS payments for area differences in the cost of hospital labor—the wage index. Section 1886(d)(3)(E) of the Act requires an annual update to the wage index based on a survey of wages and wage-related costs (fringe benefits) of short-term, acute care hospitals which the agency collects on Medicare cost reports (CMS Form 2552-10, Worksheet S-3, Parts II, III, and IV). Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program in order to construct an occupational mix adjustment to the wage index. All changes made to the wage index annually are required to be budget neutral.

A. Labor Market Areas

Hospitals are assigned to labor market areas and the wage index reflects the weighted (by hours) average hourly wage reported on Medicare cost reports. CMS uses Office of Management and Budget (OMB) Core-Based Statistical Areas (CBSAs) delineations as labor market areas. CMS is currently using OMB delineations from 2015 (based on the 2010 census) updated by OMB Bulletin numbers 13-01, 15-01, 17-01, 18-04 and 20-01.

B. Worksheet S-3 Wage Data

The final rule wage index values are based on data from FY 2020 submitted cost reports. CMS did not propose any changes to the categories of included and excluded costs for FY 2024 relative to prior years. CMS' final rule calculations of the FY 2024 wage index are based on wage data of 3,129 hospitals. The data file used to construct the final rule wage index includes FY 2020 data submitted to CMS as of June, 2023.

CMS notes that the data that it is using for the FY 2024 wage index spans the COVID-19 PHE. The proposed rule presented 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 indicated 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.

There were several comments objecting to CMS' use of hospital cost report data for the wage index that included the time period when the COVID-19 public health emergency was in effect. Public commenters suggested CMS should use alternative data and cited reports that contract labor rates are expect to stay more than 15 percent above pre-pandemic levels.

CMS's general response to these comments was that it did not find any problems with the current wage index data that would suggest it should no longer be used to determine the wage index for FY 2025. Further, any comments either did not provide any alternative or demonstrate that the current wage index data was sufficiently problematic such that it could no longer be used.

General wage index policies are unchanged from prior years. CMS proposed to exclude 88 providers due to aberrant wage data that failed edits for accuracy. However, CMS indicated in the proposed rule that if data aberrancies for these providers are resolved timely, it will include data from these providers to set the final rule FY 2024 wage indexes. For the final FY 2024 wage index, CMS restored the data of 27 hospitals because their data was either verified or improved. Thus, 61 hospitals with aberrant data remain excluded from the FY 2024 wage index.

As in past years, public commenters objected to CMS excluding wage data for hospitals that may have had a high average hourly wage relative to its labor market area where those higher costs were supported with documentation. Among other comments, public commenters requested CMS provide more transparency for when wage data is excluded from the calculation of the wage index.

CMS responded to these comments citing its responses in prior rules and further indicating that it has the discretion to exclude aberrant hospital data from the wage index even if those wages appear to be accurate. The final rule cites the example of a California hospital that has an average hourly wage that is extremely and unusually high relative to other hospitals in its CBSA. While CMS believes the wage data to support this average hourly wage is reliable, the aberrant result may be from a unique salary structure and business model of the hospital. CMS continues to believe the hospital's data should be excluded from the wage index as it is not reflective of local market conditions affecting wages.

While CMS reiterates past replies that it does not share audit protocols for desk audits of the wage index, it will consider a limited proposal regarding criteria for excluding a hospital's data from the wage index. Additionally, CMS will consider methods for communicating with stakeholders regarding the accuracy of their data.

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 final rule includes a detailed listing of these steps. CMS calculates an unadjusted national average hourly wage of $50.39.

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 (3,031 of 3,129) used to determine the FY 2024 final 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 $50.34.

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 were required to submit their completed 2022 surveys to the MACs by June 30, 2023. The preliminary, unaudited CY 2022 survey data was posted on the CMS website in mid-July 2023: https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2025-wage-index-home-page. (Select #2 which includes the occupational mix data even though the title says it is only the data collection form.)

As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2025 desk review process, the MACs will revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures. Hospitals have until September 1, 2023, to request revisions to their Worksheet S-3 wage data and CY 2022 occupational mix data as included in the wage and occupational mix preliminary public use files.

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	228 (55.3%)
Number of Rural Areas Wage Index Increasing	26 (55.3%)
Number of Urban Areas Wage Index Increasing 1%<= and <5%	122 (29.6%)
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	182 (44.2%)
Number of Rural Areas Wage Index Decreasing	21 (44.7%)

Comparison of Occupational Mix Adjusted to Unadjusted Wage Index	
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%	12 (25.5%)
Number of Rural Areas Wage Index Decreasing >5%	0 (0%)
Largest Positive Impact for an Urban Area	7.12%
Largest Positive Impact for a Rural Area	4.11%
Largest Negative Impact for an Urban Area	-5.55%
Largest Negative Impact for a Rural Area	-2.59%
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

1. Rural Floor

Background and History. 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 indicates in the final rule that the rural floor will increase the FY 2024 wage index for 646 urban hospitals (compared to 275 in FY 2023) requiring a budget neutrality adjustment factor of 0.978183 (-2.18 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 proposed 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, 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 proposed 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.

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 proposed to continue this policy. CMS also proposed 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.

Comment/Response

General Comments: Public commenters generally supported CMS' proposals stating that the inclusion of urban to rural classified hospitals in the rural wage index faithfully executes the statutory provision that these hospitals be treated "as being located in the rural area [of its state]". However, one commenter stated that the proposed changes "illustrate the complexity, inconsistency, and even irrationality of the wage index system." One commenter noted that the proposed change to the calculation of the rural wage index and rural floor would help further reduce the disparity between high and low wage index hospitals due to its larger impact on hospitals with wage index values at or below the 25th percentile. There were comments expressing concern about the magnitude of the budget neutrality requirement necessary to support this policy.

CMS responded to the comment regarding disparity in wage indexes noting that nearly half of all IPPS hospitals will be assigned their state's rural wage index in FY 2024. The final rule indicates that this number will increase in future years as hospitals adjust to the policy and as the relative value of states' rural wage index values increase due to the strategic inclusion of hospitals that

obtain urban to rural reclassifications. An outcome of this trend would be that the majority of hospitals (if not all) will be assigned identical wage index values as all others within the same state. This would greatly reduce wage index variations within a state but might dramatically increase wage index differentials between states.

With respect to the budget neutrality concerns, CMS states its policy will result in substantially more hospitals receiving the rural floor or a hold harmless floor that applies to urban counties where a hospital reclassified from urban to rural and a consequently greater budget neutrality impact. CMS acknowledges the tension between the section 1886(d)(3)(E) requirement for the wage index to reflect relative differences in hospital wage levels and the section 1886(d)(8)(E) requirement to treat urban to rural reclassified hospitals as being located in the rural area of the state. However, the latter provision produces the result that more hospitals are able to obtain a rural floor wage index increasing the level of the budget neutrality adjustment. Current statute requires that CMS apply a budget neutrality adjustment and that it be applied on a nationwide basis rather than within each state as one commenter had implied that CMS consider.

Medicare Advantage (MA): Several commenters cited potential severe financial hardships (including increased insurance rates) if MA plans are not granted adequate time to transition and adjust to the implications of the policy change. Commenters requested CMS delay changes to the rural wage index or implement a companion policy to counterbalance the effects of the policy in order to provide health plans to adjust to the change.

CMS responded that it is not convinced that the impact of this specific policy is exceptionally unique (in either form or magnitude) from other policy proposals made in past cycles. It is out of the scope of this rulemaking to implement any change in MA payment policy (for example, raising benchmark rates) and outside of CMS' authority to change the statutory bidding deadline for MA organizations (the first Monday in June of the year preceding the payment and coverage year).

Final Decision: CMS is finalizing all of its proposals without modification.

2. 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 65 hospitals by $230 million.

3. 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 $60 million to 42 hospitals in Montana, North Dakota, South Dakota and Wyoming.

4. 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 hospitals raising wages in order to get a higher wage index. For this reason, CMS proposed to continue the low-wage index policy for FY 2024.

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 appealed the District Court decision in Bridgeport. Although CMS proposed to continue this policy for FY 2024, it indicated that it may take a different approach in the final rule, depending on public comments or developments in the court proceedings.

Public Comments:

Future Plans. Several public commenters supported CMS' proposed policy indicating that the policy should be continued until CMS has at least 4 years of post-COVID-19 wage data to evaluate the policy's effectiveness. Some commenters asked that CMS provide clarification on its plans for this low-wage index hospital policy moving forward, urging CMS to specify how many years of data it expects to need in order to evaluate whether the policy has increased wages for low-wage hospitals. One commenter urged CMS to begin evaluation of the policy by specifying criteria for the policy's potential success and at what point it should be terminated.

CMS responded to comments regarding its future plans by reiterating the basis for its proposal—at this time, CMS only has one year of relevant data to evaluate any potential impacts of this policy. Give the lack of sufficient data with which to evaluate the low wage index hospital policy, CMS believes it is necessary to wait until it has useable data from additional fiscal years before making any decision to modify or discontinue the policy. The final rule does not say how long CMS intends to keep the policy in effect as commenters requested.

Budget Neutrality. Several commenters urged CMS to adopt the policy without applying budget neutrality; not applying budget neutrality to hospitals with a wage index below the 25th percentile; only reducing the wage index for hospitals above the 75th percentile, and working with Congress to establish a national floor on the wage index.

CMS cited its response to comments about budget neutrality in prior rules. In summary, CMS believes the statute requires budget neutrality. There is no authority in the statute for budget neutrality to be waived. But even if the statute did not require budget neutrality, CMS does not believe the wage index should be a tool to increase or decrease overall IPPS spending. CMS does not view the wage index as a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage-related costs of IPPS hospitals.

The response further notes that CMS' original proposal was to lessen wage index disparities by increasing the wage index for low wage hospitals and decreasing the wage index above the 75th percentile by a uniform amount to finance the increase. CMS was convinced by public commenters not to adopt that policy. Commenters presented reasonable arguments that CMS should consider regarding the relationship between targeting high wage hospitals and the design of the wage index to be a relative measure of the wages and wage-related costs of IPPS hospitals in the United States.

With regard to establishing a national floor on the wage index, CMS indicates that it does not have evidence a national rural labor market exists or would be created if it were to adopt this alternative. Further, such an alternative would not increase the accuracy of the wage index. CMS also opposed exempting hospitals below the 25th percentile from the budget neutrality adjustment noting the policy distinction between narrowing disparities in the wage index and applying budget neutrality through a uniform adjustment to the standardized amount.

Other Comments. Several commenters opposed the low wage index hospital policy, stating that it is inappropriately redistributive, ineffective, and outside the agency's statutory authority under section 1886(d)(3)(E) of the Act. Specifically, some commenters stated that although the policy is intended to help rural hospitals, some rural hospitals in certain states do not benefit. One commenter stated that the policy undermines the intent of the wage index by not recognizing real differences in labor costs.

CMS cites to responses in earlier rules regarding its legal authority for the low wage index policy. The final rule further reiterates responses from prior rulemaking that CMS sees a need to raise low wage indexes to allow low-wage hospitals the ability to increase wage rates that will eventually be reflected in the wage index. CMS believes the policy is succeeding as there were

public commenters indicating that hospitals have used the higher wage indexes to increase wages.

The final rule indicates that CMS intends to retain the policy until its effects are reflected in the wage index data. Regarding the policy's effect on rural hospitals, CMS reiterates that the intent of the low wage hospital policy is to increase the accuracy of the wage index as a technical adjustment, and not to use the wage index as a policy tool to address non-wage issues related to rural hospitals, or the overall financial health of hospitals in low wage areas or broader wage index reform.

Bridgeport: Some public commenters opposed continuing the policy in light of the *Bridgeport* case . These public commenters also said CMS should undo the budget neutrality adjustments for the low-wage policy for FY 2020 through FY 2023. Other commenters supported CMS appealing the decision in *Bridgeport*. CMS thanked public commenters for their input noting that the case remains in litigation as CMS has appealed the District Court's decision finding CMS' low-wage policy unlawful.

Final Decision: CMS is finalizing the policy as proposed. For FY 2024, the 25th percentile wage index value across all hospitals is 0.86667. To ensure the policy neither increase or decreases total spending, CMS is applying a budget neutrality adjustment of -0.26 percent.

5. 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. CMS is continuing this policy for FY 2024 and estimates the wage index reduction cap will require a budget neutrality adjustment of -0.04 percent.

G. Wage Index Tables

Final rule wage index tables 2, 3 and 4 can be found at: https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page#Tables. Select #2 under FY 2024 Final 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*.

1. Geographic Reclassifications. There are 466 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2024. There are 271 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2022 that will continue for FY 2024. There are 325 hospitals approved for wage index reclassification in FY 2023 that may continue for FY 2024. CMS indicates that there will be 1,062 hospitals in MGCRB reclassification status for FY 2024 (with 187 of these hospitals reclassified back to their home area).

42 CFR §412.273 indicates that "a request for termination [of a geographic reclassification approved for FY 2024] must be received by the MGCRB within 45 days of the date that CMS' annual notice of proposed rulemaking is issued 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 have been 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.

2. 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 the date that CMS' annual notice of proposed rulemaking is issued in the *Federal*

Register" that it is declining its Lugar reclassification). CMS received three timely requests to waive Lugar reclassification that it approved. It declined one request as being untimely. Requests to withdraw Lugar reclassifications are 45 days from public display of the IPPS proposed rule at the *Federal Register* (May 25, 2023).

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 proposed 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 $52 million to 173 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. See section V. C. of this summary for more detail.

K. Process for Wage Index Data Corrections

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

hospitals to request corrections or revisions to audit adjustments. A hospital that fails to meet the procedural deadlines does not have a later opportunity to submit wage index data corrections or to dispute CMS' decision on requested changes.

CMS posts the wage index timetable on its website including all of the public use files made available during the wage index development process. All deadlines are eastern time. The FY 2025 wage index process has already begun. For the FY 2025 wage index timetable go to: https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/fy-2025-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 of 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. Indian Health Service (IHS), Tribal and Puerto Rico Hospitals

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), CMS established a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. This payment was established to help to mitigate the impact of the decision to discontinue the use of low-income insured days as proxy for uncompensated care costs for these hospitals. The supplemental payment for a fiscal year is determined as the difference between the hospital's base year amount (what the hospital would have received in 2022 when it used low-income insured days as a proxy) and its uncompensated care payment for the applicable fiscal year (based on using uncompensated care data from Worksheet S-10).[34] This policy was to prevent undue long-term financial disruption for these providers. If the base year amount is higher than the hospital's uncompensated care payment for the current fiscal year, then the hospital would receive a supplemental payment based on the difference. If it is equal or lower the hospital would not receive a supplemental payment.

The MAC makes a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year.

Comment/Response

Many commenters reiterated their support for CMS' decision in last year's proposed rule to establish a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. These commenters also requested that CMS make all acute care hospitals in Puerto Rico eligible to receive uncompensated care payments, including those that do not qualify for empirically justified DSH payments. MedPAC recommended that CMS alter its methodology for making interim supplemental payments as an add-on payment to the IPPS payment rates for Puerto Rico hospitals to avoid distorting Medicare Advantage (MA) benchmarks. It argued that the $80 million in supplemental payments to Puerto

[34] The base year amount is adjusted for a given hospital by one plus the percent change in the total uncompensated care amount between the base and the applicable fiscal year. If the total uncompensated care amount decreased between the base and applicable fiscal year by 10 percent, for example, then the base year uncompensated care amount for a given hospital used in the supplemental payment calculation would decrease by that percentage.

Rico hospitals in 2023 would inappropriately boost payments to MA plans operating in Puerto Rico by almost $1 billion per year.

In response, CMS continues to believe that its new supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico is needed to address the unique financial circumstances and challenges faced by these hospitals. CMS notes as adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622 and 50623) that hospitals, including Puerto Rico hospitals, must be eligible to receive empirically justified Medicare DSH payments to receive an additional Medicare uncompensated care payment for that year. In response to MedPAC's concern that the supplemental payments would indirectly boost payments to MA plans, CMS notes that about 70 percent of uncompensated care payments represented in Puerto Rico claim records were associated with Part A-only beneficiaries and thus excluded from the MA ratebook calculation.

C. Uncompensated Care Payments

1. 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) June 2023 Medicare DSH estimates, which were based on the March 2023 update of the HCRIS and the FY 2024 IPPS final rule impact file. Starting with these data sources, OACT applies inflation updates and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

OACT's June 2023 Medicare estimate of DSH payments for FY 2024 is $13.354 billion. **The Factor 1 amount is seventy-five percent of this amount, or $10.015 billion.** The final Factor 1 for 2024 is about $446 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 obtain the current DSH estimate for FY 2024. Changes in the factors applied from the proposed to the final rule appear to have been driven largely by changes in the "Other" category.

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	0.9963	0.9919	13.150
2022	1.025	0.941	0.997	0.9939	0.9558	12.568
2023	1.043	0.959	1.005	1.0347	1.0398	13.068
2024	1.031	0.982	1.005	1.0043	1.0219	13.354

- 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 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). CMS notes the "Other" column also includes the estimated impacts on Medicaid enrollment from the COVID-10 pandemic and the end of the PHE declaration on May 11, 2023.[35] It also incorporates the expectation that DSH payments will grow faster than IPPS payments in 2023.

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	3.3	-0.2	0.0	3.1

Comment/Response

Commenters continue to request greater transparency in the methodology used by CMS and OACT to calculate Factor 1 and, in particular, asked for greater detail from CMS on the calculation of the "Other" component. They emphasized their inability to replicate CMS' calculations and some suggested that CMS disaggregate the variables that contribute to the "Other" factor and demonstrate the impacts of each of those variables on the final value.

In its response, CMS disagrees with commenters' assertion regarding the lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. It provides additional context that Factor 1 is not estimated in isolation from other projections made by OACT. CMS does not, however, provide a step-by-step explanation and it does not appear as if it can easily provide that level of detail given the nature of how the calculation and its dependence on data sources that are not available to those trying to replicate the exact values. CMS states, for example, that Factor 1 estimates are generally consistent with the economic assumptions and actuarial analyses used to develop the President's Budget estimates under current law.

CMS refers to other sources that could be helpful in how it calculates Factor 1 but does not provide the step-by-step explanation requested by some commenters.

[35] Medicaid enrollment changes are estimated to increase 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.

- For a general overview of the principal steps involved in projecting future inpatient costs and utilization, CMS refers readers to the "2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds.[36]

- For a discussion on trends in MA enrollment, CMS refers readers to the 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, which contains actuarial projections and assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures.[37]

2. 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.[38] In the final rule, CMS uses the most recent NHEA estimates for the rate of uninsurance, which account for the legislative impacts from the expiration of the Families First Coronavirus Response Act's Medicaid continuous coverage requirement and extension of the American Rescue Plan's Marketplace enhanced premium tax credits and effects of the COVID-19 PHE on insurance coverage.

Using the most recent NHEA data 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 7.7 percent and 8.5 percent, respectively. The uninsured rates based on the update NHEA data are significantly lower than the proposed rule estimates for CYs 2023 and 2024 of 9.3 percent and 9.2 percent, respectively. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates the 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: 7.7 percent.

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[36] See https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/trusteesreports

[37] See https://www.cms.gov/oact/tr

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

- Percent of individuals without insurance for CY 2024: 8.5 percent.
- Percent of individuals without insurance for FY 2024 (0.25 times 0.077) + (0.75 times 0.085): 8.3 percent

Factor 2 = 1-|((0.14-0.083)/0.14)| = 1 - 0.4701 = 0.5929 (59.29 percent)

CMS calculated Factor 2 for the FY 2024 rule to be 0.5929 or 59.29 percent, and the uncompensated care amount for FY 2024 to be $10.015 billion x 0.5929 = $5.938 billion which is about $936 million less than the FY 2023 UCP total of about $6.874 billion; the percentage decrease is 13.6 percent. The table below shows the Factor 1 and Factor 2 estimates for FY 2023 and the factors for FY 2024.

FY 2024 Change in UCP
($ in billions)

	FY 2023	FY 2024	$ Change	% Change
Factor 1	$10.461	$10.015	-$0.446	-4.3%
Factor 2	0.6571	0.5929	-0.0642	-9.8%
UCP	$6.874	$5.938	-$0.936	-13.6%

Comment/Response

Commenters urged CMS to use more recent and accurate data sources to account for the anticipated increases in the uninsured population. Several commenters expressed their concern that the NHEA data that CMS proposed to use for Factor 2 do not reflect current trends in the uninsured rate as the COVID-19 PHE ends, as they appear to be the same data utilized in the FY 2023 IPPS/LTCH PPS final rule.

In reply, CMS states that in this final rule, it is updating Factor 2 using the most recently updated NHEA projections that were released in June 2023, which reflect the most recent historical data and updated expectations for the uninsurance rate. It also refers readers to the OACT memo that accompanies this final rule, which provides additional information regarding the development of the uninsurance rate projection and the reasons why the uninsured projection have declined as related to FY 2024.[39]

In this memorandum, the Actuary states:

> The projected uninsured rate (the percentage of the population who have no source of comprehensive health insurance) for FY24 reflects a combination of factors that result in a projected uninsured rate that is higher in FY24 (8.3 percent) than the lows experienced during the public health emergency (PHE) (7.9 percent in FY22 and 7.7 percent in FY23), but lower than that observed prior to the PHE (9.6 percent in FY19).

[39] OACT Memorandum on Certification of Rates of Uninsured. July 3, 2024. Available at: https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/dsh

The Actuary is indicating that the rate of uninsured for FY 2023 was 7.7 percent. However, the rate of uninsured used to determine the FY 2023 UCP pool was 9.2 percent. Per statute, CMS does not revise these estimates for after-the-fact data that changes projections. Nevertheless, the implication of the Actuary's findings is that the UCP pool for FY 2023 was based on a higher estimate of the rate of uninsurance than the actual rate based on later information which may largely explain the reduction in the UCP pool.

