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Fiscal Year 2025 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Final Rule Summary

On August 1, 2024, the Centers for Medicare & Medicaid Services (CMS) released its final rule describing federal fiscal year (FY) 2025 policies and rates for Medicare's hospital 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, 2024.

The payment rates and policies described in the IPPS/LTCH final rule (CMS-1808-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 final rule also sets forth rate-of-increase limits for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals and religious nonmedical health care institutions, which are paid based on reasonable costs. Unless otherwise specified, policies will be effective October 1, 2024.

CMS is also adopting a mandatory model, the Transforming Episode Accountability Model (TEAM), to test whether episode-based payments for five common, costly procedures would reduce Medicare expenditures while preserving or enhancing the quality of care. Other policies in the rule include a requirement to report respiratory syncytial virus and a payment subsidy for small independent hospitals to maintain a buffer stock of essential medicines.

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/payment/prospective-payment-systems/acute-inpatient-pps/fy-2025-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 final rule will increase FY 2025 combined operating and capital payments to approximately 3,082 acute care hospitals paid under the IPPS by an estimated $2.9 billion. This net impact is primarily driven by the changes in FY 2025 operating payments, including uncompensated care payments (UCP), FY 2025 capital payments, and the expiration of the temporary changes in the low-volume hospital (LVH) and the MDH program in its entirety. As shown below, this net impact reflects a reduction of $232.2 million in UCP payments and an additional reduction in expenditures for the LVH and MDH programs of $267 and $152 million respectively.

A. Inpatient Hospital Operating Update

The above are changes to aggregate IPPS payments. The estimated percentage increase in IPPS *payment per service* is estimated at 2.9 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 2.9 percent rate increase is the net result of a market basket update of 3.4 percent less 0.5 percentage points for productivity. The payment rate update factors are summarized in the table below.

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. The reduction is ¼ of the market basket for hospital failing IQR, ¾ of the market basket for hospitals that are not meaningful users of EHR, and 100 percent of the market basket for hospitals failing both programs.

Updates for Hospitals Failing IQR