The Actuary also states that the largest impact to the FY 2024 uninsured projection is the "unwinding" of the Medicaid enrollment increases from the past few years. Medicaid enrollment on a month-to-month basis is anticipated to decline by about 17-18 million, from a peak in April 2023 to the end of the unwinding process expected in fall 2024. However, OACT points out that many of those being disenrolled from Medicaid already have overlapping comprehensive coverage from other sources (including private health insurance, the Children's Health Insurance Program, or Medicare). In addition, for those covered under private health insurance the low unemployment rate has maintained strong enrollment in Employer Sponsored Insurance and enrollment in individually purchased insurance is expected to remain robust due to the Inflation Reduction Act's expanded subsidies. Medicare enrollment is also expected to grow as baby boomers continue to become eligible for the program.

3. 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.

CMS uses Worksheet S-10 of the Medicare hospital cost report to determine each hospital's share of uncompensated care costs relative to the national aggregate.

b. Methodology for Calculating Factor 3 for FY 2024

CMS finalizes its proposal to use the same methodology applied in FY 2023 to determine Factor 3 for FY 2024 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. CMS uses the March 2023 update of HCRIS to calculate the final Factor 3 for the final rule (updated from the December 2022 HRCIS used in the proposed rule).

CMS describes the steps it uses to calculate 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)).

Comment/Response

As in the past, some commenters suggested that uncompensated care should include shortfalls from Medicaid, and State and local indigent care programs. However, CMS states that it has compelling arguments for excluding such shortfalls from the definition of uncompensated care and refers readers to past final rules (85 FR 58826; 86 FR 45238; and 87 FR 49039). Some of the reasons CMS has previously cited included that it would be operationally problematic because Medicaid pays hospitals a single DSH payment that in part covers the hospital's costs in providing care to the uninsured and in part covers estimates of the Medicaid "shortfalls." Further, in some states, providers return a portion of their Medicaid revenues to the State via provider taxes, making the computation of "shortfalls" even more complex.

Commenters also provided feedback on the audits of the FY 2020 Worksheet S-10 data and their recommendations for future audits. Similar to prior year comments, commenters suggested a standard audit timeline, a more transparent audit process by disclosing criteria used to identify hospitals for audits, and audit protocols published in advance to allow hospitals time and opportunity to respond to audits and address findings through notice and comment rulemaking. In response to commenters' requests for a standard audit timeline, CMS states it does not intend to establish a fixed timeline for audits across MACs at this time, to ensure it can retain the flexibility to use its limited audit resources to address and prioritize audit needs across all CMS programs each year. CMS also emphasizes that it does not make review protocols public as CMS desk review and audit protocols are confidential and are for CMS and MAC use only.

Commenters expressed concern that the reductions in uncompensated care payments do not align with the Federal Government's focus on equity. One commenter stated, for example, that safety-net hospitals provide eight times more uncompensated care than other hospital types, which disproportionately impacts safety-net hospitals' payments. CMS states that it may consider this issue further in future rulemaking. It also notes that in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27187 through 27190), it included a RFI that sought public feedback on the challenges faced by safety-net hospitals and potential approaches to help safety-net hospitals meet those challenges. CMS states that it is in the process of reviewing those comments.

c. 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 final 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 proposed 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. After consideration of comments received, CMS modified its proposal and will calculate the per-discharge amount of uncompensated care payments using two years of data from FY 2021 and FY 2022. CMS excludes the FY 2020 discharge data as it believes that it would underestimate discharges due to the effects of the COVID-19 PHE in FY 2020.

To reduce the risk of overpayments of interim uncompensated care payments and the potential for unstable cash flows for hospitals and MA plans, CMS continues its voluntary process through which a hospital may submit a request to its MAC for a lower per discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the fiscal year and/or once during the fiscal year. The hospital would have to provide documentation to support a likely significant recoupment – for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000. The only change that would be made would be to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC. This does not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

Comment/Response

Several commenters supported excluding FY 2020 data from the per-discharge amount calculation for interim uncompensated care payments because of continued concerns about lower discharge volumes related to COVID-19 PHE. CMS agrees and notes that it believes the FY 2020 discharge data would underestimate discharges. Thus, CMS finalizes its proposal with modification, and will calculate the per-discharge amount of uncompensated care payments using FY 2021 and FY 2022 discharge data.

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.[40]

For FY 2024 and subsequent years, CMS finalizes its proposal 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.

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

CMS received one comment on this issue that asserted that the proposal affects all hospitals, not just those with recent or pending mergers, and that the time period after the final rule is an important opportunity to address errors and/or verify the final rule's DSH Supplemental File. CMS disagrees and believes the opportunities for providers to notify CMS of discrepancies during the comment period on the proposed rule is sufficient.

D. Section 1115 Waiver Days

1. History of 1115 Waiver Days in the Medicaid Fraction

Medicare makes DSH and UC payments to IPPS hospitals that serve more than a threshold percentage of low-income patients. To be eligible for these payments, the hospital's disproportionate patient percentage (DPP) must meet a minimum percentage. The DPP is the sum of two fractions:

- Medicare Fraction: The proportion of inpatient days for Medicare eligible patients receiving Supplemental Security Income (SSI) over total Medicare inpatient days.
- Medicaid Fraction: The proportion of inpatient days for Medicaid patients not eligible for Medicare over total inpatient days.

For an inpatient day to be included in the Medicaid fraction, the patient must be eligible for inpatient benefits under Medicaid. Not all patients that are Medicaid eligible receive inpatient benefits. Other low-income people may not be eligible for Medicaid at all. Through a section 1115 demonstration project, some states will extend inpatient benefits to patients and to populations that could not have been made eligible for medical assistance under the Medicaid state plan.

CMS reviews the history of its policy on when section 1115 inpatient days could be included in the numerator of the Medicaid fraction of the DPP:

- Prior to 2000, CMS only included section 1115 inpatient days for patients that could have been made eligible for Medicaid under the Medicaid state plan (CMS calls these "hypothetical" Medicaid patients). CMS did not include inpatient days for patients made eligible for Medicaid under a section 1115 waiver that were ineligible for mandatory or optional coverage (CMS calls these "expansion" groups).
- In 2000, CMS changed that policy to include in the DPP Medicaid fraction numerator all patient days of demonstration expansion groups made eligible for matching funds under title XIX, regardless of whether the patients could have been made eligible for Medicaid under a Medicaid state plan.
- In FY 2004, CMS refined this policy to include only those patients eligible to receive inpatient hospital insurance benefits under the terms of a section 1115 demonstration or under the Medicaid state plan in the Medicaid fraction.

In 2005, two federal courts in *Portland Adventist* and *Cookeville*[41] ruled that CMS' policy was contrary to statute reasoning that patients in demonstration expansion groups were necessarily

[41] Portland Adventist Med. Ctr. v. Thompson, 399 F.3d 1091, 1096 (9th Cir. 2005); Cookeville Reg'l Med. Ctr. v. Thompson, 2005 U.S. Dist. LEXIS 33351, *18 (D.D.C. Oct. 28, 2005)

"eligible for medical assistance under a state plan" (that is, eligible for Medicaid even if the coverage did not include inpatient hospital benefits), and the statute had always required including their days in the Medicaid fraction. The preamble to the proposed rule and responses to comments in this final rule indicate that these court decisions were effectively overruled by Congress' enactment of section 5002 of the Deficit Reduction Act (DRA). CMS describes the DRA as ratifying CMS' earlier policy nullified by the courts.

The statutory language that is the basis for CMS' conclusion is section 1886(d)(5)(F)(vi) of the Act, as added by the DRA:

> In determining [the Medicaid fraction] the number of the hospital's patient days for such period which consist of patients who (for such days) were eligible for medical assistance under a State plan approved under title XIX, the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.

The statutory ratification argument is a central feature of CMS' response to comments on this issue. CMS argues that while the *Portland Adventist* and *Cookeville* cases found CMS's pre-2000, 2000 and 2004 policies to be contrary to the statute, those cases were decided in 2005 prior to the enactment of the DRA. The DRA was signed into law on February 8, 2006 or a short time after these cases were decided. CMS argues that in the DRA, Congress affirmed that the Secretary could determine the meaning of "regarded as [Medicaid-eligible]" for determining which inpatient days to include in the numerator of the Medicaid fraction. According to CMS, this statutory action effectively overturned the *Portland Adventist* and *Cookeville* cases.

The proposed rule and responses to comments in the final rule indicate that section 5002 of the DRA provided prospective statutory discretion to the Secretary to determine "the extent" to which patients "not so eligible" for Medicaid benefits "may" be "regarded as" eligible "because they receive benefits under a demonstration project approved under title XI" (e.g., the Secretary has the discretion as to when section 1115 waiver days may be included in the numerator of the Medicaid fraction).

At the time of enactment of the DRA, CMS did not believe further changes to its regulations were necessary as the regulations reflected its intent to include patient days of those populations who, under a demonstration project, receive benefits, including inpatient hospital coverage benefits, that are similar to the benefits provided to traditional Medicaid beneficiaries. This would not include circumstances where states extended coverage only for specific services (such as family planning) that do not include insurance coverage for hospital care.

In CMS' view, neither the statute nor the DRA permit or require the Secretary to count in the DPP Medicaid fraction numerator days of just any patient who is in any way related to a section 1115 demonstration. Rather, section 1886(d)(5)(F)(vi) of the Act limits including days of expansion group patients to those who may be "regarded as" "eligible for medical assistance under a state plan approved under title XIX." Even if the statute did not require this result, CMS argues that the DRA explicitly gives it authority to adopt the policy changes it proposed and is now finalizing.

2. Uncompensated/Undercompensated Care Funding Pools

CMS's overall policy for including section 1115 demonstration days in the Medicaid fraction numerator has rested on the presumption that the demonstration provided a package of health insurance benefits that were essentially the same as what a state provided to its Medicaid population. More recently, however, some section 1115 demonstrations include funding for uncompensated/undercompensated care pools that help to offset hospitals' costs for treating uninsured and underinsured individuals but do not expand the group of people who receive health insurance.

Payments from these pools serve essentially the same function as Medicaid DSH payments under sections 1902(a)(13)(A)(iv) and 1923 of the Act, which are also title XIX payments to hospitals meant to subsidize the cost of treating the uninsured, underinsured, and low-income patients. These payments promote the hospitals' financial viability and ability to continue treating Medicaid patients. However, payments from these pools do not provide the certainty of health insurance coverage to a particular individual as occurs when a section 1115 demonstration provides inpatient hospital benefits to an individual directly through Medicaid or by providing premium assistance to purchase a health plan.

3. Recent Court Decisions

Several federal courts concluded that CMS' regulations require section 1115 inpatient days to be included in the numerator of the Medicaid fraction where hospitals have received payment from an uncompensated care pool or the patients received premium assistance to purchase health insurance under a section 1115 demonstration program.[42] These courts have concluded that if a hospital received payment for an otherwise uncompensated inpatient hospital treatment of a patient, that patient is "eligible for inpatient hospital services" within the meaning of the current regulation.

CMS disagreed with these court decisions and has argued that numerous other cases support its position (citing *Adena Regional Medical Center and Owensboro Health, Inc*. as examples)[43]. The final rule states:

> …Federal courts across the country have universally held, the patients whose care costs are indirectly offset by such Medicaid DSH payments are not "eligible for medical assistance" under the Medicare DSH statute and are not included in the DPP Medicaid fraction numerator.

The final rule indicates that CMS never intended to include days of patients that benefited so indirectly from a demonstration in the numerator of the Medicaid fraction. In response to these court decisions, CMS made proposals in the FY 2022 and FY 2023 IPPS proposed rules to

[42] Bethesda Health, Inc. v. Azar, 980 F.3d 121 (D.C. Cir. 2020); Forrest General Hospital v. Azar, 926 F.3d 221 (5th Cir. 2019); HealthAlliance Hosps., Inc. v. Azar, 346 F. Supp. 3d 43 (D.D.C. 2018).
[43] For more information on this distinction, as upheld by courts, see Adena Regional Medical Center v. Leavitt, 527 F.3d 176 (D.C. Cir. 2008), and Owensboro Health, Inc. v. HHS, 832 F.3d 615 (6th Cir. 2016).

modify its policies consistent with its longstanding view that section 1115 waiver days should only be included in the Medicaid fraction of the DPP where the waiver provides inpatient benefits directly to the patient.

For FY 2022, CMS proposed that only those section 1115 waiver days for expansion populations receiving inpatient benefits directly from Medicaid could be included in the Medicaid fraction. Days of patients who receive premium assistance through a section 1115 demonstration and the days of patients for which hospitals receive payments from an uncompensated or undercompensated care pool created by a section 1115 demonstration would not be included in the DPP Medicaid fraction numerator.

For FY 2023, CMS modified the proposal for those patients receiving premium assistance to purchase health insurance that includes inpatient benefits. Inpatient days for these patients could be included in the Medicaid fraction if the premium assistance receives matching funds under Title XIX, the insurance provides "essential health benefits" as defined under the Affordable Care Act, and the assistance is equal to or greater than 90 percent of the cost of the insurance.

CMS did not finalize either of these proposals but indicated that it would revisit them in future rulemaking.

4. Proposal for Discharges Occurring on or After October 1, 2023

In a proposed rule published in the *Federal Register* on February 28, 2023, CMS made a similar proposal to the one that it did not finalize for FY 2023. The proposed rule indicates that in order for days associated with section 1115 demonstrations to be counted in the DPP Medicaid fraction numerator, the statute requires those days to be for patients who can be "regarded as" eligible for Medicaid. CMS proposed to modify its regulations to explicitly state that patients may only be "regarded as" eligible for Medicaid if the patient receives health insurance through a section 1115 demonstration where state expenditures to provide the insurance may be matched with federal funds under title XIX (Medicaid).

CMS proposed that for a section 1115 inpatient day to be included in the numerator of the Medicaid fraction, the patient must:

1. Receive health insurance authorized by a section 1115 demonstration that provides inpatient hospital benefits; or
2. Buy health insurance with premium assistance provided under a section 1115 demonstration that accounts for 100 percent of the premium cost to the patient, where state expenditures to provide the health insurance or premium assistance is matched with federal funds under title XIX.

Under CMS' proposal, patients whose inpatient hospital costs are paid for with funds from an uncompensated care pool authorized by a section 1115 demonstration are not patients "regarded as" eligible for Medicaid. The days of such patients may not be included in the numerator of the Medicaid fraction. CMS proposed to make the policy effective for discharges occurring on or after October 1, 2023.

The only difference between CMS' proposal for FY 2023 and its current proposal is that CMS is now proposing to require the premium assistance cover 100 percent of the cost of the insurance, rather than 90 percent. Public comments on that aspect of CMS' proposal indicated that it would be burdensome to determine if the 90 percent threshold percentage was met. CMS' understanding is that any current state waiver that provides premium assistance that includes inpatient hospital benefits covers 100 percent of the cost of the insurance. Therefore, CMS sees this change to the policy as being consistent with current practice. Further, it believes hospital burden would be reduced because once the hospital determines the patient became eligible for inpatient benefits through an 1115 waiver that provided premium assistance, it would follow that the waiver provided 100 percent of the cost of the insurance.

5. CMS' Authority and Public Comments

CMS argued in the proposed rule that section 1886(d)(5)(F)(vi) of the Act provides clear discretionary authority to determine when section 1115 days may be included in the Medicaid fraction. The proposed rule argued that use of the word "may" and the phrase "to the extent and for the period the Secretary determines appropriate" allow the Secretary to determine when section 1115 days may be included in the Medicaid fraction.

Public commenters disagreed with CMS' prior proposals, arguing the statute requires CMS to "regard as" Medicaid eligible those patients with uncompensated care costs for which a hospital is paid from a demonstration funding pool and to count those patients' days in the numerator of the Medicaid fraction. These commenters assert that uninsured patients "effectively" receive insurance from an uncompensated/undercompensated care pool, and thus, cannot be reasonably distinguished from patients who receive insurance from the Medicaid program.

CMS preemptively responded to arguments against its proposal by stating:

- It sees a clear difference between inpatient days where the patient is provided with insurance through an 1115 waiver and where the 1115 waiver compensates the hospitals for uncompensated care. For the former, CMS argues that the patient receives a direct insurance benefit while for the latter the hospital is being compensated for an uninsured patient's costs and the patient is not receiving any health insurance benefit (or at least not directly). The former patient is "regarded" as eligible for Medicaid while the latter is not.
- The Medicare fraction uses SSI and the Medicaid fraction uses Medicaid eligibility as a proxy for low-income patient status. Patients may not necessarily be low-income when their inpatient costs are compensated from an uncompensated care pool.
- Including section 1115 inpatient days from uncompensated care pools in the Medicaid fraction would advantage states with relatively broad uncompensated care pools relative to others that do not, even though the burden of uncompensated care may be no different between the states.

6. Public Comments and CMS Responses

Public commenters opposed CMS' proposed policy. The arguments essentially followed the past history of this issue as summarized above. Some additional comments not reflected above are

provided below. Note: There were some states-specific comments that are not addressed here (specifically for Massachusetts, Indiana and Connecticut).

Burden on Hospitals. Several commenters indicated that a requirement to furnish "data adequate to prove eligibility for each Medicaid patient day" would place an undue burden on hospitals to be able to count days associated with section 1115 premium assistance programs as hospitals will not know how much premium assistance the demonstration is providing.

CMS responds that its understanding is that all states with current 1115 premium assistance demonstration programs provide 100 percent premium assistance to individuals (except for special issues with Massachusetts that CMS separately addressed in a comment and response). Based on this understanding, CMS estimated that it would cost 310 hospitals a total of approximately $18,350,169 annually to determine whether a patient received premium assistance that paid for 100 percent of the cost of a health insurance plan that provides inpatient hospital services coverage. While public commenters may disagree with these estimates, CMS uses them to indicate that it considered the potential burden associated with the new requirement. The final rule further states that the state will continue to be able to furnish hospitals with the eligibility data necessary for the hospitals to document eligibility to include inpatient days associated with a section 1115 waiver in the numerator of the Medicaid fraction.

Financial Impact on Hospitals: Some hospitals objected to the policy on the basis that it will create financial hardships for hospitals, affect health equity in general and safety-net hospitals specifically. While CMS acknowledges that its policy will result in lower DSH and (UCP than the alternative, maximizing these payments is neither required by the Medicare statute nor an appropriate policy goal of Medicare DSH policy.

7. Final Decision

CMS is finalizing its policy as proposed effective for discharges occurring on or after October 1, 2023.

E. Payment Impacts

The regulatory impact analysis presented in Appendix A of the final rule includes the effects of the changes to Medicare DSH payments of counting certain days associated with Section 1115 demonstrations in the Medicaid fraction and the estimated effects of the changes to uncompensated care payments and supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals for FY 2024.

a. Effects of the Changes to Medicare DSH Payments of Counting Certain Days Associated with Section 1115 Demonstrations in Medicaid Fraction

There would be no payment impact in seven states that have section 1115 waivers that explicitly include premium assistance (Arkansas, Massachusetts, Oklahoma, Rhode Island, Tennessee, Utah, and Vermont). Hospitals in six states (Florida, Kansas, Massachusetts, New Mexico, Tennessee, and Texas) would no longer be eligible to report section 1115 inpatient days for patients for which they received payments from uncompensated/undercompensated care pools.

In these states, CMS does not have the data to determine the payment impact because the Medicare cost report does not include lines for section 1115 demonstration days separately from other types of days.

However, CMS did use unaudited data on the amounts in dispute from the plaintiffs in the cases referenced above to estimate the potential impact per bed at $2,477. Extrapolating this figure to the number of beds in the above six states would yield annual Trust Fund savings of approximately $348.7 million. However, CMS cautions against extrapolating from these unaudited amounts to Trust Fund savings and indicates the amounts could be higher or lower than its estimates.

Comments/Responses: Many comments found CMS' regulatory impact analysis to be inadequate. These commenters indicated that CMS could have used data on the amount in dispute from Provider Review Reimbursement Board cases. CMS responded that its limited regulatory impact analysis is due to the agency's lack of data on the number of days paid for under a section 1115 demonstration. Nevertheless, CMS did do an economic analysis from data available through litigation on this issue and believes the $347.8.million impact represents 0.3 percent of total IPPS payments. CMS does not believe that using more unaudited data from hospitals with pending administrative appeals or who have protested amounts on their cost reports will produce a more accurate estimate of the total savings than what was included in the February 2023 proposed rule.

Other comments expressed concern about the impact on low-income patients or safety-net hospitals that treat these patients. CMS indicates that nothing in this rule diminishes or eliminates any benefit low-income patients receive from section 1115 demonstrations. These patients will continue to benefit by having some part of their hospital bill paid for by an uncompensated care pool or by having a portion of their health insurance premium paid with state assistance. Only the hospital treating such a patient will be affected by CMS' final rule policy. CMS reiterates that the purpose of the DSH payment adjustment is not to provide as much money as possible to hospitals, but to reflect payment for a hospital's provision of a disproportionate share of care to low-income patients.

There were comments indicating that CMS is not in compliance with the Regulatory Flexibility Act (RFA) because the agency did not analyze the impact of the proposed rule on small entities consistent with the RFA's requirements. Another comment said CMS' RFA analysis was in conflict as it certified the rule would not have a significant impact on a large number of small entities while also declaring that proposed rule was considered a major rule.

CMS indicated that its practice with respect to the RFA is to consider the effects of a policy as economically significant if the proposal affects greater than five percent of providers in the amount of three to five percent or more of total revenue or total costs. CMS estimated that DSH payments are approximately 2.8 percent of all payments under the IPPS for FY 2023. Therefore, the Secretary certified that the impact of the February 2023 proposed rule being finalized will not have a significant economic impact on a substantial number of small entities. On the issue of whether a rule is a major rule, CMS indicates that requirement results from section 3(f) of Executive Order 12866 and not the RFA.

There was one comment that indicated that the impact of the rule is far more significant than CMS indicates as it does not address or account for the impact on Medicare uncompensated care payments. While CMS notes earlier in the preamble that is policy will affect Medicare DSH and UCP without quantifying the impact, CMS responded here that its proposal will have no impact on Factor 1 of the FY 2024 Medicare uncompensated care payments. That response is accurate as UCP will be based on historical DSH payments in a prior year as forecast for FY 2024 based on factors explained earlier. However, it is unresponsive to the public comment as CMS' policy will eventually have an impact on DSH and UCP at some future point once the reduction in Medicare DSH payments is used to forecast future UCP payments.

b. Medicare DSH Uncompensated Care Payments and Supplemental Payments for IHS and Tribal Hospitals and Hospitals Located in Puerto Rico

CMS estimate the 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 2,384 hospitals that are projected to be eligible for DSH in FY 2024.

The total amount of uncompensated care payments ($5.938 billion) combined with supplement payments for IHS/Tribal hospitals and Puerto Rico hospitals ($83.2 million) is $6.021 billion. This is a 13.62 percent decrease from FY 2023 payments (about $950 million). Changes in FY 2024 payments are driven by decreases in Factor 1 and Factor 2.

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 -13.62 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 -13.62 percent indicates the category of hospitals is receiving a smaller decrease in payments than the average for all hospitals. The table below shows impacts for selected categories of hospitals, including uncompensated care payments and supplemental payments.

Hospital Type	**Dollar Difference FY 2023-FY 2024 ($ in millions)**	**Percent Change**
All Hospitals	-$950	-13.62%
Urban	-898	-13.62
Large Urban	-544	-13.35
Other Urban	-354	-14.05
Rural	-52	-13.65
Beds: 0-99 (Urban)	-29	-11.06
Beds: 250+ (Urban)	-677	-14.01
New England (Urban)	-22	-12.39
Middle Atlantic (Urban)	-105	-13.77
South Atlantic (Urban)	-119	-15.66
East South Central (Urban)	-235	-13.71

Hospital Type	Dollar Difference FY 2023-FY 2024 ($ in millions)	Percent Change
West North Central (Urban)	-64	-15.04
West South Central (Urban)	-165	-11.77
Pacific (Urban)	-86	-14.03
Mountain (Rural)	-3	-24.31
Puerto Rico	-12	-13.36
Teaching with 100 or more residents	-355	-13.29
Teaching with fewer than 100 Residents	-369	-14.91
Non-Teaching	-225	-12.35
Voluntary	-563	-14.02
Proprietary	-127	-12.66
Government	-259	-13.30

Rural hospitals are projected to receive a slightly larger decrease in uncompensated care payments of 13.65 percent compared to a decrease in UCP payments of 13.62 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 14.91 percent. Nonteaching hospitals and teaching hospitals with 100 or more residents are expected to receive smaller than average decreases of 12.35 and 13.29 percent respectively. Proprietary and government hospitals are expected to receive smaller than average decreases of 12.66 and 13.30 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 hospital discharge to a post-acute care setting occurring prior to the geometric mean length of hospital stays.[44] CMS makes payment to the transferring hospital at:

- Twice the per diem amount for the first day with each subsequent day paid at the per diem amount up to the full MS-DRG payment; or
- 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).

[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.

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

2. Changes for FY 2024

CMS proposed to make changes to a number of MS-DRGs effective for FY 2024. As a result of its review, CMS proposed 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 proposed to make these MS-DRGs subject to the special payment methodology. CMS is finalizing the proposed changes to the MS-DRGs without modification. Therefore, CMS is finalizing its addition of MS DRG 276 and 277 to the list of MS-DRGs subject to the post-acute care transfer policy and the special payment methodology.

B. Inpatient Hospital Update

The 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.

CMS proposed an update of 2.8 percent for hospitals that receive the full update based on its estimate of the market basket of 3.0 percent for FY 2024 using data from IHS Global Insight, Inc.'s (IGI) 4th quarter 2022 forecast (with historical data through the 3rd quarter of 2022) and a total productivity offset of 0.2 percentage points.

Comment/Response

Base the Update on MedPAC's Recommendation. Many public comments requested that CMS adopt MedPAC's recommendation that the update be the amount in current law plus 1 percentage point. There were comments requesting a higher update to reflect that hospitals are experiencing their lowest Medicare margins in decades. According to MedPAC, Medicare hospital margins were a negative 6.2 percent in 2021 (after accounting for temporary COVID-19 relief funds). CMS does not have the authority to adopt MedPAC's recommendation. The Medicare statute requires the update to be based on CMS' estimate of the market basket less total factor productivity.

Alternative Data Sources. Commenters stated the significant increases in labor expenses over the last couple of years have been largely driven by use of higher cost contract labor that is not recognized in

hospital market basket. These comments stated that the Bureau of Labor Statistics (BLS) Employment Cost Index (ECI) does not accurately reflect the shift in costs from salaried employees to contract labor. As an alternative, commenters recommended use of a closely related measure—the Employer Costs for Employee Compensation (ECEC)—that may be a better and more timely data source for growth in hospital compensation costs. The commenter claimed that all else equal, if the hospital ECI growth had matched the hospital ECEC growth, the market basket would have been 3.0 percentage points higher over the 2019 to 2022 time period.

One commenter suggested that CMS consider using the average growth rate in allowable Medicare costs per risk adjusted discharge for IPPS hospitals between FY 2019 and FY 2021 to calculate the FY 2024 final rule market basket update. The commenter stated this growth rate will capture the increased cost of contract labor, unlike the ECI. According to this commenter, this methodology would yield an unadjusted market basket update of 4.39 percent for FY 2024 rather than the 2.8 percent net market basket update proposed by CMS.

CMS responded that it does not believe the Medicare cost report is suitable data source for determining the trend in compensation prices for the market basket update because it reflects factors that are beyond those that impact wage or price growth. The final rule indicates that the ECEC data is limited in its usefulness because it reflects changes in compensation and changes in employment. The wage measure in the market basket should not reflect changes in employment to be consistent with the statute that the market basket percentage increase be based on an index of appropriately weighted indicators of changes in wages and prices.

While CMS acknowledges that the ECI only reflects price changes for employed staff and not contract labor, the final rule states that the latest Medicare cost reports reflect that employed labor represents 96 percent of hospital compensation hours. CMS further notes that when developing its forecast of the ECI for hospital workers, IGI considers overall labor market conditions (including the rise in contract labor employment due to tight labor market conditions) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital.

CMS further notes that IGI's forecast is that price pressures are expected to slow in FY 2024 relative to FY 2022 and FY 2023. Nevertheless, IGI's market basket forecast for the final rule based on later data is 3.3 percent compared to 3.0 percent for the proposed rule. CMS further notes that this forecast is higher than the 10-year historical average (2013- 2022) growth rate of the 2018-based IPPS market basket of 2.5 percent that includes a 10-year historical average (2013-2022) growth rate for compensation prices equal to 2.4 percent.

Rebasing the Market Basket. One commenter requested that CMS rebase the market basket more often than once every four years. CMS responds that it rebases the market basket every four years, in part, because the cost weights do not change much from year to year. However, CMS evaluated how rebasing based on 2021 cost report data would affect the market basket. CMS indicates that a 2021-based market basket would have a compensation weight that is about 1 percentage point lower than the 2018-based IPPS market basket compensation cost weight of 53.0 percent. The rebased weight would reflect a combined decrease in the salary and benefit cost weights that is larger than the increase in the contract labor cost weight. The major cost categories that show an increase in the cost weight over this period are pharmaceuticals and home office contract labor compensation costs.

Forecast Error Correction. Several commenters requested CMS use its "exceptions and adjustments" authority (section 1886(d)(5)(I)(i) of the Act) to apply a forecast error adjustment to the FY 2022 update for the 3.0 percentage point difference between the forecast and actual market basket in FY 2022. These commenters indicated that failure to make a forecast error correction will perpetuate inaccuracies in IPPS payments into the future. Other commenters suggested that forecast error corrections be made a permanent part of the IPPS payment update methodology or that there be a forecast error adjustment above a threshold amount similar to the capital PPS and the SNF PPS.

CMS responded that while the projected IPPS hospital market basket updates for FY 2021 and FY 2022 were less than the actual rate of increase, this was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 PHE. The final rule further indicates that over 10 years (2013 through 2022), forecasted increases were greater than actual increase by an aggregate of 1.1 percent. For each year from 2012 through 2020, the forecasted FY hospital market basket update was higher than the actual hospital market basket update. With respect to the SNF and capital PPS, CMS indicates that forecast error adjustments were adopted very early in both systems and have been consistently addressed (both upwards and downwards).

Productivity Adjustment. Several commenters indicated that the PHE has had unimaginable impacts on hospital productivity. Even before the PHE, the Office of the Actuary's analysis indicated that hospitals cannot recognize the same level of productivity as is achieved economy-wide. Commenters asked CMS to use its "exceptions and adjustments" authority to not apply the productivity adjustment for the years the PHE was in effect. While CMS appreciates the commenters concerns, it responded that section 1886(b)(3)(B)(xi) of the Act requires the application of the productivity adjustment.

Final Decision: CMS is finalizing its proposal but is using more recent data to determine the FY 2024 market basket update and total factor productivity adjustment for the final rule than the proposed rule. IGI's 2nd quarter 2023 forecast (with historical data through the 1st quarter of 2023) for the hospital market basket is 3.3 percent. IGI's 2nd quarter 2023 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	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.825	-0.825
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.475	0.0	-2.475
Productivity Adjustment	-0.2	-0.2	-0.2	-0.2
Applicable Percentage Increase	**3.1**	**0.625**	**2.275**	**-0.2**

The updates above apply to the national standardized amount and the hospital-specific rates for MDHs and SCHs. 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 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.

CMS proposed to make an additional change to the effective date for SCHs in the case of a merger of two hospitals for FY 2024. In these cases, CMS has not considered the application to be complete unless the application indicates 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 proposed 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.

The policy is only being proposed for SCHs and not MDHs. CMS does not believe MDHs will be in a situation where its qualification for special status will be dependent on a merger.

Public comments supported CMS' proposal but asked that it be made retroactive to address pending appeals on this issue. There were also public comments that requested CMS specify the requirements for a complete application. Consistent with past practice, CMS is making the change to the regulations prospective for SCH applications received on or after October 1, 2023. CMS did not propose any changes to the requirements for a complete application and refers the commenter to Chapter 28 of the Provider Reimbursement Manual section 2810. B. for documentation that must be included with a request for SCH classification. This section of the manual is the process of being updated for this regulatory change.

CMS is finalizing this proposal without modification.

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 proposed 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 1.80655 (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)	1.5272
2. Middle Atlantic (PA, NJ, NY)	1.5791
3. East North Central (IL, IN, MI, OH, WI	1.6726
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7392
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.65775
6. East South Central (AL, KY, MS, TN	1.662
7. West South Central (AR, LA, OK, TX	1.8348
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.8582
9. Pacific (AK, CA, HI, OR, WA)	1.8094

The median regional CMIs in the final rule reflect the March 2023 update of the FY 2022 MedPAR containing data from bills received through March 2023. 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

Fiscal Year	Distance Criteria	Discharge Criteria	Payment Methodology
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 through FY 2024 the criteria and payment methodology in place from FYs 2019 through FY 2022.

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

CMS proposed 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 proposed 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 proposed that any approval will be effective prospectively within 30 days of the date of the MAC's determination. There were no public comments on this proposal. CMS is finalizing the proposal without modification.

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.

CMS further proposed conforming changes to the regulations consistent with the statutory extension of the MDH program in the CAA, 2023. These conforming changes are being made final for FY 2024—the last year the MDH program will remain in effect absent another statutory extension. There were no public comments on these proposals.

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 did not propose any policy or regulatory changes to the IME regulations. It merely used the FY 2024 IPPS proposed rule to respond to questions it has received regarding application of the affiliated group provisions to the IRB ratio. The proposed rule indicated 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.

Public commenters were generally appreciative of CMS' efforts to clarify the instructions and being responsive to teaching hospitals. There were several highly technical comments that disagreed with and suggested alternatives to some of the clarifications CMS proposed. CMS disagreed with some of these suggestions but agreed with others and is proceeding to make the changes in the cost reporting instructions as modified per public comments.

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 fringe 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 used the same logic to propose allowing hospitals to count resident training time at 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 proposed 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.

Public comments universally supported CMS' proposed rule citing a host of beneficial impacts that will result from allowing hospitals to count resident training time in REHs. Public commenters requested that when the REH incurs the cost of the resident training time in the REH, CMS pay at 101 percent of reasonable costs for the training just as it does with CAHs. CMS responded that the statutory authority for its policy under sections 1886(k)(2)(D) (payment to nonhospital providers) and 1861(v)(1)(A) of the Act (reasonable cost) do not specify that payment may be made at 101 percent reasonable cost as do the CAH statutory provisions (sections 1814(l) and 1834(g) of the Act).

CMS is finalizing its proposed policy without modification.

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 DGME payments. The Medicare Administrative Contractors (MACs) continued

to use this change request as the basis for reducing MA payments and distributing nursing and allied health education payment for the next 17 years.

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. The 14.13 percent reduction to MA DGME payments was also more than necessary to fund nursing and allied health education MA payments capped at $60 million.

The next change request was released on December 14, 2020 and applied retroactively to nursing and allied health education MA education payments for the years 2002 to 2018. Payments should have ranged from $8.7 million to $60 million for nursing and allied health MA payments and reductions to MA DGME payments ranging from 4.58 to 9.88 percent during this 17-year period. As CMS had overpaid for nursing and allied health education MA payments and reduced MA DGME payments more than necessary, CMS began the recoupment and repayment process after releasing this change request.

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 proposed 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 used the 4th quarter 2022 update of the 2020 HCRIS projected forward two years to estimate 2022 payments in the proposed rule. For the final rule, CMS is using the 1st quarter 2023 update of the 2020 HCRIS. For 2022, CMS will be distributing $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. During this period, nursing and allied health education payments exceeded the $60 million cap and ultimately 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 detailed CMS' instructions to the MACs 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. 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 to national aggregate MA days. To be eligible to receive these payments, the hospital must have been receiving nursing and allied health MA payments on an interim basis as of December 29, 2022.

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						
YEAR	**Section 4143 CAA POOL**	**FFS NURSING AND ALLIED HEALTH (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%

Public commenters generally agreed with CMS' proposal and its process for how previously recouped nursing and allied health education payments would be returned or no longer recouped.

Some commenters indicated that CMS should suspend its cost report reopening regulations to allow the return of recouped overpayments to hospitals with cost reports that may be beyond the 3-year reopening period. CMS does not see a need to suspend its limitation on reopening of cost reports that have been closed and settled for more than 3 years because any recoupments would have occurred within the timeframe that a cost report remains reopenable.

Other commenters objected to CMS requiring that the hospital be receiving nursing and allied health MA payments on an interim basis as of December 29, 2022 to be eligible for relief under section 4143 of the CAA, 2023. These commenters indicated that such a requirement was not

specified in statute and will deny relief to hospitals that have nursing and allied health education programs where the MAC denied payment but the issue is under appeal.

CMS responded that in these cases, it believes the normal appeals process should be followed. If the hospitals prevail in their appeal, and the MAC restores nursing and allied education payments, CMS would treat the hospitals as though they were receiving interim nursing and allied health MA payments as of December 29, 2022. This policy would not apply to hospitals that closed a nursing and allied education program because of denial of payment before December 29, 2022 even if that denial of payment is under appeal. The statute requires that the hospital must still be operating a nursing and allied health education program as of December 29, 2022 to be eligible for relief under section 4143 of the CAA, 2023.

I. Clinical Trial and Expanded Access Use 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 (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 proposed to adopt these same policies for FY 2024 with the following changes:

- No longer use $373,000 in drug costs as a proxy for determining that a case is a clinical trial case as CMS 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.
- Use condition code ZB to eliminate expanded use access claims from the relative weight calculation.
- Use condition code ZC to identify clinical trial cases where a different drug is under investigation so that these claims can be used in the relative weight calculation as the hospital continues to have a cost for the drug.

CMS did not receive any public comments on these proposals. For FY 2024, CMS proposed an adjustor of 0.28 to MS-DRG 018 in the above scenarios where the hospital does have a cost for the CAR-T or other immunotherapy product. Using later data for the final rule, CMS is adopting an adjustment of 0.27.

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 were no proposals or updates in the FY 2024 IPPS/LTCH PPS proposed rule for the HRRP.

The estimated percentage of hospitals that will be penalized under the HRRP for the FY 2024 HRRP is 85.52 percent (2,356 of the 2,855 hospitals), with total penalties for all such penalized hospitals estimated to be 0.44 percent of total payments for such hospitals.[46]

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

CMS finalizes its proposals 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;
- Make 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.

No changes were proposed to the existing policies on domain weighting,[47] the policies on retention and removal of measures from the HVBP measure set, the minimum numbers of

[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.

[46] Table I.G.-03 in the final rule shows the estimated percentage of hospitals penalized and penalty as share of payments for the FY 2024 HRRP by hospital characteristic.

[47] 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.

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 2,523 hospitals an average net percent payment adjustment of 0.025 percent. There is no estimated change in burden associated with the finalized proposals since they 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 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 and then creating domain scores that 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 March 2023 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 were proposed to these policies.

b. Codification of Current HVBP Program Measure Removal Factors

CMS finalizes, with minor technical modifications, its proposal to codify at §412.164(c) the 8 measure removal factors[48] 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. Substantive Measure Modifications

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

CMS finalizes its proposal 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 will 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.

[48] 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.

- 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 will 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).

Selected Comments/Responses. Some commenters did not support the re-evaluated measure believing that hospitals need more time to understand how the measure refinements will affect hospital performance and raising concern about additional burden on hospitals. CMS responds that the re-evaluated measure will have been included in the Hospital IQR program for four years before the measure is implemented in the VBP program for the FY 2028 program year and that hospital-specific reports for the measure in the IQR program will be available for review in October 2023. Several commenters raised concerns that the re-evaluated measure will result in hospitals being penalized twice. CMS explains that the MSPB hospital measure (whether in the IQR or VBP program) and the condition- and procedure-specific readmission measures used in the HRRP assess readmissions for different purposes and therefore would not result in hospitals being penalized twice. The re-evaluated MSPB measure assesses hospitals' cost efficiency for the hospital and patient. The HRRP condition- and procedure-specific measures in contrast are to reduce avoidable readmissions. CMS further clarifies that for the re-evaluated measure an episode is triggered by an initial inpatient admission and the episode window begins 3 days before the admission and ends 30 days after discharge. A readmission for the same patient during the 30-day period will trigger a new episode with the window for that new episode starting 3 days before the readmission and ending 30 days after discharge from the readmission. The new episode may result in some services being assigned to multiple episodes but those services will be counted only once per episode.

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 finalizes its proposal 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 will 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.[49]

[49] 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).

The performance standards calculation methodology for the updated measure is 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.

Selected Comments/Responses. Several commenters recommended the measure capture inpatient and outpatient procedures to take into account shifts of procedures from an inpatient to outpatient setting. CMS believes the measure accurately reflects hospital performance regardless of whether the patients receiving the procedures in the inpatient setting are sicker on average than those treated in the outpatient setting. A few commenters recommended including risk adjustments around socioeconomic and SDOH considerations. CMS explained that, as part of the last CBE endorsement maintenance submission for the measure, testing was conducted that included an assessment of the impact of social risk captured by dual eligibility and the AHRQ SES Index (which considers a number of factors such as median household income, percentage of individuals below the Federal poverty line, unemployment, and education). The testing showed that adjustment for these factors did not materially impact hospital RSCRs. CMS will continue to reevaluate risk adjustment as part of routine measure maintenance.

3. New Measure for HVBP Program Set

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

CMS finalizes its proposal to adopt into the HVBP Program, beginning with the FY 2026 Program Year, the Severe Sepsis and Septic Shock: Management Bundle measure (which is currently in the Hospital IQR 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.

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.

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 will further the goal of advancing health equity as the standardized protocols could mitigate potential biases that lead to variation in outcomes.

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.[50]
- 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).

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.

Selected Comments/Responses. Many commenters supported the measure because they agreed that the measure is warranted by the severity of the diagnosis, won't create additional burden,

[50] 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.

allows flexibilities for clinician judgment, and aligns with the Surviving Sepsis Campaign International Guidelines for Management of Severe Sepsis and Septic Shock. Many other commenters did not support the measure because of documentation and data collection burden and because they believe that frequent updates make it difficult to implement the measure as well as make it difficult to establish accurate baselines for evaluating hospital performance. CMS notes that hospitals have already been reporting on the measure in the Hospital IQR Program so does not believe that adoption in the VBP Program will increase burden. It is working with the CDC to develop a sepsis outcome eCQM that is less burdensome and could replace the Severe Sepsis and Septic Shock: Management Bundle measure in the future. The agency also emphasizes the updates made to the measure (as compared to the IQR Program measure) are minor technical updates that will not affect performance. Many commenters voiced concern that the measure creates incentives to increase antibiotic use and recommended more flexibility be provided for clinician judgment. CMS is not aware of published literature linking the measure to overuse of antibiotics but will continue to monitor the literature. It also believes that clinical judgment is preserved by providing exclusions for patients based on clinical documentation, such as documentation that the patient does not have severe sepsis or an infection within 6 hours following clinical criteria being met. Many commenters did not support linking the measure to a pay-for-performance program. CMS reminds commenters that under the program's scoring methodology the highest performing hospitals will receive achievement points regardless of whether they are performing at 100 percent and the measure will be included in the Safety domain which has 5 other measures and is weighted at 25 percent of the TPS.

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

No changes were proposed to the FY 2024 and FY 2025 measure sets.

Table V.K-01 in the final rule shows previously adopted measures for FY 2024 and FY 2025 measure sets and Table V.K-02 in the rule shows adopted measures (including newly adopted measures as finalized in the rule) for the FY 2026 through FY 2030 program years. The below table consolidates the information, with the new measure in italics.

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

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*		*X*	*X*
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 adopted in final rule to the MSPB measure beginning with FY 2028 program year
**Substantive updates adopted in final rule to the THA/TKA Complications measure beginning with the FY 2030 program year.

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

CMS finalizes its proposal to make the same updates to the form and manner of administration of the HCAHPS Survey measure for the HVBP Program as are being finalized for the Hospital IQR Program under section IX.C.10.h of the final 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 Adopted Baseline and Performance Periods

CMS finalizes its proposal to adopt January 1, 2022 to December 31, 2022 as the baseline period and January 1, 2024 to December 31, 2024 as the performance period for the Severe and Septic Shock: Management Bundle measure for the FY 2026 program year. For each subsequent

program year there will also be 12-month baseline and performance periods beginning with January 1st of the respective corresponding baseline and performance year.

The below table consolidates information from Tables V.K.-03 and V.K.-04 in the final rule and shows the baseline and performance periods previously updated for FY 2025 and FY 2026, as well as the periods finalized for adoption for the SEP-1 measure in italics. Tables V.K.-05 through V.K.-07 in the final rule show similar baseline and performance periods for FY 2027 through FY 2029 program years.

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 for the Safety domain measures 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 through FY 2029 program years have been updated and are set out in Tables V.K.-09, V.K.-10, V.K.-11, V.K.-12, and V.K.-13 of the final rule.

6. Change to the Scoring Methodology

a. Background.

CMS 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 modifying the existing scoring methodology to reward high level care in underserved populations.

b. Revision of 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

CMS finalizes its proposal to, beginning with the FY 2026 program year, add Health Equity Adjustment (HEA) bonus points to a hospital's TPS and to codify the scoring change (with minor technical modifications to text) at §412.160 and §412.165(b). The HEA bonus points will 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 dual enrollment status in Medicare and Medicaid (DES). This is similar to the health equity adjustment finalized in the Shared Savings Program and the health equity adjustment finalized in the FY 2024 Skilled Nursing Facility (SNF) PPS final rule for the SNF VBP program.

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 a health equity-focused scoring modification in the VBP programs is to create better outcomes for all populations in the programs. CMS points to 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.

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

- First, calculate the measure performance scaler for each domain.[51] 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.

[51] Table V.K-13 shows examples of the measure performance scaler a hospital would receive for each domain based on performance.

    - The calculation is 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.[52]
    - 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 requiring 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.
    - The adjustment uses DES data since the data are readily available and already used in the HRRP. 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,[53] 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.

Selected Comments/Responses. Several commenters did not support using DES as an indicator for the HEA for various reasons including that it provides an incomplete picture of health equity and varies across states. Other commenters did not believe ADI or Part D LIS were reasonable alternative proxies for social risk. CMS believes DES is a strong indicator of poorer healthcare outcomes but will consider alternative approaches in future years. In response to comments raising concern that the HEA bonus points may penalize hospitals, CMS notes that even if a hospital receives a penalty under the VBP program (per statute) it can still gain from the HEA. That is, HEA bonus points may be applied regardless of whether a hospital would otherwise be receiving a bonus or penalty under the program. Also, since the HEA bonus points are added before the TPS is calculated, the HEA would only result in changes to the hospital's relative position to other hospitals and not affect the distribution of bonuses and penalties by reason of the budget neutral structure of the program. In response to concerns regarding the impact of the HEA on safety net hospitals and rural hospitals, CMS clarifies that the increase in the number of hospitals receiving a bonus (after application of the HEA) occurs mostly among safety net hospitals compared to non-safety net hospitals and the greatest gains were to safety net and rural hospitals.

Impact Analysis. CMS assessed the potential impact of the HEA bonus points 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 finalized 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 methodology CMS is finalizing

[52] See Figure V.K.-01 in the final rule for a comparison of logistic scoring, linear scoring, and actual scoring calculations.
[53] See Table V.K.-14 in the final rule for an example of a Calculation of Health Equity Adjustment Points

resulted in the largest percent of hospitals gaining from the HEA bonus overall – that is, it spreads the bonuses among more hospitals, with medium and smaller hospitals having a higher increase percentage over larger hospitals. 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 finalized approach.[54] The simulated analysis predicts for the FY 2026 program year the average bonus payment with the HEA bonus points, as finalized, would be $3,724 and the average penalty would be -$4,246.

CMS determined the impact analysis supported its determination to finalize the HEA bonus points as proposed, and not the alternative.

Modification of TPS Maximum. TPS is currently defined in regulation as a numeric score ranging from 0 to 100. CMS finalizes its proposal to modify the TPS maximum to be 110 (and codify the change at §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. This allows 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. In the FY 2024 IPPS/LTCH PPS proposed rule CMS issued an RFI on potential additional changes to address health equity in the VBP Program. It specifically requested feedback on the use of alternative or additional indicators of underserved populations (such as Medicare Part D LIS or ADI), using alternative HEA bonus point thresholds for scoring (such as a quintile-based HEA bonus scoring approach instead of 3 levels of performance), ways to assess patient-level data, whether a linear scoring function or actual scoring should be used for calculating the underserved multiplier instead of the proposed logistic exchange function, and whether there are any other approaches that the HVBP Program could proposed to adopt to advance health equity.

Selected Comments. Several commenters recommended incorporating the ADI or LIS indicators along with DES. Recommendations were also provided for other alternatives, such as a socioeconomic index, a designation for hospitals that identifies those serving marginalized populations, a stratification by patients' HRSN, an index using regression, and a social needs predictor that assesses the availability of ICD-10 Z-codes.

A few commenters recommended alternative thresholds for scoring, such as using quartiles or quintiles for performance scaler points, or giving greater weight for improvement starting from a lower quintile than similar improvement starting from a higher quintile. Many commenters recommended alternative scoring methodologies, including excluding the Cost and Effectiveness Domain from the scaler, stratifying results, measuring performance of different measures within a domain as separate score, and considering the portion of behavioral health patients treated.

CMS is not responding to specific comments but may consider them in future rulemaking.

c. Domain Weighting and Minimum Numbers of Measures for Domains

[54] See Table V.K.-16 in the final rule.

For hospitals that receive a score in all 4 domains, an equal weight of 25 points for each domain is provided. To receive a TPS score a hospital must receive domain scores on at least 3 of the 4 domains.[55] If a hospital has sufficient data for only 3 domains, then its TPS will be proportionately reweighted. No changes were proposed to these policies.

d. Minimum Numbers of Cases for HVBP Program Measures

CMS finalizes its proposal to codify the minimum numbers of cases at §412.165(a)(1)(i).

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 finalized minimum number of cases for the newly adopted Severe Sepsis and Septic Shock: Management Bundle (SEP-1) 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 is a minimum of 25 cases required to be reported; for each measure in the safety domain (other than 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 SEP-1 measure, hospitals will be required to report a minimum number of 25 cases.

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

CMS finalizes its proposal to add to the HAC Reduction Program a validation reconsideration process, beginning with the FY 2025 program year (affecting 2022 discharges). CMS also summarizes feedback received in response to its 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 changes to the HAC Reduction Program measure set were proposed in the FY 2024 IPPS/LTCH PPS proposed rule. Nor were changes proposed to the measure removal and retention policy, the measure technical specifications, or to the scoring calculations review[56] and correction period process.

CMS estimates that for the FY 2024 HAC Reduction Program, out of 2,997 hospitals, 749 hospitals will be included in the worst-performing quartile (and subject to the program's penalty).

[55] See the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266) for the requirements for the minimum numbers of measures necessary to receive domain scores.
[56] 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.

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

In the FY 2024 IPPS/LTCH proposed rule, CMS did 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);
    - 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 believes 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. The agency is reviewing patient safety and healthcare-associated infection measures.

In the FY 2024 IPPS/LTCH PPS proposed rule CMS sought input on potential future measures, particularly to promote patient safety and address equity gaps, and on weighting and scoring methods to better assesses performance and promote equity. Specifically, the agency sought feedback on 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 finalized for adoption in the Hospital IQR in section IX.C.5. of the final rule.

Selected Comments. Recommendations included new measures that address medication safety related to adverse events and procedure or surgery related adverse events, a hospital-onset COVID-19 measure, and a hospital onset bacteremia (HOB) measure with a blood culture contamination benchmark of less than one percent. Many commenters supported future adoption in the HAC Reduction Program of the hospital harm and patient safety eCQMs currently in the Hospital IQR Program as well as the three patient safety eCQMs finalized for inclusion in the Hospital IQR Program in the final rule. Many commenters did not support the future adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography in Adults eCQM because of the metrics, calculation methods, and software used for the measure. Many commenters generally did not support the addition of eCQMs because of the associated burden and cost. CMS will consider the feedback and any future proposal will be announced through notice and comment rulemaking.

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.[57] After validating all quarters of the fiscal year, CMS calculates a total score reflecting a 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.

Adoption of Validation Reconsideration Process. CMS finalizes its proposal to add a validation reconsideration process, beginning with the FY 2025 program year (affecting 2022 discharges). Hospitals that fail validation will be allowed to request reconsideration of their final validation

[57] 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 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.

scores before use of the scores in the Program scoring calculation (similar to the reconsideration processes used in the Hospital IQR Program).[58] The validation reconsideration process will 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 will receive notification on how to submit to CMS a reconsideration request. The request must 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 will be provided to the hospital 90 days after receipt of the request. The hospital's confidence interval will be recalculated based on the results of the reconsideration to determine if the hospital passed or failed validation. The updated validation results will be used and could impact the hospital's payment adjustments.

Update to the Targeting Criteria for Hospitals Granted an Extraordinary Circumstances Exception (ECE). As finalized in the Hospital IQR Program in section IX.C.11.b of the final rule, CMS finalizes its proposal 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. 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 will be targeted for validation in the subsequent validation year and will not fail data validation in the HAC Reduction Program for the validation year involved. This exception will not except a hospital from participation in the HAC Reduction Program, and the hospital will still receive a Total HAC Score. This policy aligns 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".

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

[58] 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).

participants. CMS describes the budget neutrality calculation in detail. In summary, CMS compares reasonable cost payments to what IPPS payments would have been in the absence of the demonstration. IPPS rates are adjusted for the difference. Interim reasonable cost payments from as submitted cost reports are initially used and then later reconciled as cost reports become final.

2. FY 2024 Budget Neutrality Adjustment

CMS continues 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 $37,766,716 in FY 2024, which it will incorporate into the budget neutrality offset adjustment for FY 2024.

All of the finalized cost reports for the 29 hospitals that completed cost report periods beginning in FY 2018 under the demonstration payment methodology were available for the final rule. The actual cost of the demonstration for FY 2018 is $46,745,899, which exceeds the amount that was estimated for FY 2018 ($31,070,880) by $15,675,019. Thus, CMS includes the difference between the actual and estimated costs of the demonstration for FY 2018 within the budget neutrality offset amount in the final rule.

The total budget neutrality adjustment for FY 2024 is $53,441,735.

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. The FY 2024 national capital federal rate will be $503.83, a 4.14 percent increase over FY 2023. Below are explanations of the update factor and other adjustments that account for this 4.14 percent increase in the national capital federal rate.

Update Factor:

For FY 2024, CMS will increase the national capital federal rate by 3.8 percent based on the capital input price index (CIPI) of 2.9 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). Because the projected increase 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 making 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 at least 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 CIPI was 2.0 percent. As the difference (0.9 percentage points) is greater than 0.25 percentage points, CMS is adopting 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		2.9
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		3.8

Other Adjustments:

For FY 2023, CMS estimates that outlier payments will be 5.51 percent of total capital IPPS payments. CMS estimates that capital outlier payments will be 4.04 percent of total capital payments in FY 2024. Therefore, the FY 2024 outlier adjustment factor is 0.9598 (-4.02 percent), compared to 0.9449 (-5.51 percent) in FY 2023. The net change is 1.57 percent (0.9598/0.9449-1). Thus, the outlier adjustment increases the FY 2024 capital federal rate by 1.57 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 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 (referred to below as “quartile/cap”).

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 divided the capital federal rate by 0.9972, which was the effect of these policy adjustments in FY 2023.

CMS then continues with its 2-step approach to determining GAF budget neutrality as detailed above.

- The impact of 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) is 0.9869.
- The impact of the quartile/cap is 0.9964.

CMS also incorporates an adjustment for FY 2024 MS-DRG changes and recalibration inclusive of a 10 percent cap on the reduction in the relative weights and the associated budget neutrality adjustment. This adjustment is 1.0016. The combined adjustment due only to the wage index in step 1 above and for changes for MS-DRGs and recalibration is 0.9885 (0.9869 x 1.0016, or -1.15 percent). The quartile/cap adjustment of 0.9964 (or -0.36 percent) is then applied.

Final Rule Calculation:

The final 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	1.0380	1.0380	3.8
GAF/DRG Adjustment Factor*	N/A	0.9885	0.9885	-1.15
Quartile/Cap Adjustment Factor**	0.9972	0.9964	0.9992	-0.08
Outlier Adjustment Factor**	0.9449	0.9598	1.0157	1.57
Capital Federal Rate	$483.79	$503.83	1.0414	4.14

* 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 0.9885 (or -1.15 percent).
** The lowest quartile adjustment and outlier 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 Quartile/Cap adjustment is 0.9964/0.9972 or 0.9992 (-0.08 percent). The net change to the resulting from the FY 2024 outlier adjustment factor is 0.9598/0.9449, or 1.0157 (1.57 percent).

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.[59] 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' 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 proposed that effective for discharges occurring on or after October 1, 2023, hospitals reclassified as rural will still be considered urban for purposes of determining eligibility for capital DSH payments.

Public commenters supported CMS' proposal. One commenter asked CMS to expand capital DSH to geographically rural hospitals. CMS responded that the comment was out-of-scope to CMS' proposed rule. CMS is finalizing the proposal without modification.

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 as well as 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 (RNCIs), previously known as Christian Science Santoria) 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 3.3 percent. This figure is based on IGI's 2nd quarter 2023 forecast of the FY 2024 hospital market basket with historical data through the 1st quarter of 2023.

B. Report on Adjustment Payments

TEFRA hospital cost limits may be adjusted for specific factors after the hospital submits its Medicare cost report. Section 4419(b) of Pub. L.105-33 requires the Secretary to publish a report annually in the *Federal Register* describing the total amount of adjustment payments made to

[59] 42 CFR §412.320(a)(1)(iii)

excluded hospitals and hospital units. Total adjustment payments made to IPPS-excluded hospitals during FY 2021 were $4,338,890 as shown by hospital type in the below table.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	2	$11,974,166	$3,645,981
Children's Hospitals	5	$1,038,797	$625,277
RNHCIs	1	$160,881	$67,632
Total	8	$13,173,844	$4,388,890

C. Critical Access Hospitals (CAHs)

The Frontier Community Health Integration Project (FCHIP) Demonstration[60] 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 proposed the same application of budget neutrality if the demonstration is found to increase costs—through an adjustment to payments for all CAHs nationwide. However, CMS 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.

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

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

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

A. Background

Since FY 2016, LTCHs have been paid under a dual-rate payment structure. An LTCH case is either paid at the "LTCH PPS standard federal payment" when the criteria for site neutral payment rate exclusion are met or a "site neutral payment rate" when the criteria are not met. Site neutral cases 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 updates the LTCH PPS using a process that is generally consistent with prior regulatory policy and that cross-links to relevant IPPS provisions; modifications are discussed below. 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.

CMS uses the most recent data available, including FY 2022 MedPAR claims and FY 2021 cost report data, for FY 2024 LTCH PPS rate setting.

Summary of Changes to LTCH PPS Rates for FY 2024*	
Standard Federal Rate, FY 2023	$46,432.77
Final Rule Update Factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+3.3%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+3.3% (1.033)
Net update LTCHs not reporting quality data	+1.3% (1.013)
Final Rule Adjustments	
Area wage index budget neutrality adjustment	1.0031599
Final Standard Federal Rate, FY 2024	
LTCHs reporting quality data ($46,432.77 x 1.033 x 1.0031599)	$48,116.62
LTCHs not reporting quality data ($46,432.77 x 1.013 x 1.0031599)	$47,185.03

Summary of Changes to LTCH PPS Rates for FY 2024*	
Final Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$59,873
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$42,750
Impact of Policy Changes on LTCH Payments in FY 2024	
Total estimated impact	0.2% (≈ $6 million)
LTCH standard federal payment rate cases (68% of LTCH cases)	-0.2% (≈ -$4 million)
Site neutral payment rate cases (32% of LTCH cases)**	3.2% (≈ $10 million)
*More detail is available in Table IV, "Impact of Payment Rate and Policy Changes to LTCH PPS Payments For LTCH PPS Standard Federal Payment Rate Cases for FY 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-DRG Classifications 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 applies the same MS-DRG classification system used for the IPPS payments to the LTCH PPS in the form of MS-LTC-DRGs. MS-DRG system updates are incorporated into the MS-LTC-DRG system for FY 2024 since the two systems share an identical base. The MS-DRG changes are described elsewhere in this summary and details can be found in section II.F. of the preamble of the final rule. Other changes to the MS-DRGs that affect assignments under the GROUPER Version 41 are discussed in section II.E, including changes to the Medicare Code Editor (MCE) software and the ICD-10-CM/PCS coding system, apply to the LTCH PPS.

3. 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 proposed 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).

Selected comments and responses. A commenter observed that if a MS-LTC-DRG requires longer care, the relative weight should increase. CMS determined that 16 of the top 25 MS-LTC-DRGs

would see a decrease in their relative weights relative to FY 2023 relative weight, and the proposed geometric length of stay would increase for 3 of these It observes that a MS-LTC-DRG relative weight represents the average resources required to treat an LTCH patient grouped to that MS-LTC-DRG compared to the average resources require to treat all LTCH patients. Concern was also expressed regarding the high concentration of LTCH discharges (more than 40 percent) assigned to only two MS-LTC-DRGs: 189 (Pulmonary edema and respiratory failure) and 207 (Respiratory system diagnosis with ventilator support 96+ hours); CMS was encouraged to split and refine the two MS-LTC-DRGs, which it indicates it may do. Another commenter objected to the budget neutral application of the 10-percent cap; however, CMS declines to change its policy on this issue.

CMS finalizes its proposal to return to the use of 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 budget neutral 10-percent cap on the reduction to a MS-LTC-DRG's relative weight in a given year.

Consistent with its historical practice, CMS uses three different categories of MS-LTC-DRGs based on volume of cases within specific MS-LTC-DRGs to determine relative weights for the FY 2024 LTCH PPS:

- 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.

a. Relative Weights Source Data

FY 2024 relative weights are derived from the March 2023 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, and because 118 of this LTCH's 166 cases had charges that were exactly, or within ten dollars of, $10 million, CMS removed 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 also removed cases with a length of stay of 7 days or less.

b. Volume-related Adjustments

CMS continues to account for low-volume MS-LTC-DRG cases using its quintile methodology 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 236 such MS-LTC-DRGs in the claims, and the quintiles each contained 47 MS-LTC-DRGs, with a remainder of 1. It assigned that 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. CMS then determines the relative weight and (geometric) average length of stay for each quintile; each quintile's weight and length of stay was 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.)

c. Remove Statistical Outliers

CMS removes statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. It continues to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS-LTC-DRG. After removing statistical outlier cases and cases with a length of stay of 7 days or less in each set of claims, CMS has applicable LTCH cases that have a length of stay greater than or equal to 8 days, which it refers to as "trimmed applicable LTCH cases."

d. Adjust Charges for Short Stay Outliers

The effect of short stay outlier (SSO) cases (i.e., those with a length of stay of five-sixths or less of the average for that MS-LTC-DRG) is adjusted for by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the SSO case to the average length of stay for the MS-LTC-DRG for non-SSO cases.

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

CMS continues 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 will 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). For FY 2024, when relative weights decrease as severity increases in a DRG ("nonmonotonic"), CMS combines 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 final 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 (429 of these MS-LTC-DRGs were identified for the final rule), CMS cross-walks it to another MS-LTC-DRG based on clinical similarities in resource use intensity and relative costliness to assign an appropriate relative weight. If the MS-LTC-DRG that is similar is a low-volume DRG that has been assigned to one of the five quintiles noted above, then the zero volume MS-LTC-DRG is assigned to that same quintile.

CMS removes from this total the 11 transplant, 2 "error" and 15 psychiatric or rehabilitation MS-LTC-DRGs. Thus, there are 401 no-volume MS-LTC-DRGs for which CMS assigned relative weights based on clinical similarity and relative costliness to 1 of the remaining 337 (766 – 429 = 337) 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 assigns a 0.0000 relative weight for each of the following:

- The 11 transplant MS-LTC-DRGs (since no LTCH has been certified by Medicare for transplantation coverage);
- The 2 "error" MS-LTC-DRGs (998 and 999) (which cannot be properly assigned to an MS-LTC-DRG group); and
- The 15 psychiatric and rehabilitation MS-LTC-DRGs (because these MS-LTC-DRGs would never include any LTCH cases meeting the site neutral payment rate exclusion criteria).

h. Budget Neutrality

Annual updates to the MS-LTC-DRG classifications and relative weights are done in a budget neutral manner. CMS continues to 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 applies 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) Normalizing the Relative Weights

For FY 2024, CMS normalizes relative weights using its established methodology for purposes of the application of budget neutrality. 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 MS-LTC-DRG relative weights for FY 2024, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by the normalization factor in the first step of the budget neutrality methodology, which produces "normalized relative weights."

To do so, CMS 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 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." CMS calculated a normalization factor of 1.31064.

(2) Budget neutrality for uncapped relative weights.

CMS determines 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 calculated a budget neutrality factor of 0.9964763, which is applied to each uncapped normalized relative weight.

(3) 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 caps the FY 2024 MS-LTC-DRG relative weight at 90 percent of that MS-LTC-DRG's FY 2023 relative weight.

Under its 3-step methodology to determine the budget neutrality adjustment factor for its 10-percent cap on relative weight reductions, CMS does the following:

- Simulates estimated total FY 2024 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the capped relative weights for FY 2024 (determined in Step 10) and GROUPER Version 41;
- Simulates estimated total FY 2024 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the uncapped relative weights for FY 2024 (determined in Step 9) and GROUPER Version 41; and
- Calculates the ratio of the estimated total payments.

The budget neutrality adjustment factor for the 10-percent cap is 0.9984221. To determine the FY 2024 MS-LTC-DRG relative weights, CMS multiplies each capped relative weight by the budget neutrality factor to meet the budget neutrality requirement.

Extensive discussion of the entire 13-step process to determine MS-LTC-DRG relative weights, including examples, is provided in the final rule (pages 1260 through 1279 of the display copy).

C. Payment Rates and Other Changes

1. Overview LTCH PPS Standard Federal Payment Rates

As noted earlier, only LTCH discharges meeting the site neutral payment rate exclusion criteria are paid based upon the LTCH PPS standard federal payment rate. The LTCH PPS uses a single payment rate to cover both operating and capital-related costs, so the LTCH market basket includes both operating and capital cost categories.

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

Using IGI's second quarter 2023 forecast, CMS finalizes an update to the 2017-based LTCH market basket of 3.5 percent less 0.2 percentage points (PP) for multifactor productivity meaning an update factor of 1.033 to the FY 2024 LTCH PPS standard Federal payment rate. For LTCHs failing to submit data to the LTCH Quality Reporting Program (QRP), the annual update is 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 LTCH update for FY 2024 is:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	3.5%	3.5%
Multifactor Productivity	-0.2 PP	-0.2 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	3.3%	1.3%

Commenters objected to the lower updates calculated for the proposed rule; they argue that labor costs, especially for clinicians and contract nurses, and medical supply costs far exceed what CMS factors into its market basket for the LTCH update. They asked for temporary LTCH payment increases to offset these costs and unexpectedly high inflation. CMS responds that a market basket is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services; additionally, it believes IGI's forecasts take into account inflation. CMS declines to make any temporary payment adjustments. It explains that the LTCH market basket update forecast uses IGI's independent projections of price, wage, and economic expectations and that these projections are not based on similar considerations as those used to derive the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. However, as

described below, CMS is modifying its methodology for establishing the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases.

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[61] (issued on March 6, 2020) effective for FY 2022 under the LTCH PPS. The agency determined that the changes in this OMB Bulletin do not affect the CBSA-based labor market area delineations used under the LTCH PPS. Thus, no changes to the specific wage index updates are necessary as a result of its adoption of the updates in OMB Bulletin 20-01. CMS did not propose 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 68.5 percent based on IGI's second quarter 2023 forecast of the 2017-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (64.3 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. 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 continues to use the same data it uses to compute the 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 are calculated consistent with the "urban" and "rural" geographic classifications, but they do not take into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act. CMS also continues 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, which is consistent with the IPPS policy.

To determine area wage index values for areas where there are no IPPS wage data, CMS uses its existing methodology. Thus, 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

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

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). CMS 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. CMS declines to adopt a commenter's suggestion to waive the application of budget neutrality to this policy.

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 final rule applies would not be subject to the cap (even when other LTCHs in the same geographic area are receiving a wage cap).

CMS also 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 applied a budget neutrality factor to 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. Budget Neutrality Adjustments

CMS computes the wage index in a manner that is consistent with prior years; this includes ensuring that any changes to the area wage index values or labor-related share are implemented in a budget neutral manner. As noted above, the 5-percent cap on wage index decreases is included in the determination of the area wage level budget neutrality factor. CMS determined a FY 2024 LTCH PPS standard federal payment rate area wage level adjustment budget neutrality factor of 1.0031599.

4. Cost-of-Living (COLA) Adjustment

CMS will 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 uses 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 COLAs for FY 2024 which are unchanged from the COLAs in effect for FY 2023.

Area	**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
Hawaii	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

5. Adjustment for High-Cost Outlier (HCO) Case Payments

CMS includes an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Section 1886(m)(7)(A) of the Act requires CMS to reduce the LTCH standard federal payment rate by 8 percent for high-cost outliers (HCOs). Section 1886(m)(7)(B) requires CMS to set an outlier threshold such that estimated outlier payments equal 99.6875 percent of the 8 percent estimated aggregate payments for standard federal payment rate cases (that is, 7.975 percent). Under the HCO policy, an LTCH receives 80 percent of the difference between the estimated cost of the case and the HCO threshold, which is the sum of the LTCH PPS payment for the case and the fixed-loss amount for that case.

a. Determining LTCH CCRs

CMS 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.

LTCH total CCR ceiling. CMS used its established methodology to determine the LTCH total CCR ceiling based on IPPS total CCR data from the March 2023 update of the PSF. Thus, it

finalizes an LTCH total CCR ceiling of 1.289 under the LTCH PPS for FY 2024 for HCO cases under either payment rate and for the site neutral payment rate.

LTCH statewide average CCRs. CMS also used its established methodology to determine the LTCH statewide average CCRs for urban and rural hospitals, based on the most recent complete IPPS total CCR data from the March 2023 update of the PSF (listed in Table 8C in section VI. of Addendum A). They are effective for discharges occurring on or after October 1, 2023 through September 30, 2024. No comments were received for either of these proposals.

Payments for HCO cases are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge.

b. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

As noted above, CMS establishes a fixed-loss amount so that total estimated outlier payments under the LTCH PPS for federal standard payments are projected to equal 8 percent of total estimated payments under the LTCH PPS. 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.

In the proposed rule, using its established methodology CMS calculated a proposed fixed-loss amount for standard federal rate cases of $94,378 for FY 2024, which was significantly higher than the fixed-loss amount finalized for FY 2023 ($38,518). It used 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, which it believed was the best available data to approximate the inpatient experience in part because CMS believed that COVID-19 cases would continue to be treated with similar frequency at IPPS hospitals and LCTHs in FY 2024. The agency did not believe there was a reasonable bases for it to assume there would be a meaningful difference in the number of COVID-19 cases treated at LTCHs in FY 2024 relative to FY 2022. Commenters strenuously objected to the proposed methodology and outcome.

Concerns were raised about using FY 2022 data without modifications to account for the impact of COVID-19 on the ratesetting data, and many commenters exclaimed that FY 2022 was the worst year for COVID-19 hospitalizations and since then there has been a sustained decline in these cases. Commenters also believed increases in vaccination rates and natural immunity also supports the assumption that the number of these cases will decrease in FY 2024. Many suggestions were made for changes to the methodology, including modifying the charge inflation factor, which commenters believe was too high and reflected a patient complexity occurring during the pandemic.

CMS acknowledges a lower trend in COVID-19 hospitalizations recently and increased vaccinations, but they did not find a significantly different number of cases that did not meet the statutory patient criteria for exclusion from the site neutral payment rate from prior years. It also declines to adopt a suggestion to exclude dialysis claims in calculating the fixed-loss threshold for FY 2024. Upon review of more recent data, CMS concludes that it is not likely that charges will continue to increase at the rates observed during the FY 2021 to FY 2022 period.

Thus, while it uses the FY 2022 MedPAR claims file and the FY 2021 HCRIS for purposes of the FY 2024 LTCH PPS ratesetting in the final rule, it is modifying the charge inflation factor and the CCR adjustment factor.

Specifically, it will apply the same charge inflation factor it used in both the FY 2022 final rule and the FY 2023 final rule. Similarly, it will also apply the same CCR adjustment factor used in both the FY 2022 final rule and the FY 2023 final rule to determine the FY 2024 outlier fixed-loss amount.

(1) Charge Inflation Factor

In the FY 2022 IPPS/LTCH PPS final rule, CMS made a technical change to the methodology for determining charge inflation because of a significant difference between estimated and actual charge inflation; under that change, the charge inflation factor is determined based on the historical growth in charges for the LTCH PPS standard federal payment rate cases. CMS calculates the inflation factor using historical MedPAR claims data instead of using estimates calculated from quarterly market basket update values determined by the CMS Actuary. CMS uses a three-step methodology:

- Identify standard federal payment rate cases for the two most recently available fiscal years, removing any Medicare Advantage or all-inclusive rate provider claims.
- Remove statistical outliers, by calculating a provider's average charge in both fiscal years; dividing the average charge for the more recent fiscal year by the average charge for the prior year; and trimming claims for providers whose calculated charge growth factor is outside 3 standard deviations from the mean provider charge growth factor.
- Using remaining claims, calculate a national charge inflation factor by dividing the national average charge for the more recent fiscal year by the average charge for the prior year.

In the proposed rule, CMS computed a 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 proposed 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. As noted above, commenters objected to this methodology and outcome.

In the final rule, CMS will apply the same charge inflation factor it used in both the FY 2022 final rule (86 FR 45565) and the FY 2023 final rule (87 FR 49446). This 2-year charge inflation factor of 1.125133 is based on the 6.0723 percent growth in charges that occurred between FY 2018 and FY 2019, which is the last 1-year period before the COVID-19 PHE. The agency notes that, using data it would ordinarily use to determine the charge inflation factor for the final rule (i.e., FY 2021 MedPAR claims data from the March 2022 update and FY 2022 MedPAR claims data from the March 2023 update), it calculated a 2-year charge inflation factor of 1.29349.

(2) 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 proposed to continue using 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.

In the proposed rule 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 resulted in a proposed 1-year national CCR adjustment factor of 0.975513. Commenters similarly objected to this outcome.

In the final rule, CMS will apply the same CCR adjustment factor used in both the FY 2022 final rule (86 FR 45565) and the FY 2023 final rule (87 FR 49447) to determine the FY 2024 outlier fixed-loss amount. This CCR adjustment factor of 0.961554 is based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF, which is the last 1-year period before the COVID-19 PHE. CMS notes that, using data it would ordinarily use for purposes of determining the CCR for the final rule (i.e., the March 2022 PSF and the March 2023 PSF), it calculated a 1-year national CCR adjustment factor of 0.996923.

(3) Fixed-loss Amount for LTCH PPS Standard Federal Payment Rate Cases

CMS did not propose any changes to its methodology to calculate the applicable fixed-loss amount for standard federal rate cases. The 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 March 2023 update of the FY 2022 MedPAR file adjusted for charge inflation (as modified in the final rule) and adjusted CCRs (as modified in the final rule) from the March 2023 update of the PSF, CMS calculated for FY 2024 a fixed-loss amount for standard federal rate cases of $59,873. While substantially lower than the threshold calculated in the proposed rule ($94,378), it is still significantly higher than the fixed-loss amount finalized for FY 2023 ($38,518).

The HCO payment will continue to equal 80 percent of the difference between the estimated cost of the case and the outlier threshold.

(4) HCO Payments for Site Neutral Payment Rate Cases

CMS continues to believe that the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount. For FY 2024, the fixed-loss amount for site neutral payment rate cases is equal to $42,750. CMS also finalizes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2024. Consistent with the policy adopted in FY 2019, the HCO budget neutrality adjustment is not 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

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. Using more recent data available for the final rule, CMS determines that the DSH/uncompensated care amount for FY 2024 equals 69.47 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. Impacts

CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the finalized payment rates and factors for all LTCHs will result in an increase of 0.2 percent or approximately $6 million in aggregate payments. Based on the FY 2022 LTCH cases that were used for the analysis in the final rule, roughly 32 percent of those cases were classified as site neutral payment rate cases, and the Office of the Actuary 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. Aggregate LTCH PPS payments for these site neutral payment rate cases are estimated to increase by approximately 3.2 percent (or approximately $10 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the updates to the IPPS rates and payments reflected in its estimate of the IPPS comparable per diem amount.

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 0.2 percent (or approximately $4 million), which is primarily due to the projected 2.9 percent decrease in high-cost outlier payments as a percentage of total LTCH PPS standard federal payment rate payments. This change in projected payments is primarily being driven by a downward revision in this final rule to CMS' estimate of FY 2023 high-cost outlier payments to LTCH PPS standard Federal payment rate cases.

CMS estimates that aggregate FY 2024 LTCH PPS payments will be approximately $2.609 billion, as compared to estimated aggregate proposed FY 2023 LTCH PPS payments of approximately $2.603 billion.

Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments For LTCH PPS Standard Federal Payment Rate Cases for FY 2024" in the final rule shows the detailed impact by location, participation date, ownership type, region, and bed size for 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	**Percent Change in Payments per Discharge**
All LTCH providers	332	-0.2
By Location:		
Rural	18	0.3
Urban	314	-0.2
By Ownership Type:		
Voluntary	54	-1.8
Proprietary	269	0.1
Government	9	-0.7
By Region		
New England	10	-1.7
Middle Atlantic	19	0.8
South Atlantic	61	-0.4
East North Central	47	-1.2
East South Central	31	-0.7
West North Central	22	-2.6
West South Central	92	0.8
Mountain	27	1.0
Pacific	23	0.3
*More detail is available in Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2024" on pages 2107-2108 of the display copy.		

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. Overview

Under this section, CMS responds to public comments on and finalizes proposals relating to the Hospital IQR Program, PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, Long-Term Care Hospital Quality Reporting Program (LTCH QRP), and Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs).

B. COVID-19 Vaccination Among Healthcare Personnel Measure

CMS finalizes its proposal to, beginning with the quarter 4 of the 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, 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.

1. Background

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). Subsequent to the COVID-19 public health emergency (PHE) declaration by the Secretary of HHS on January 31, 2020, the measure was adopted across multiple quality reporting programs, including the Hospital IQR Program (86 FR 45374), PCHQR Program (86 FR 45428 through 45434), and the LTCH QRP (86 FR 45438 through 45446).[62] 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). Even though the COVID-19 PHE declaration expired on May 11, 2023, CMS 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. 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. Measure Specifications

[62] In addition, 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).

Calculation.

- *Denominator*. 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.[64] There were no proposed changes to the denominator from that of the current measure.
- *Numerator*. The number of HCP in the denominator population who are considered up to date[65] with CDC recommended COVID-19 vaccines.

Pre-rulemaking. The current version of the HCP COVID-19 Vaccine measure received endorsement by the CBE on July 26, 2022 (CBE #3636). The CDC is pursuing CBE endorsement for the modified version of the measure.[66]

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.

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 will begin with the quarter 4 of 2023 reporting period. Providers are to collect data 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 will 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.[67]

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[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] Facilities are required to submit data to the NHSN on the 3 named categories of HCP plus the fourth HCP category of "Other contract personnel". However, the measure will not include data on that fourth HCP category.
[65] 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 in the Q3 of the CY 2023 reporting period if the individual received an updated bivalent booster dose.
[66] CMS is adopting the modified measure consistent with the exception for non-CBE-endorsed measures, having found no currently available, alternative measure that is comparable, CBE-endorsed, feasible, and practical. See section 1886(b)(3)(B)(viii)(IX)(bb) of the Act for the Hospital IQR Program; section 1866(k)(3)(B) of the Act for the PCHQR Program; section 1886(m)(5)(D)(ii) of the Act for the LTCH QRP.
[67] The reporting requirements under the Hospital Conditions of Participation (CoP) were revised after the expiration of the PHE on May 11, 2023. CMS will communicate changes to the CoP through Quality Safety & Oversight memoranda when new policies are finalized.

- CMS will publicly report the COVID-19 HCP vaccination coverage rate as calculated by the CDC. Public reporting of the modified measure begins with the October 2024 Care Compare refresh, or as soon as technically feasible, for the Hospital IQR Program, PCHQR Program, and LTCH QRP.

4. Selected Comments/Responses.

While many commenters supported adoption of the modified measure, many others did not support updating the specifications, particularly because the COVID-19 PHE has expired and the conditions of participation (CoP) for hospitals no longer include vaccination requirements. CMS responds to clarify that (i) the hospital and CAH infection prevention and control CoP currently requires hospitals and CAHs to continue to report on a reduced number of COVID-19 data elements until April 30, 2024, unless the Secretary sets an earlier end date, (ii) reporting requirements under the quality programs are not tied to the end of the PHE declaration, and (iii) the measure aligns with public health goals to protect communities from the COVID-19 virus similar to other immunization measures. Other concerns raised included the burden and uncertainty around frequent changes to the CDC's definition of up to date and future vaccination schedules, and included the suggestion to reduce the required reporting frequency. CMS responds that the evolving definition and schedules are necessitated by the changes in the virus's transmission and community spread and the measure modification aligns with the responsive approach to prevent the worst consequences of the virus. The agency says that if the COVID-19 vaccination strategy becomes seasonal it intends to model reporting on the measure after the Influenza Vaccination Coverage among HCP measure, which is reported annually. It also notes that facilities have experience reporting on the revised measure since the CDC began, with the Q3 of the 2023 surveillance period, using the same definition of up to date as is reflected in the measure modification. Some comments included recommendations for exclusions to the measure, such as to take into account individuals with sincerely held religious beliefs or other factors outside the control of facilities. CMS responds that the measure is not requiring vaccination but is intended to provide transparent data to assist patient and caregiver decision-making, and that reporting of the measure based on one self-selected week per month over each quarter may mitigate some of the effects outside of the control of facilities. In response to questions on NHSN reporting, CMS clarifies that (i) the CDC counts data submitted for a week that crosses two months as data submitted for the month in which that week ends; and (ii) NHSN data submission for the measure meets reporting requirements under the Hospital IQR program.

C. Hospital Inpatient Quality Reporting (IQR) Program

CMS finalizes its proposed changes to the Hospital IQR program, including:

- Adding 3 new electronic clinical quality measures (eCQMs) beginning with the CY 2025 reporting period/FY 2027 payment determination;
- Besides the updated HCP COVID-19 Vaccine measure described above, updating 2 further measures beginning with CY 2027 payment determination;
- Removing 3 measures;
- Updating the HCAHPS Survey Measure beginning with FY 2027 payment determination; and
- Making changes to the measure validation process.

CMS also summarizes public comment in response to an RFI on the potential future adoption of two geriatric care measures.

CMS estimates its finalized policies for the Hospital IQR Program will result in a total information collection burden decrease for 3,150 IPPS hospitals of 144,836 hours at a savings of $6,834,886 annually across a 4-year period from the CY 2024 reporting period/FY 2026 payment determination through the CY 2028 reporting period/FY 2030 payment determination, compared to its currently approved information collection burden estimates.

CMS further estimates that for FY 2024, 65 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 2.275 percent update; 110 hospitals will not receive the full update for not being meaningful EHR users (but do meet the IQR Program requirements) and will receive a 0.625 percent update; and 31 hospitals will not receive the full update for failure to satisfy both requirements and will receive a -0.2 percent update.

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 did not propose any changes to its 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.[68] CMS finalizes in section IX.C.7.d. of the final rule its proposal to codify this policy at §412.140.

3. Removal Factors for Hospital IQR Program Measures

CMS does not propose any changes to the measure removal factors policy[69] and finalizes in section IX.C.7.d. of the final rule its proposal to codify this policy at §412.140.

4. Considerations in Expanding and Updating Quality Measures

CMS did not propose any changes to the considerations used to expand and update quality measures under the Hospital IQR Program.[70]

5. New Measures for the Hospital IQR Program Measure Set

CMS finalizes its proposals to adopt 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.

CMS also finalizes in section IX.F. its proposals to adopt these measures in the Medicare Promoting Interoperability Program.

a. Adoption of Hospital Harm – Pressure Injury eCQM

Background. 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. 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.

Measure Specifications. 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.

[68] The finalized measure retention policy can be found in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 and 53513).
[69] See FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors.
[70] See FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for considerations used to expand and update quality measures.

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.

- *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.[71]

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).[72]

Data Source. The measure is to 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.

Selected Comments/Responses. Many commenters supported the addition of this eCQM for reasons such as it increases public transparency to encourage patient safety best practices. Other commenters raised concerns whether there is a sufficient performance gap on the measure to allow for a meaningful difference in performance. CMS responded that it will monitor the performance gap as hospitals begin to report the measure.

Several commenters did not support adoption of the measure because of concerns about implementation burden, including because of limited health IT resources. CMS emphasizes that the eCQM addition is in alignment with the transition to a fully digital quality measurement system, which will help decrease burden in the long term. The agency also notes that the measure will not be required but will be one of the eCQMs hospitals may self-select for reporting. In response to a few requests for clarifications on how the measure relates to other programs, CMS

[71] The COVID-19 exclusion is 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.
[72] CMS is adopting the measure, consistent with the exception for non-CBE-endorsed measures under sec.

explains that meeting the Hospital IQR Program eCQM requirement will also satisfy the eCQM reporting requirement for the Medicare Promoting Interoperability Program for hospitals and CAHs, but the HAC Reduction Program reporting requirements for the Patient Safety Indicator (PSI 90) are separate. CMS also clarifies the numerator of the measure is determined through the ICD-10-CM coded diagnoses or structured clinical documentation.

b. Adoption of Hospital Harm – Acute Kidney Injury eCQM

Background. 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.

Measure Specifications. The Hospital Harm – Acute Kidney Injury measure is an outcome, risk-adjusted eCQM that assesses the proportion of inpatient hospitalizations for patients 18 years and older who have a stage 2 or greater AKI[73] (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.

- *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 is to be calculated by the hospitals' CEHRT (using the patient-level data collected through hospitals' EHRs) and then submitted by hospitals to CMS.

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).[74]

[73] 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).
[74] CMS is adopting the measure, consistent with the exception for non-CBE-endorsed measures section

Selected Comments/Responses. A few commenters raised concerns that the measure is duplicative with the claims-based measure of Acute Kidney Injury in the HAC Reduction Program (PSI- Postoperative Acute Kidney Injury Requiring Dialysis Rate within the CMS PSI 90 composite). CMS responds by distinguishing the two measures: The HAC Reduction Program measure only captures patients who develop postoperative kidney failure requiring renal replacement therapy, uses claims data, and is focused on Medicare FFS beneficiaries. In contrast the new IQR program measure (i) assesses how often stage 2 or greater AKI occurs in the inpatient setting, whether or not the patient received dialysis, and whether or not the patient had surgery before developing AKI, (ii) is an eCQM, and (iii) is for adult inpatients regardless of payer. The agency intends to fully transition to digital quality measurement, including for the HAC Reduction Program, but until that time intends to retain PSI 10 (within the PSI 90 composite) in the HAC Reduction Program as well as include the eCQM in the Hospital IQR Program. Several commenters did not support the measure because of concern about false positives, giving the example that serum creatinine levels can be influenced by factors such as medications and underlying medical conditions. CMS believes the exclusions and risk adjustments address the concerns about underlying medical conditions influencing the measure data, and that with appropriate monitoring, medications would not result in significant increases in serum creatinine levels.

c. 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.

Measure Specifications. 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.

- *Numerator*. The number of diagnostic CT scans that have a size-adjusted radiation dose greater than the threshold defined for the specific CT category[75] 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.

[75] 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.

- *Exclusions*. CT scans that cannot be categorized by the area of the body being imaged or reason for imaging[76] and CT scans missing information on the patient's age, Calculated CT Size-Adjusted Dose, or Calculated CT Global Noise.

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.

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 software (Alara Imaging Software for CMS Measure Compliance), which will be made available to all reporting entities for free and will be accessible by creating a secure account through the measure developer's website. 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.

Selected Comments/Responses. Several commenters supported the measure, including for the reasons that it will improve patient safety, will address a lack of oversight of CT scans, and is CBE-endorsed. Many commenters suggested making the eCQM mandatory and CMS responded that it will consider that for future rulemaking.

Many commenters did not support the measure, raising concerns with the measure's technical specifications and that the fixed limits for noise and dose may prevent CT scan operators from adjusting radiation doses as needed. CMS responds that the measure went through extensive testing in both inpatient and outpatient settings, and was developed with input from diverse technical expert panels (TEPs) and using consensus-based clinical guidelines. The agency also emphasizes the measure seeks to reduce harm from excessive radiation and is not to replace appropriate clinical judgment if adjustments need to be made. Many commenters expressed concern about additional burden, especially with respect to integrating proprietary software within existing IT systems. CMS responds that while the Alara Imaging Software is proprietary it will be available and accessible to all reporting entities for free and that the overall burden is comparable to that of existing eCQMs since the software accepts a wide range of formats for EHR data, in accordance with the agency's goal of encouraging interoperability based on the FHIR Application Programming Interface. CMS further explains that the software runs automatically to create three data elements needed for the measure ((i) CT dose and image quality category, (ii) calculated CT size-adjusted dose, and (iii) calculated CT global noise) and that the hospitals send the data to its EHR for measure calculation and reporting without any additional hardware needed and without any manual data entry.

[76] This exclusion includes scans that cannot 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.

6. Refinements to Current Measures in the Hospital IQR Program Measure Set

CMS finalizes its proposals to modify the following two measures (in addition to the HCP COVID-19 Vaccination measure finalized for inclusion beginning with the quarter 4 of the CY 2023 reporting period, as discussed above):

- 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.

a. *Modification of Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measure*

Background. CMS adopted, in the FY 2022 IPPS/LTCH PPS final rule,[77] 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).

Measure Overview. 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 is modifying the 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 FFS patients to a cohort which includes both FFS and Medicare Advantage (MA) patients. All other specifications for the measure remain the same.

- *Cohort*. The expanded cohort (FFS plus MA) will 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).
- *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.

[77] 86 FR 45365 through 45374

Data Submission and Reporting. Hospitals will submit data to CMS using Quality Reporting Data Architecture (QRDA) Category I files, consistent with the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program. To successfully submit the measure, hospitals will need to submit the core clinical data elements in the measure for all FFS and MA beneficiaries between 65 and 94 years of age discharged from an acute care hospitalization in the one-year measurement period, and to successfully submit six linking variables (from the hospitals' HER systems) that are necessary to merge the core clinical data elements with the CMS claims data to calculate the measure.

Selected Comments/Responses. Some commenters raised concerns about reliability of adding the MA population to the measure due to incomplete data for that population, and others raised concern about burden. CMS responds that hospital-submitted MA claims data are already in use for DSH and GME payment calculations and MA organization-submitted encounter data are already in use for calculating MA beneficiary risk scores (and those sources of data will be used for calculating the measure). In addition, the agency notes that including the MA patient data improves reliability, narrows the confidence intervals of measure scores, and results in more hospitals and beneficiaries being included. CMS encourages hospitals to participate in the voluntary reporting periods as a means of obtaining feedback on their performance on the measure, to provide the agency with feedback based on their experience, and to troubleshoot any problems. CMS also clarifies that the addition of the MA population to the cohort will not change the way the measure is publicly reported—that is, the measure will continue to be reported as an aggregate summary score (and not separately by FFS and MA) by each hospital's CCN.

b. Modification of Hybrid Hospital-Wide All-Cause Readmission (HWR) Measure

Background. CMS adopted, in the FY 2020 IPPS/LTCH PPS final rule,[78] 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 is modifying the 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

[78] 84 FR 42465 through 42479.

cohort which includes both FFS and MA patients. All other specifications for the measure will remain the same.

- 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 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.

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.

Data Submission and Reporting. Hospitals will 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. Hospitals will need to submit the core clinical data elements included in the measure for all FFS and MA beneficiaries 65 years of age and older discharged from an acute care hospitalization in the one-year measurement period. These core data elements are data that hospitals routinely collect and that can be extracted from hospital EHRs. Hospitals will also need to submit the six linking variables that are necessary to merge the core clinical data elements with the CMS claims data to calculate the measure.

7. Measure Removals for the Hospital IQR Program Measure Set and Codification of Measure Removal Factors

CMS finalizes its proposals 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. 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.[79]

CMS is now removing 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, along with finalizing the adoption of the modified measure under the Hospital VBP Program (as described in section V.K. of the final rule) 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. 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[80] 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[81] 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.[82]

CMS is now removing the updated measure (CBE# 2158) from the Hospital IQR Program beginning with the FY 2028 payment determination, along with finalizing the adoption of the updated measure under the Hospital VBP Program (as described in section V.K. of the final rule) 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. 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)

[79] Per 42 CFR §412.164(b), before inclusion in the Hospital VBP Program, measures must be publicly reported in the Hospital IQR Program for 1 year prior to the beginning of the performance period.
[80] 76 FR 51618 through 51627.
[81] 83 FR 41559 and 41560.
[82] Per 42 CFR §412.164(b), before inclusion in the Hospital VBP Program, measures must be publicly reported in the Hospital IQR Program for 1 year prior to the beginning of the performance period.

CMS adopted the Elective Delivery Measure in the FY 2013 IPPS/LTCH PPS final rule.[83] 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[84] 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,[85] as well as the adoption of the Birthing-Friendly Hospital designation.

CMS is removing 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 performance can no longer be made (i.e., the measure is "topped out").[86] CMS also justifies that the addition of the 2 new eCQMs supports justification for the removal of the topped-out measure.

Selected Comments/Responses. Several commenters did not support removal of the measure because they did not believe that the measure set includes a suitable alternative, and that maternal morbidity and mortality is an ongoing public health concern regardless of whether the measure is topped-out. CMS notes that the Cesarean Birth eCQM and Severe Obstetric Complications eCQM will begin mandatory reporting in the 2024 reporting period/FY 2026 payment determination so there will be no gap in reporting on Cesarean births.

d. Codification of Measure Retention and Removal Policies

CMS finalizes its proposal to codify the existing measure retention and removal[87] policies for the Hospital IQR Program at §412.140(g)(1) through (3).[88]

8. Summary of Previously Finalized and Newly Adopted Hospital IQR Program Measures

[83] 77 FR 53528 through 53530.
[84] See the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365).
[85] 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.
[86] See Table IX.C-01 in the final rule showing PC-01 data from reporting hospitals for Q1 2016 through Q4 2021.
[87] 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.
[88] 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.

CMS provides tables (Table IX.C-02 through Table IX.C-05) showing the Hospital IQR Program measure set for each of the FY 2025 through FY 2028 payment determinations and subsequent years, including the finalized policies. 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 (CBE #500)	X	X	X	X
PC-01 Elective delivery < 39 weeks gestation (CBE#0469)	X	*Removal effective*		
Electronic Clinical Quality Measures				
• AMI-8a Primary PCI w/in 90 minutes arrival • CAC-3 Home Mgmt Plan Document to Caregiver • STK-2 Antithrombotic therapy for ischemic stroke (CBE #0435) • STK-3 Anticoagulation therapy for Afib/flutter (CBE #0436)*** • STK-5 Antithrombotic therapy by end of hospital day 2 (CBE #0438) • STK-8 Stroke education • STK-10 Assessed for rehabilitation services (CBE #0441) • VTE-1 VTE prophylaxis (CBE #0371) • VTE-2 ICU VTE prophylaxis (CBE #0372) • ED-1 Time from ED arrival to departure for admitted patients (CBE #0495) • ED-2 Time from admit decision to ED departure for admitted patients (CBE #0497)**** • EDHI-1a Hearing Screening Pre-Hospital Discharge • PC-01 Elective delivery < 39 completed weeks gestation (CBE #0469)	Report 4 calendar quarters of data for Safe Use of 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	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications AND 3 of the following 9 eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-01 HH-02 HH-ORAE GMCS	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth* AND Severe Obstetric Complications AND 3 of the following 12 eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-01 HH-02 HH-ORAE GMCS *HH-PI* *HH-AKI* *ExRad*	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications AND 3 of the following 12 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**
• PC-05 Exclusive breast milk feeding (CBE #0480) • Safe Use of Opioids – Concurrent Prescribing (CBE #3316c) • HH-01 Hospital Harm-Severe Hypoglycemia (CBE #3503e) • HH-02 Hospital Harm-Severe Hyperglycemia (CBE #3533e) • Hospital Harm Opioid Related Adverse Events HH-ORAE • ePC-02 Cesarean Birth • ePC-07/SMM Sever Obstetric Complications • Global Malnutrition Composite Score GMCS (CBE #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 (CBE #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 (CBE #1789)	X	Removal effective		
Excess days in acute care after hospitalization for AMI (CBE #2881) Refined	X	X	X	X

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting				
	2025	**2026**	**2027**	**2028**
Excess days in acute care after hospitalization for HF (CBE #2880)	X	X	X	X
Excess days in acute care after hospitalization for PN (CBE #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
Patient Safety				
PSI-04 Death among surgical inpatients with serious, treatable complications (CBE #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	*Removal effective*
Patient Experience of Care				
HCAHPS survey (CBE #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
* Update beginning for FY 2025 Payment Determination				

Summary Table IQR Program Measures by Payment Determination Year X= Mandatory Measure, V= Voluntary Reporting				
	2025	2026	2027	2028
** 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 determination (84 FR 42465 through 42481). CMS is revising the measures beginning with the FY 2027 payment determination in this final 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 is revising the measures beginning with the FY 2027 payment determination in this final 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). # Inclusion beginning with CY 2027 payment determination. ##Including Care Transition Measure (CBE 0228)				

9. Future Considerations

In the FY 2024 IPPS/LTCH PPS proposed rule, CMS described that some of the Hospital IQR Program quality measures may not capture the full spectrum of geriatric care needs and, after reviewing various research, concluded that a more holistic approach that includes patient-centered care would be beneficial. Therefore, CMS sought public comment on two attestation-based structural measures, the Geriatric Hospital measure and the Geriatric Surgical measure, it is considering for potential future proposals for the Hospital IQR Program, and on the potential future proposal for a hospital designation focused on hospitals that participate in patient-centered geriatric care health system improvement initiatives. The below describes the proposals for possible future consideration and summarizes the feedback.

a. Potential Future Inclusion of Two Geriatric Care Measures: Geriatric Hospital and Geriatric Surgical Measures

Overview of measures. The measure developer, the American College of Surgeons (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 two measures were included in the 2022 MUC list. During the MAP review, concern was raised about burden in reporting two 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 two measures or focusing on one 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., identifying goals of care, medication management, cognition and delirium, preventing delirium related events, function and mobility, social determinants of health, care transitions, and ensuring quality care for high-risk patients). Table IX.C–06 of the final rule lists the 8 attestation domains and 14 attestation questions.[89]

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). Table IX.C–07 of the final rule lists the domains and attestation questions. 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.

c. Selected Comments/Responses

Many commenters supported a combined geriatric measure that includes the attestation domains of the geriatric hospital and geriatric surgical measures, which could then be the foundation of a

[89] For example, the first attestation statement (under the domain of identifying goals of care) pertains to advance care planning and says, "Advance Care Planning. Please attest that your hospital provides education to patients and providers regarding advance care planning and ensures that advance care planning preferences are captured, updated, and available for review in the medical record."

geriatric hospital designation. Other commenters did not support the measures, believing that burden would outweigh potential benefits and not seeing a link between attestation and improving outcomes. Recommendations were provided for other geriatric care considerations, such as the role of caregivers, new attestations, clinical guidelines, screening tools, and provider education on the needs of geriatric patients. CMS did not propose these measures or hospital designation at this time and will consider these comments in any future rulemaking on geriatric care in the Hospital IQR Program.

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,[90] the submission deadlines for eCQM data,[91] 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 were proposed to these policies in the proposed rule, except for the HCAHPS survey measure data submission and reporting requirements described below.

Updates to the HCAHPS Survey Measure (CBE #0166) Beginning with the FY 2027 Payment Determination:

CMS finalizes its proposals for the following changes to the HCAHPS Survey measure:

- Adding three new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) to the current Mail Only, Phone Only, and Mail-Phone modes, beginning with January 2025 discharges.
- Removing the requirement that only the patient may respond to the survey and therefore allowing a patient's proxy to respond to the survey, beginning with January 2025 discharges.
- Extending the survey data collection period from 42 to 49 days, beginning with January 2025 discharges.
- Limiting the number of supplemental items permitted to be added to the survey to 12 items, which aligns with other CMS CAHPS Surveys.
- 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, beginning with January 2025 discharges.
- Removing, 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.

[90] Hospitals (i) must submit eCQM data via the QRDA I file format, (ii) may use third parties to submit the data, and (iii) may use abstraction or pull the data from non-certified sources to input into certified EHR technology.
[91] Submission deadlines of eCQMs are aligned with that of the Medicare Promoting Interoperability program – the end of two months after the close of the calendar year.

The HCAHPS Survey measure 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.[92]

In 2021, CMS conducted a large-scale mode experiment to test the following:

- Adding the web mode (Web-Mail, Web-Phone, and Web-Mail-Phone) to the current 3 modes (Mail Only, Phone Only, and Mail-Phone);
- New survey content related to care coordination, discharge experience, communication with patients' families, emotional support, sleep, and summoning help; and
- Other updates to the form, manner, and timing of HCAHPS Survey data collection and reporting.

The mode experiment findings included the following:

- The addition of the 3 modes resulted in increased response rates.
- Excluding proxies did not impact HCAHPS measure scores.
- Extending the data collection period resulted in an increased rate of completion of the survey, including from patients typically under-represented in HCAHPS.
- Increasing the number of supplemental items that may be added to the survey decreased the survey response rate.

These findings informed CMS' proposed changes and determination to finalize those proposals. Comments were generally in support of these changes.

Potential Addition of Patients with a Primary Psychiatric Diagnosis to the HCAHPS Survey Measure. In the FY 2024 IPPS LTCH PPS proposed rule, CMS solicited 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:[93]

- 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.

Many commenters supported the potential inclusion of patients with a primary psychiatric diagnosis in the HCAHPS survey but suggested that CMS first conduct further testing specific to that population and consult with hospitals and other interested parties in technical expert panels. Other commenters did not support the potential inclusion of the population and suggested to

[92] The HCAHPS survey and its protocols can be found in the HCAHPS Quality Assurance Guidelines at https://www.hcahpsonline.org/en/quality-assurance/.
[93] The HCAHPS Survey measure instrument can be found at https://hcahpsonline.org/en/survey-instruments/.

instead conduct a separate survey that addresses psychiatric care. CMS notes that the HCAHPS survey excludes patients with a primary diagnosis code related to psychiatric care and that since the exclusion was part of the development of the survey (because of concerns about the privacy of such information) HCAHPS may not address aspects of the population's experiences. The Agency for Healthcare Research and Quality (AHRQ) has funded a patient experience of care survey development project that is addressing patients with a primary psychiatric diagnosis, and CMS plans to monitor this project to better inform future proposals on how to evaluate this population's experience of care.

11. Addition to Targeting Criteria for Validation of Hospital IQR Program Data

CMS finalizes its proposal to modify the targeting criteria for validation of hospitals granted an extraordinary circumstances exception (ECE).

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 will 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.[94]
- 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.

Additional criterion. Beginning with validations of CY 2024 reporting period data for the FY 2027 payment determination, CMS will add to the existing 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 will not fail the validation-related requirements for the annual payment update (APU) determination for the payment year for which an ECE provides hospitals with an exception from

[94] 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.

data reporting or validation requirements. These hospitals could be selected for validation in the following year.[95]

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

CMS finalizes its proposals 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), which are in addition to the HCP COVID-19 Vaccination measure finalized for inclusion in section IX.B. of the final rule.
- Publicly report the Surgical Treatment Complications for Localized Prostate Cancer measure beginning with data from the FY 2025 program year.
- Modify data submission and reporting requirements for the HCAHPS survey measure beginning with the FY 2027 program year.

CMS estimates a total information collection burden increase associated with its finalized policies for the PCHQR program for the 11 PCHs of 188 hours at a cost of $4,088 annually beginning with the FY 2027 program year.

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 did not propose any changes to the measure removal or retention policies.

3. Adoption of the Facility Commitment to Health Equity Measure

CMS finalizes its proposal to adopt the Facility Commitment to Health Equity measure, which is an attestation-based structural measure, beginning with the FY 2026 program year. This is consistent with the Hospital IQR Program's adoption of the measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191-49201).

[95] 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).

Background. CMS describes significant and persistent disparities in healthcare outcomes and points to studies demonstrating that facility leadership can influence patient outcomes and quality and experience of care. Such leadership can assist in setting goals for assessing progress towards achieving equity goals and ensuring accessibility to high-quality care.

Measure Description. The Facility Commitment to Health Equity 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 final 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 will be required to submit information for the measure once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System beginning with the 2026 program year.

Pre-rulemaking. The measure is not CBE-endorsed.[96] 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.

4. Adoption of 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

CMS finalizes its proposal to adopt the Screening for Social Drivers of Health (SSDOH) measure beginning with voluntary reporting in the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year. The SSDOH measure and the Screen Positive Rate for Social Drivers of Health (SPRSDOH) measure (finalized in section IX.D.5 of the final rule) will be the first measurements of social drivers of health in the PCHQR Program.

Background. The CMMI Accountable Health Communities (AHC) Model 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[97] to screen for HRSNs that were applied in the AHC Model are used in the SSDOH and the SPRSDOH measures. Both

[96] CMS is adopting 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.
[97] The 5 domains are described in detail in Table IX.D-02 of the final rule.

measures were adopted into the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule.[98]

Measure Description. 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). 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 guardian or caregiver available to do so on the patient's behalf.

Data Collection, Submission, and Reporting. PCHs will 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 will be able to select the tool to screen for the 5 HRSNs. Potential sources of data include electronic clinical data, standardized patient assessments, administrative claims data, and patient-reported data. CMS encourages PCHs to use digital standardized screening tools.[99]

Pre-Rulemaking. The measure is not CBE-endorsed.[100] The MAP conditionally supported the measure 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.

Selected Comments/Responses. Many of the comments and responses pertained to both the SSDOH and SPRSDOH measures. A few of the commenters who expressed support for the measures also suggested recommendations, including adding economic insecurity as a social risk factor for screening and allowing occupational therapists to collect the data. CMS notes that the measure is an initial building block for a potentially more comprehensive suite of measures.

Other commenters raised concern about the potential for misalignment with NCQA's Social Need Screening and Intervention measure proposed for adoption in HEDIS and for SDOH measures that could be included in the Medicaid Core Set. CMS responds that its approach to health equity is evolving, the SSDOH and SPRSDOH measures align with other quality reporting and value-based purchasing programs under Medicare (such as the Hospital IQR program and MIPS), and it will continue to look for ways to align programs to minimize provider burden. In response to a comment recommending CMS address technical challenges of

[98] FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220).
[99] CMS references the Social Interventions Research and Evaluation Network (SIREN) website for additional information on resources.
[100] CMS is adopting the measure under the exception under section 1866(k)(3)(B) of the Act.

the measure, the agency encourages PCHs to implement digital standardized screening tools that conform to health IT standards that enable interoperability across systems.

5. Adoption of the Screen Positive Rate for Social Drivers of Health

CMS finalizes its proposal to adopt the SPRSDOH process measure, beginning with voluntary reporting in the FY 2026 program year and followed by mandatory reporting beginning in the FY 2027 program year, 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.

Background. The SPRSDOH measure is a companion measure to the SSDOH measure described above. Whereas the SSDOH measure enables identification of individuals with HRSNs, the SPRSDOH measure captures the extent of such needs and estimates the impact of individual-level HRSNs on healthcare utilization. The Hospital IQR Program adopted this measure in the FY 2023 IPPS/LTCH PPS final rule.[101]

Measure Description. The measure provides information on the percent of patients (18 or older on the date of admission to the PCH and who were screened for an HRSN) who screened positive for at least one of the 5 HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety). The measure is intended to inform PCHs for taking measures to close equity gaps unique to their patient population and is not intended for comparing PCHs.

- *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. PCHs will 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.

Pre-Rulemaking. The measure is not CBE-endorsed.[102] 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.

6. Adoption of Documentation of Goals of Care Discussions Among Cancer Patients Measure

[101] 87 FR 49215 through 49220.

[102] CMS is adopting the measure under the exception under section 1866(k)(3)(B) of the Act.

CMS finalizes its proposal to adopt the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year. This process measure assesses the presence of documentation in the EHR of goals of care conversations. PCHs will 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.

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.

Measure Description.

- *Population*. The population is 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. PCHs will 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 is not CBE-endorsed.[103] The MAP recommended conditional support pending CBE endorsement and testing indicating the measure is reliable and valid.

7. Summary of Previously Adopted and New PCHQR Program Measures for the FY 2026 Program Year and Subsequent Years

CMS summarizes the PCHQR program measures in table IX.D.-03 and the public display dates for the measures in table IX.D.-04. The below table consolidates those two tables and shows the

[103] CMS is adopting the measure under the exception under section 1866(k)(3)(B) of the Act.

previously adopted and (in italics) the newly modified and added measures, with corresponding public display start dates.

PCHQR Program Measures for FY 2026 and Subsequent Years	
Measure	**Public Display Start Date**
Safety and Healthcare Associated Infection	
Colon/Abdominal Hysterectomy SSI (CBE #0753)	2019
NHSN CDI (CBE #1717)	2019
NHSN MRSA bacteremia (CBE #1716)	2019
NHSN Influenza vaccination coverage among health care personnel (CBE #0431)	2019
*NHSN COVID-19 vaccination coverage among health care personnel**	October 2022
NHSN CLABSI (CBE #0139)	October 2022
NHSN CAUTI (CBE #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) (CBE #0210)	July 2024 or as soon as feasible thereafter
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (CBE #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) (CBE #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) (CBE #0213)	July 2024 or as soon as feasible thereafter
Patient Experience of Care	
HCAHPS (CBE #0166)	2016
*Documentation of Goals of Care Discussions Among Cancer Patients***	*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 (CBE # 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***	*July 2026 or as soon as feasible thereafter*
*Screening for Social Drivers of Health***	*July 2027 or as soon as feasible thereafter*
*Screen Positive Rate for Social Drivers of Health***	*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 measure updated in the final rule. ** Indicates new measures added in the final rule.	

8. No changes were 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.

b. Public Display of Surgical Treatment Complications for Localized Prostate Cancer (PCH-37) Measure

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 reports of PCH performance on this measure to individual PCHs. The PCHs will have had 2 years of receipt of confidential facility specific reports before CMS this public display policy begins.

CMS finalizes its proposal to begin public display of the PCH-specific results for the PCH-37 measure beginning with the FY 2025 program year data in the summer of 2024, which will reflect PCH performance for the July 1, 2021 through June 30, 2022 reporting period. The data will be made publicly available after a 30-day period for PCHs to first review the data. This will allow PCHs to have had 2 years of receipt of confidential facility specific reports before public display begins.

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. Updates to the Data Submission and Reporting Requirements for the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (CBE #0166)

CMS finalizes its proposal to make similar updates to the form and manner of administration of the HCAHPS Survey measure under the PCHQR Program as are being finalized under the Hospital IQR Program under section IX.C.10.h. of the final rule. Those changes are, beginning with January 2025 discharges (for the FY 2027 Program Year):

- 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.

11. No changes were proposed to the ECE policy[104] under the PCHQR Program.

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

CMS finalizes its proposals to:

- Beginning with the FY 2025 LTCH QRP:
  - Modify the HCP COVID-19 Vaccination measure;
  - Adopt the Discharge Function Score measure; and
  - Remove the (i) Application of Percent of LTCH Patients with an Admission and Discharge Function Assessment and a Care Plan that Addresses Function measure and (ii) Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function measure;
- Beginning with the FY 2026 LTCH QRP, adopt the COVID-19 Vaccine: Percent of Patients/Residents Who are Up to Date measure; and
- Begin public reporting of 4 measures.

CMS finalizes, with modification, its proposal to increase the LTCH QRP data completion thresholds.

CMS also summarizes public comment received in response to its request for information on principles the agency could use to select and prioritize LTCH QRP quality measures in future years, as well as comments received about its update on efforts to close the health equity gap.

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 associated with the finalized policies across the FY 2025 and FY 2026 program years.

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.[105] 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

[104] See FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624) for the finalized ECE policy.
[105] Post-acute care providers required to report SPADEs are long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.

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).

Quality measures currently adopted for the FY 2024 LTCH QRP are shown in Table IX.E.-01 of the final rule. A summary table of Program measures for FY 2024-2027, including measure changes finalized in this rule, 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 (CBE #0138)	X	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (CBE #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 (CBE #0431)	X	X	X	X
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (CBE #1717)	X	X	X	X
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #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 (CBE #2631)	X	R	R	R
Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function (CBE #2631)	X	R	R	R
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (CBE #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		F	F	F
COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date			F	F

LTCH QRP Measure Set, by Rate (Program) Year				
Measure Title	**FY 2024**	**FY 2025**	**FY 2026**	**FY 2027**
*Modification to measure, as finalized in the rule, beginning for FY 2025 program year X shows previously adopted measures F shows finalized inclusion of a new measure pursuant to the final rule R shows removal of a measure pursuant to the final rule				

2. Overview of LTCH QRP Quality Measures

a. Modification of the HCP COVID-19 Vaccination Measure

In section IX.B. of the final rule, CMS finalizes its proposal to modify the 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.

b. Discharge Function Score (DC Function) Measure

CMS finalizes its proposal to adopt the DC Function measure, an assessment-based outcome 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. Assessing functional status as a health outcome in LTCHs is important 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.

- Measure Description. The DC Function measure is a cross-setting measure that 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 will be added. The measure replaces the topped-out Application of Functional Assessment/Care Plan cross-setting measure being removed in section IX.E.4.c. of the final rule. 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. Also, the measure includes the LTCH population regardless of ventilator status (unlike any other adopted measure in the LTCH QRP).
- 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.[106]

Measure testing. Validity was assessed for the measure performance,[107] the risk adjustment model,[108] face validity, and statistical imputation models.[109]

Pre-Rulemaking. The measure is not CBE-endorsed.[110] CMS intends to submit the proposed measure to CBE for consideration of endorsement when feasible.

Selected Comments/Responses. Several commenters opposed the measure because they believe that LTCH patients' capabilities and goals are different from other PAC settings and the measure is therefore inappropriate for the LTCH setting. CMS recognizes that LTCH patients' goals may be to maintain function rather than obtain significant improvement in function and notes that the measure assesses whether a patient met or exceeded their expected discharge score, which does account for those who are not expected to improve since the expected discharge score is risk-adjusted. CMS also clarifies that cross-setting measures are not to compare facilities across settings but are to standardize measure specifications across settings while comparing providers within the specific setting type. A couple commenters opposed the measure because they believe the imputation method would override clinical judgment of the treating clinicians. CMS clarifies that the use of statistical imputation to calculate a quality measure does not override clinical judgment and that clinicians are still expected to determine whether activities can be safely attempted by patients. The already adopted Change in Mobility Score for Ventilator Patients measure currently uses imputation but imputes a value of "1" (the minimal score) for "Activity Not Attempted" (ANA) codes. In contrast, the imputation method used in the DC Function

[106] 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.
[107] Validity testing of measure performance tested the strength and directional correlations between the measure's performance for providers with 20 or more stays and the performance of other publicly reported LTCH quality measures. Results indicated that the DC Function measure captures the intended outcome, as detailed in Table IX.E.-02 of the final rule.
[108] 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.
[109] Validity testing of the measure's statistical imputation models indicated that the models produce more precise and accurate estimates of function scores for items with missing scores when compared to the current imputation approach.
[110] CMS is adopting the measure under the exception at section 1899B(e)(2)(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.

measure uses the patient's available functional and clinical information to estimate each ANA value had the item been completed.

c. 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

CMS finalizes its proposal to remove the Application of Functional Assessment/Care Plan measure beginning with the FY 2025 LTCH QRP. Public reporting of the measure will end by the September 2024 Care Compare refresh or as soon as technically feasible, when public reporting of the proposed DC Function measure will begin.

- LTCHs will 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 will 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. The removal is based on the measure satisfying the following removal factors:[111]

- 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, i.e., the measure has "topped out."[112]
- Removal factor six: There is an available measure that is more strongly associated with desired resident functional outcomes, specifically the DC Function measure.

d. Removal of the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan (Functional Assessment/Care Plan) Measure

CMS finalizes its proposal to remove the Functional Assessment/Care Plan measure beginning with the FY 2025 LTCH QRP. LTCHs will no longer be required to submit data on the measure beginning with patients admitted on or after October 1, 2023. Public reporting of the measure will end by September 2024 or as soon as technically feasible.

Basis for Removal. The basis for removal is removal factor one (i.e., the measure is topped out).[113] The measure reports the percent of LTCH patients with, both at admission and discharge, a functional assessment and a care plan that addresses function. Functional assessment and function outcomes in LTCH settings will still be represented in the LTCH QRP through the

[111] Section 412.560 of title 42, CFR, specifies eight factors considered for measure removal from the LTCH QRP.
[112] The final 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).
[113] 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).

Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.

e. COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) Measure

CMS finalizes its proposal to adopt the Patient/Resident COVID-19 Vaccine measure beginning with the FY 2026 LTCH QRP.

Background. CMS describes how COVID-19 remains a major challenge to PAC facilities, including LTCHs., and reviews the advantages of COVID-19 vaccine protection, as discussed above.

Measure Description. The measure is an assessment-based process measure that reports the percent of stays in which patients in a LTCH are up to date[114] on their COVID-19 vaccinations per the CDC's latest guidance. The measure has no exclusions and is not risk adjusted.

- *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.

Pre-rulemaking. The measure is not CBE-endorsed.[115] The MAP did not recommend adoption of the measure, with 3 potential mitigation strategies presented:

- Reconsider exclusions for medical contraindications;
- Complete reliability and validity measure testing; and
- Seek CBE endorsement.

CMS explains that (1) 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, (2) exclusions for medical contraindications were not included because they believe raw vaccination rates would be most helpful in resident and family/caregiver decision-making, and (3) the agency plans to conduct reliability and validity measure testing once there is enough data and to submit the measure to the CBE when feasible.

Selected Comments/Responses. Several commenters opposed the measure, some of whom stated that the measure was not fully tested for reliability and validity. CMS responds that validity testing is not yet complete because a COVID-19 vaccination item does not yet exist on the LCDS. Instead, CMS developed clinical vignettes as a proxy for patient records with the most common and challenging cases to test item-level reliability and the results demonstrated strong agreement at 80 percent. In addition, the measure is based on similar vaccination assessment items such as for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonable Influenza Vaccine measure used in the IRF QRP and LTCH QRP. Other

[114] The definition of "up to date" may change based on CDC's latest guidelines and can be found on the CDC webpage at https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.
[115] 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.

commenters opposed the measure because they believe it will increase administrative burden in an environment of staffing shortages while having a minimal impact on patient health. The agency believes that providing the information on the measure informs patients for decision-making, which does affect their health. To address burden, CMS points to the flexibility that providers have to use multiple sources of information for the measure, that LTCHs should be assessing patients' vaccination status as part of their routine care and infection control process anyway, that the measure does not require the LTCHs to administer the vaccine, that the agency will be providing free training to LTCHs and publishing coding instructions, and that the measure will require only one additional LCDS item collected at discharge.

3. Principles for Selecting and Prioritizing LTCH QRP Quality Measures and Concepts under Consideration for Future Years

In the FY 2024 IPPS/LTCH PPS proposed rule, CMS solicited comments on the following:

- A set of principles for selecting measures for the LTCH QRP. CMS identified: (i) actionability, (ii) comprehensiveness and conciseness, (iii) focus on provider response to payment, and (iv) compliance with statutory requirements.
- The identification of measurement gaps in the LTCH QRP, specifically in (i) cognitive function, (ii) behavioral and mental health, (iii) patient experience and patient satisfaction, and (iv) chronic conditions and pain management.
- Measures that are available for immediate use, or that may be adapted or developed for use, in the LTCH QRP to address the identified measurement gaps.

CMS summarizes the comments received in response to the request for information (RFI). Although several commenters agreed there are measurement gaps, some are concerned about the burden associated with additional measures. Recommendations included using measures and assessment data already available (i.e., claims data, LCDS, and NHSN); prioritizing operational improvements to the LTCH QRP (such as through training, consideration of time needed to conduct assessments, removing low-value measures) rather than adding measures; and selecting measures that are reliable, feasible, valid, and CBE-endorsed. Measurement gaps identified that had not been identified by CMS in the RFI included measures focusing on care provided to patients with chronic kidney disease, measures to address health equity (including measures on malnutrition), a measure of patients pharmacologically restrained during an inpatient stay and subsequently discharged to an LTCH to be titrated off their medication, an updated version of the NHSN healthcare associated Clostridioides difficile infection outcome measure, and measures associated with vents, wounds, nutrition, and dialysis.

CMS is not responding in the final rule to specific comments submitted in response to the RFI, but intends to use the input to inform future efforts.

4. Health Equity Update

CMS reiterates its focus on advancing health equity[116] and whole-person care. The agency references its solicitation of public comment in the FY 2023 IPPS/LTCH PPS proposed rule (87

[116] 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,

FR 28570 through 28576) regarding principles for measuring equity and healthcare quality disparities across CMS quality programs, and notes that it will take comments into account as it continues work in this area.

CMS is considering including social determinants of health (SDOH) as part of new LTCH QRP quality measures and 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 SPADEs. The agency emphasizes the value in aligning SDOH items according to existing health information technology codes sets across all care settings.

CMS had not solicited comment on this update but received some feedback, some of which included overwhelming support of its efforts to mitigate health inequities, recommendations to stratify reporting of all LTCH QRP measures, support for adoption in the measure set of the Screening and Referral to Services for Social Needs measure and the Screening for Social Drivers of Health measure, and a recommendation that a nutrition-related measure could address health equity.

5. Form, Manner, and Timing of Data Submission under the LTCH QRP[117]

a. Reporting Schedule for LCDS Assessment Data for the Discharge Function Score Measure Beginning with the FY 2025 LTCH QRP

CMS finalizes its proposal that:

- Beginning with patients admitted or discharged on October 1, 2023, for purposes of the FY 2025 LTCH QRP, LTCHs will be required to report LCDS assessment data on the DC Function measure.
- Beginning in 2024, beginning for purposes of the FY 2026 LTCH QRP, LTCHs will be required to submit data for the entire calendar year.

b. 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

CMS finalizes its proposal that:

- For the FY 2026 LTCH QRP, LTCHs will be required to submit LCDS data beginning with patients discharged on October 1, 2024.
- Beginning with the FY 2027 LTCH QRP, LTCHs will be required to submit data for the entire calendar year (i.e., for 2025 in the case of the FY 2027 QRP).
- CMS will 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. Increase to the LTCH QRP Data Completion Thresholds for LCDS Data Items Beginning with the FY 2026 Payment Determination

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gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes."

[117] The current policies for reporting LTCH QRP data can be found at 42 CFR §412.560(b).

CMS finalizes its proposal to increase the LTCH QRP data completion thresholds for LCDS data items, but with modification. The proposal had been to require LTCHs to report 100 percent of required data items collected using the LCDS on at least 90 percent of the assessments submitted through the CMS-designated submission system. As finalized, however, beginning in 2024 (beginning for purposes of the FY 2026 program year) LTCHs will be required to report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on *at least 85 percent* (instead of the proposed 90 percent) of the assessments they submit through the CMS-designated submission system. CMS believes this more iterative approach maintains the goal of moving toward more complete data.

Selected Comments/Responses. A number of commenters opposed the proposed 90 percent threshold, including for the reasons that it would put unnecessary pressure on those achieving the current minimum 80 percent threshold, potentially negatively affect the accuracy of the data, disadvantage those treating highly complex patients while not incentivizing others to report better data, and remove a buffer that is necessary to take into account instances when it is not possible to complete the assessment for clinical reasons. CMS responds that it believes it is important to have the increased information collection, that the 90 percent threshold would allow for a buffer for instances where LTCHs may not be able to complete the assessment, and that the majority of LTCHs are already meeting the 90 percent threshold.

Several commenters raised concern that LTCHs may not reach the higher threshold because of technical non-compliance and system error issues and therefore should not be held to the higher threshold (which could make them more likely to be subject to a 2 percent payment penalty) until CMS adopts safeguards against technical non-compliance and system error issues experienced by LTCHs with the NHSN and CMS' Internet Quality Improvement and Evaluation System (iQIES). Some commenters also suggested a grace period to allow LTCHs to confer with CMS, NHSN, and iQIES staff to determine any data that was not properly submitted or received and resolve any issues to avoid penalty. CMS notes since the threshold is only for assessment-based data, NHSN would not be used; that for iQIES submitted data LTCHs already have 4.5 months to submit, review, and correct data for a CY quarter as well as access to reports within iQIES, which would satisfy the goals of having a grace period; and that there is a reconsideration and exception and extension process if any LTCH believes a finding of non-compliance is an error.

6. Policies Regarding Public Display of Measure Data for the LTCH QRP[118]

a. 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 finalizes its proposal to publicly display data for these 2 measures based on 4 rolling quarters, initially using discharges from January 1 through December 31, 2023, and to begin publicly reporting these measures with the September 2024 refresh of Care Compare, or as soon

[118] 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.

as technically feasible. CMS will 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. Public Reporting of the Discharge Function Score (DC Function) Measure Beginning with the FY 2025 LTCH QRP

CMS finalizes its proposal to publicly display data for the measure based on 4 quarters of data, initially using data collected from January 1 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 will be distributed in June 2024, or as soon as technically feasible. CMS will not publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases in any quarter.

c. 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 finalizes its proposal 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-December 31, 2024). Provider preview reports will be distributed in June 2025 for data collected in Q4 2024, or as soon as technically feasible. Data publicly displayed will be based on one quarter of data and updated quarterly. CMS will 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.

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 finalizes its proposal for the EHR reporting period in CY 2025 to be a minimum of any continuous 180-day period within CY 2025.

Some commenters objected to the continuous 180-day period stating a preference for a continuous 90-day period. They believe that vendors need more time and additional resources and note that hospitals are still grappling with the financial and workforce implications of the COVID-19 pandemic. CMS believes continuing the 180-day EHR reporting period in CY 2025 will not impact the efforts of eligible hospitals and CAHs to update, implement, and test their EHR systems to maintain effective use of CEHRT.

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.

CMS finalizes its proposal, starting with the EHR reporting period in CY 2025, 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.

CMS will also continue its existing policy for CAHs; thus, for CAHs in CY 2025, the EHR reporting period is any continuous 180-day period within CY 2025 and applies 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 proposed requiring 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. This proposal is finalized without modification.

Selected comments and responses. Many commenters objected to the perceived burden of this requirement, especially for small, rural hospitals with limited resources, noting the requirement to collect documentation from staff, partner organizations and other vendors. In response, CMS clarifies the policy does not require eligible hospitals and CAHs to confirm that they have

implemented any of the SAFER Guides practices—only that they have completed the self-assessment using each of the nine SAFER Guides. Other commenters pointed to the high cost of compliance, which the agency acknowledges. Concerns were raised about the time necessary to meet this requirement with one vendor stating that they would not have time to provide any development or other software support to their clients. Again, CMS acknowledge the challenges, but it believes the benefits outweigh the burden and that over time the challenges of self-assessments will lessen.

Some commenters objected to the addition of the SAFER Guides measure to the PIP program as inappropriate, and others asserted the SAFER Guides do not offer the potential that CMS asserts. CMS notes that the addition of this measure was done in consultation with ONC. A recommendation was also made to update the SAFER Guides (last updated in 2016) to ensure their relevancy to patient safety in hospitals due to the rapid development of health IT. CMS will work with ONC to see if updates are necessary.

Clarification was sought on the level of action required to attest “yes” for the measure. The agency responds that only a review and annual self-assessment of each of the nine SAFER Guides is required for eligible hospitals and CAHs to attest "yes" to this measure. Implementation of any of the recommended practices is not required. CMS will provide resources such as specification sheets, fact sheets, webinars, and events to provide details about the SAFER Guides measure and its appropriate fulfillment.

3. Scoring Methodology for the EHR Reporting Period in 2024

CMS did 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:	5 points	Optional

Objective	Measures	Maximum Points	Required/Optional
	Public Health Registry Reporting Clinical Data Registry Reporting	(bonus)	

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored. 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. 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 entitled "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 finalizes its proposal 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.

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 changes adopted in the final rule. Table IX.F.-04. lists the 2015 Edition certification criteria required to meet the objectives and measures.

CMS also makes 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 final rule summarize the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare PIP for the CY 2023 reporting period and the CY 2024 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. eCQM Adoptions

Because CMS intends to continue to align the Medicare PIP eCQM reporting requirements with similar requirements under the Hospital IQR Program, it finalizes its proposal to adopt the following three new eCQMs for the Medicare PIP eCQM measure set beginning with the CY 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) as well as the agency's responses to comments on the measures. Table IX.F.-07 shows the newly adopted and previously finalized eCQMs for the CY 2025 reporting period and subsequent years.

c. 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 CY 2024 reporting period, CMS modified its

previously finalized requirements for eligible hospitals and CAHs; beginning with the CY 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 CY 2024 reporting period and subsequent years. CMS reminds readers 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 CY 2023 reporting period, but they are mandatory beginning with the CY 2024 reporting period and for subsequent years.

Because CMS adopts 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 in the final rule, these measures are available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the CY 2025 reporting period and subsequent years.

X. Other Provisions

A. Rural Emergency Hospitals (REHs)

As indicated in section V.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 proposed to codify these additional information requirements already in effect into regulation.

CMS also proposed:

1. To revise the definition of a "provider of services or provider" at 42 CFR §488.1 to include REHs as well as to add REHs to other applicable provisions of the regulations.
2. Modify 42 CFR §488.2 to include the statutory basis for the REH program.
3. To 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.
4. Add new regulation text to 42 CFR §488.70 requiring an REH that submits an enrollment application to Medicare must submit additional information as specified in this final rule.

REHs are also subject to the following requirements that CMS proposed 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, 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.

Comments were supportive of the changes CMS is making to the regulations. One commenter was concerned about the regulations being overly burdensome and a potential deterrent to enrollment of REHs. CMS responded that it is only adopting regulatory provisions required by statute. Other commenters requested CMS establish specific requirements for nurse staffing and the provision of maternity services. CMS referred the first commenter to the condition of participation established on nurse staffing. CMS responded to the second commenter by stating that REHs may provide low-risk labor and delivery supported by any emergency surgical procedures necessary if identified by a health needs assessment of their community and in accordance with the conditions of participation for additional outpatient medical and health services.

B. Physician Self-Referral Law: 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 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 an exception request 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. 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 proposed a number of changes to the existing regulations that implement the statutory requirement for that process, including adding a new section to the regulations which would contain provisions relevant to the process. CMS also proposed to clarify a number of issues and make changes to certain requirements for an application for an expansion exception request.

The agency finalizes its proposals, with some modifications as described below, and establishes a new §411.363 that specifies the expansion exception process. It removes existing §411.362(c) from the regulations.
Reactions from stakeholders were mixed. Those in support of the proposals agreed with the agency's interpretation of the statute and those opposed argued that CMS had exceeded its authority. Those opposed claimed that the statute prohibits the agency from denying a request from a hospital that satisfies the criteria for an applicable hospital or high Medicaid facility. CMS strongly disagrees with those who believe the statute sets forth an automatic authorization to expand facility capacity for any hospital that meets the criteria; it cites certain mandatory actions the statute imposes, including requirements for a hospital to apply for an exception and for the agency to publish its final decision on that request in the Federal Register.

Some commenters also objected to what they describe as the imposition of new, additional criteria for expansion exception requests. CMS responds that it is not imposing additional criteria; rather, the agency believes it is merely establishing the sources of information and factors it will consider when deciding whether to approve or deny an expansion exception request.

a. Eligibility (§411.363(b))

CMS clarifies that an applicant must first demonstrate it meets the criteria for an applicable hospital or high Medicaid facility before CMS will consider an expansion exception request. Hospitals that satisfy those criteria must also demonstrate the following:

- The hospital has not already been approved by CMS for an expansion exception that would allow the hospital to reach 200 percent of its baseline facility capacity; and
- It has been at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent expansion exception.

b. Criteria for Applicable Hospitals and High Medicaid Facilities (§411.363(c) and (d))

CMS incorporates in new §411.363(c) the existing criteria[119] for applicable hospitals seeking an exception to the prohibition on facility expansion, including population increase, Medicaid inpatient admissions, nondiscrimination, average bed capacity, and average bed occupancy. It similarly incorporates in new §411.363(d) the existing criteria for high Medicaid facilities[120] including the sole hospital, Medicaid inpatient admissions and nondiscrimination requirements.

For the criteria applicable to both these types of providers, CMS also clarifies that for purposes of the statutorily required comparisons with respect to Medicaid inpatient admissions (i) the hospital is only required to compare itself to other hospitals that have a Medicare participation agreement with CMS and are located in the county in which the hospital is located; (ii) a hospital is located in the county and State in which the main campus of the hospital is located; and (iii) beginning with requests submitted on or after October 1, 2023, hospital may use only filed Medicare cost report data from HCRIS to perform the required calculations. CMS has determined that HCRIS now contains sufficiently complete inpatient Medicaid discharge data to perform the calculations to estimate Medicaid inpatient admissions for both the existing expansion exception process and the modified one finalized under this rule.

c. Procedure for Submitting a Request for an Exception (§411.363(e))

CMS finalizes its proposal to expand and clarify existing requirements for information that must be included in an application, with modifications. Applicants must provide the name of the county where the main campus of the hospital is located and also include the names of any counties in which the hospital provides inpatient or outpatient hospital services. In a modification from the proposed rule, the applicant must also include its tax identification number (TIN) and CMS certification number among the other required demographic information for the hospital. This is intended to eliminate potential confusion regarding the need to submit more than one TIN or CMS certification number.

The nondiscrimination statement[121] is expanded such that the hospital must show how it meets the nondiscrimination requirement and provide supporting information if available.

Under the final rule, the applicant must provide documentation supporting whether and how it has used any previously-approved expansion facility capacity. However, in a change from the proposed rule, other information may be provided at the election of the hospital, such as (i) whether it plans to use expansion facility capacity to provide specialty services if the request is approved; and (ii) the hospital's current or future need for additional operating rooms, procedure rooms, or beds. CMS believes this reduction in the required information will lessen the burden on applicant hospitals. Because any facility capacity expanded under an approved expansion exception request submitted on or after October 1, 2023, will be restricted to the main campus of

[119] https://www.ecfr.gov/current/title-42/part-411/section-411.362#p-411.362(c)(2)
[120] https://www.ecfr.gov/current/title-42/part-411/section-411.362#p-411.362(c)(3)
[121] 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.

the requesting hospital, CMS finds that it is unnecessary to request information regarding the location of any planned CMS-approved expansion of operating rooms, procedure rooms, or beds.

All expansion requests, and the required signed certification, must be submitted to CMS electronically and include an email address as well as a hardcopy mailing address for the contact person for the hospital.

d. Community Input (§411.363(f))

As finalized, the definition of the term "community" includes (i) the geographic area served by the hospital (as defined at §411.357(e)(2)); (ii) the county in which the hospital's main campus is located; and (iii) the counties in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request.

One significant modification in the final rule applies to the notice required of applicants. Specifically, CMS will require the hospital seeking the expansion exception to provide actual notification of its request only to those hospitals whose data are part of the comparisons required to show that it meets the criteria for an applicable hospital or a high Medicaid facility; this notice must be provided directly to these hospitals. CMS does not finalize its proposal to require that the requesting hospital also provide actual notice directly to hospitals that are located in the remainder of the requesting hospital's community.

Some commenters suggested that community input should be limited to whether the applicant meets the criteria for an applicable hospital or high Medicaid facility. CMS rejects this position, and it clarifies 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.

CMS finalizes its proposal to double the length of the period for community input from 30 to 60 days. In response to a request from a commenter, the 30-day period for the hospital's rebuttal statement is also doubled to 60 days in the final rule.

e. Timing of Complete Request

CMS reduces the period after which it deems an application to be complete from no later than 180 days to no later than 90 days. This is because the final rule requires the use of CMS-provided Medicare hospital cost report data from HCRIS for all expansion exception requests submitted on or after October 1, 2023. Thus, as proposed, an application is deemed to be complete no later than 90 days after (i) the end of the 60-day comment period if CMS does not receive written comments from the community; or (ii) the end of the 60-day rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement, if CMS receives written comments from the community.

In a transition rule, CMS clarifies that if an expansion exception request is submitted before October 1, 2023 and includes data from an external data source, community input, or the hospital's rebuttal statement, then the request would continue to be deemed complete no later

than 180 days after the end of the comment period if CMS does not receive community input or, if it does receive community input, 180 days after the end of the rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement.

f. Decisions to Approve or Deny an Application (§411.363(h) and (i))

CMS finalizes its proposals, with modifications, for the process it will use to approve or deny an application for an expansion request.

First, CMS will determine whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility. This will be based on the information submitted in the application as well as on community input.

Then, in reviewing a request, the agency will consider the information submitted by the hospital in the application, community input, and information provided by the applicant hospital in its rebuttal statement, if any. In its review, CMS could also consider other data and information relevant to its decision, which could include publicly available data and information, information provided by interested parties, and information from government agencies.

CMS will 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, or
    - any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request.

In response to comments, CMS argues that the required information and enumerated factors it will consider under the final rule neither establish an actual or *de facto* federal certificate of need program nor establish minimum thresholds that must be met or maximum thresholds that may not be exceeded by a hospital to establish a showing of need for additional facility capacity. Rather, CMS argues the information and factors are intended to help a requesting hospital and interested parties in providing useful information that could help the agency in deciding whether to approve or deny an expansion exception request. Hospitals are not limited in their application to specific data points and may include any information supportive of the request. CMS also believes the finalized policies will improve transparency and reduce the likelihood of inconsistent outcomes. The agency notes that it has not assigned any weights to any of the factors or to any particular data point.

The statute waives administrative or judicial review of its decision to approve or deny an expansion exception application; the final rule expands on this to specify that the waiver applies

to the establishment of the application process and any determination or decision under the process.

An application will 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.

g. Publication of Final Determination and Decision (§411.363(h))

Within 60 days of receipt of a complete request, CMS will publish notice in the Federal Register of its determination whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. If it determines that the applicant meets those criteria, the agency will also publish notice of its decision to approve or deny the expansion exception request in the same Federal Register notice.

h. Technical Changes. CMS finalizes a number of technical and grammatical revisions to existing regulations at §411.362.

3. Reinstatement of Program Integrity Restrictions on Approved Facility Expansion (§411.363(j))

CMS believes 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 proposed, 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. CMS finalizes its proposal without substantive modification.

Thus, the same program integrity restrictions will again apply to both applicable hospitals and high Medicaid facilities. The reinstated program integrity restrictions do not apply to an expansion exception request submitted by a high Medicaid facility on or after January 1, 2021 and before October 1, 2023. CMS also clarifies that no changes were proposed for program integrity restrictions for applicable hospitals.

CMS notes that nothing in the physician self-referral regulations or its reinstated policy 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 from its main campus to a remote

location of the physician-owned hospital before implementing an approved facility expansion on its main campus. 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. However, §411.362(c)(6) provides that any increase in the number of operating rooms, procedure rooms, or beds permitted by the Secretary through an exception may occur only in facilities on the hospital's main campus; thus, any operating rooms, procedure rooms, or beds added by reason of an approved expansion exception request can be located only on the main campus of the hospital and may not subsequently be relocated from the main campus.

Selected Comments/Responses. Reaction to the proposal was mixed, with those in support sharing the concerns expressed by CMS in the proposed rule. Commenters who opposed the policy argued that reinstating the restrictions would create barriers to care and exacerbate poor health outcomes for patients with lower incomes and socioeconomic disadvantages because high Medicaid facilities serve many patients in such categories; they also said CMS should show proof of actual cherry-picking, lemon-dropping and other harmful physician self-referral practices before finalizing the proposal. In response, CMS reiterates the policy goals of the physician self-referral law, noting that prohibitions were intended to prevent a patient from being referred for services that are not needed or steered to certain health care providers because the patient's physician may improve their financial standing through those referrals. Specific to physician-owned hospitals, the agency is concerned that, when physicians have a financial incentive to refer a patient to a particular entity, that incentive can affect utilization, patient choice, and competition. Additionally, physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered, and a patient's choice is diminished when physicians steer patients to less convenient, lower quality, or more expensive providers of health care just because the physicians are sharing profits with, or receiving remuneration from, the providers. Finally, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers if new competitors cannot win business with superior quality, service, or price.

4. Regulatory Impact

CMS does not believe any of the finalized policies will result in any change in burden under the PRA. It describes the changes to the information required to be submitted under the final rule as being primarily technical or clarifying in nature; it does not anticipate that they will meaningfully affect the time needed to prepare and submit a request. Further, it believes these changes are exempt from the PRA because the universe of potential respondents is extremely small. On average, CMS has received approximately one expansion exception request per year.

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. In the FY 2024 IPPS proposed rule, CMS proposed to correct those errors. There were no public comments on these proposals. CMS is finalizing these proposed changes without modification.

D. Safety Net Request for Information (RFI)

1. Background

To advance health equity, CMS seeks to evaluate policies to determine how it 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 evaluated two potential alternatives in the proposed rule that it believes may better target payments to these hospitals.

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 when the following circumstances are 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 solicited 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 solicited 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 evaluated to identify safety-net hospitals is an area-level index 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 requested information on potential approaches to help safety-net hospitals by asking for responses to 23 specific questions. In the final rule, CMS does not summarize the comments but appreciates the many thoughtful and wide-ranging comments it received. CMS indicates that these comments will inform future rulemaking on this issue.

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 for institutional providers.

The proposed rule indicated 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 institutional providers and suppliers that also enroll using the CMS 855A. Under the authority of sections 1866(j), 1102 and 1871 of the Act,[122] CMS proposed that all providers and suppliers that enroll in Medicare using the CMS-855A enrollment form disclose PEC and REIT ownership information. CMS further requested 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.

CMS received 10 comments on these proposals. These comments closely aligned with those received on the February 15, 2023 proposed rule, which CMS will address them when it finalizes the that proposed rule.

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. Consistent with current law, CMS is adopting an update equal to the market basket rate of increase (3.3 percent) less total factor productivity (0.2 percentage points) for hospitals that submit quality data and are meaningful users of EHR technology.

MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommends redistributing current Medicare safety-net payments (DSH and UCP) using the MedPAC-developed SNI for hospitals. In addition, MedPAC recommends adding $2 billion to this MSNI pool of funds to help maintain the

[122] 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.

financial viability of Medicare safety-net hospitals and recommended to Congress transitional approaches for a MSNI policy.

CMS looks forward to working with Congress on MedPAC's MSNI recommendations and sought comments on approaches it could take under its current authority. The final rule notes that sections 1886(d)(5)(F) and section 1886(r) of the Act require CMS to make DSH and UCP payments to hospitals respectively that serve a disproportionate share of low-income patients and for their uncompensated care costs.

TABLE I.—FY 2024 Final Rule Operating Impacts

	Number of Hospitals[1]	Hospital Rate Update[2] (1)	FY 2024 Weights and DRG Changes with Application of Budget Neutrality[3] (2)	FY 2024 Wage Data with Application of Wage Budget Neutrality[4] (3)	FY 2024 MGCRB Reclassifications[5] (4)	Rural Floor with Application of National Rural Floor Budget Neutrality[6] (5)	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment[7] (6)	All FY 2024 Changes[8] (7)
All Hospitals	3,131	3.1	0.0	0.0	0.0	0.0	0.4	3.1
By Geographic Location:								
Urban hospitals	2,416	3.1	0.0	0.0	-0.1	0.0	0.4	3.1
Rural hospitals	715	3.0	0.2	-0.3	1.8	-0.6	0.1	3.5
Bed Size (Urban):								
0-99 beds	650	3.0	-0.2	-0.1	-1.6	0.9	0.5	2.5
100-199 beds	696	3.1	0.2	0.0	-0.6	0.8	0.4	3.2
200-299 beds	414	3.1	0.1	0.0	-0.1	0.5	0.5	3.4
300-499 beds	404	3.1	0.0	0.1	0.6	0.2	0.3	3.8
500 or more beds	250	3.0	-0.1	0.0	-0.3	-0.6	0.4	2.4
Bed Size (Rural):								0.0
0-49 beds	363	2.9	0.1	-0.1	1.1	-0.5	0.2	3.1
50-99 beds	188	3.0	0.3	0.0	1.7	-0.4	0.1	4.0
100-149 beds	87	3.0	0.4	-0.2	2.0	-0.5	0.1	3.7
150-199 beds	46	3.1	0.2	-0.5	1.9	-0.7	0.0	3.2
200 or more beds	31	3.1	0.1	-0.7	2.5	-0.7	0.3	3.1
Urban by Region:								
New England	108	3.1	0.0	-0.5	4.0	0.0	0.6	0.5
Middle Atlantic	292	3.1	0.1	0.9	-0.1	-0.5	1.0	3.9
East North Central	372	3.1	0.0	-0.6	-1.1	-1.0	0.1	1.2
West North Central	156	3.1	-0.2	-0.1	-1.4	-0.9	0.6	1.3
South Atlantic	403	3.1	0.0	0.0	-0.6	-0.2	0.4	3.3
East South Central	138	3.1	0.0	0.0	-1.3	-0.9	0.1	2.2
West South Central	359	3.1	0.0	0.0	-1.5	-1.0	0.1	1.6
Mountain	177	3.1	-0.1	-0.4	0.5	1.4	0.4	3.1

	Number of Hospitals[1]	Hospital Rate Update[2] (1)	FY 2024 Weights and DRG Changes with Application of Budget Neutrality[3] (2)	FY 2024 Wage Data with Application of Wage Budget Neutrality[4] (3)	FY 2024 MGCRB Reclassifications[5] (4)	Rural Floor with Application of National Rural Floor Budget Neutrality[6] (5)	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment[7] (6)	All FY 2024 Changes[8] (7)
Pacific	360	3.0	0.0	0.1	1.0	2.7	0.1	6.4
Puerto Rico	51	3.0	0.3	-1.9	-2.5	-0.2	0.1	1.9
Rural by Region:								
New England	19	3.1	0.0	-1.2	0.9	-0.7	0.1	2.0
Middle Atlantic	47	3.1	0.2	-0.1	5.6	-0.8	0.4	7.2
East North Central	113	3.1	0.1	-0.3	1.1	-0.4	0.0	2.9
West North Central	84	3.0	0.2	-0.1	0.4	-0.3	0.3	3.1
South Atlantic	108	3.1	0.4	0.2	2.0	-0.7	0.1	3.4
East South Central	140	3.0	0.3	-0.7	1.9	-0.8	0.1	3.1
West South Central	134	3.0	0.2	-0.1	2.1	-0.7	0.0	3.1
Mountain	46	2.8	0.0	0.0	0.1	-0.2	0.8	2.6
Pacific	24	3.1	0.4	-0.2	3.6	-0.5	0.0	5.4
By Payment Classification:								
Urban hospitals	1,811	3.1	0.0	0.0	-1.8	1.1	0.6	3.3
Rural areas	1,320	3.1	0.0	0.0	1.8	-1.1	0.1	2.8
Teaching Status:								
Nonteaching	1,900	3.1	0.1	-0.1	-0.2	0.9	0.3	3.5
Fewer than 100 residents	953	3.1	0.0	0.0	0.0	0.0	0.5	3.2
100 or more residents	278	3.0	0.0	0.1	0.1	-0.7	0.4	2.6
Urban DSH:								
Non-DSH	353	3.1	-0.4	0.2	-1.8	-0.2	0.9	2.0
100 or more beds	1,099	3.1	0.1	0.0	-1.8	1.2	0.6	3.5
Less than 100 beds	359	3.1	0.2	-0.1	-1.8	1.7	0.4	3.1
Rural DSH:								
Non-DSH	108	3.0	-0.3	0.1	2.6	-1.0	0.2	2.3
SCH	257	3.0	0.3	0.0	0.3	-0.1	0.0	3.4
RRC	712	3.1	0.0	-0.1	2.0	-1.1	0.1	2.8

	Number of Hospitals[1]	Hospital Rate Update[2] (1)	FY 2024 Weights and DRG Changes with Application of Budget Neutrality[3] (2)	FY 2024 Wage Data with Application of Wage Budget Neutrality[4] (3)	FY 2024 MGCRB Reclassifications[5] (4)	Rural Floor with Application of National Rural Floor Budget Neutrality[6] (5)	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment[7] (6)	All FY 2024 Changes[8] (7)
100 or more beds	32	3.1	-0.2	0.5	-1.1	-1.2	0.1	3.7
Less than 100 beds	211	3.0	0.3	-0.1	1.9	-0.8	0.2	3.9
Urban teaching and DSH:								
Both teaching and DSH	637	3.1	0.1	0.1	-1.8	0.8	0.7	3.2
Teaching and no DSH	57	3.1	-0.3	0.6	-1.8	-0.5	1.1	2.4
No teaching and DSH	821	3.1	0.1	-0.1	-1.7	2.2	0.3	4.1
No teaching and no DSH	296	3.1	-0.4	-0.1	-1.7	-0.1	0.8	1.8
Special Hospital Types:								
RRC	133	3.2	0.0	-0.4	1.8	-0.3	0.4	3.1
RRC with Section 401 Rural Reclassification	491	3.1	-0.1	0.0	2.1	-1.3	0.1	2.7
SCH	256	3.0	0.2	0.0	0.3	-0.2	0.1	3.3
SCH with Section 401 Rural Reclassification	45	3.1	0.3	0.0	0.1	-0.1	0.0	3.4
SCH and RRC	121	3.1	0.2	-0.2	0.9	-0.3	0.1	3.4
SCH and RRC with Section 401 Rural Reclassification	43	3.1	-0.1	0.0	0.3	-0.1	0.0	2.9
MDH	116	3.0	0.1	-0.2	1.3	-0.6	0.6	3.6
MDH with Section 401 Reclassification	30	3.1	0.3	-0.2	0.6	-0.3	0.0	3.7
MDH and RRC	18	3.0	0.3	0.0	1.2	-0.4	0.1	3.5
MDH and RRC with Section 401 Reclassification	13	3.1	0.3	-0.1	0.7	-0.3	0.0	3.3
Type of Ownership:								
Voluntary	1,920	3.1	0.0	0.0	0.2	-0.2	0.4	3.0
Proprietary	778	3.1	0.0	-0.2	-0.4	1.3	0.2	3.8
Government	432	3.0	0.1	0.0	-0.6	-0.1	0.1	3.0
Medicare Utilization as a Percent of Inpatient Days:								
0-25	995	3.0	0.1	0.1	-0.5	0.3	0.2	3.6
25-50	1,945	3.1	0.0	-0.1	0.3	-0.2	0.5	2.8

	Number of Hospitals[1]	Hospital Rate Update[2] (1)	FY 2024 Weights and DRG Changes with Application of Budget Neutrality[3] (2)	FY 2024 Wage Data with Application of Wage Budget Neutrality[4] (3)	FY 2024 MGCRB Reclassifications[5] (4)	Rural Floor with Application of National Rural Floor Budget Neutrality[6] (5)	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment[7] (6)	All FY 2024 Changes[8] (7)
50-65	138	3.0	0.1	0.1	-0.6	1.6	0.6	3.5
Over 65	25	2.7	0.7	0.3	0.3	-0.2	0.0	4.1
Medicaid Utilization as a Percent of Inpatient Days:								
0-25	2,038	3.1	-0.1	0.0	0.1	-0.4	0.4	2.7
25-50	974	3.1	0.1	0.0	-0.1	0.3	0.4	3.4
50-65	91	2.9	0.8	0.5	-0.7	2.7	0.1	6.4
Over 65	28	2.9	1.1	0.3	-1.9	7.6	0.0	11.7
FY 2024 Reclassifications:								
All Reclassified Hospitals	1,054	3.1	0.0	0.0	1.9	-0.8	0.1	2.9
Non-Reclassified Hospitals	2,077	3.1	0.0	0.0	-2.0	0.8	0.6	3.2
Urban Hospitals Reclassified	869	3.1	-0.1	0.0	1.8	-0.8	0.2	2.9
Urban Non-Reclassified Hospitals	1,561	3.1	0.0	0.1	-2.4	1.0	0.7	3.2
Rural Hospitals Reclassified Full Year	298	3.1	0.3	-0.3	2.3	-0.6	0.0	3.3
Rural Non-Reclassified Hospitals Full Year	403	3.0	0.2	-0.3	1.0	-0.5	0.4	3.7
All Section 401 Rural Reclassified Hospitals	659	3.1	-0.1	0.0	1.8	-1.1	0.1	2.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	3.1	0.2	-0.4	4.0	-0.9	0.0	3.9

[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 hospital rate update, including the 3.1 percent update to the national standardized amount and the hospital-specific rate (the 3.3 percent market basket rate-of-increase reduced by 0.2 percentage point for the productivity adjustment).

[3] This column displays the payment impact of the changes to the Version 41 GROUPER, the 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 recalibration budget neutrality factors of 1.001463 and 0.999928.

[4] This column displays the payment impact of the 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 wage budget neutrality factor. The wage

budget neutrality factor is 1.000702.

[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 geographic budget neutrality factor of 0.971295.

[6] This column displays the effects of the rural floor and the 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 rural floor budget neutrality factor applied to the wage index is 0.978183.

[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 payments from FY 2023 to FY 2024.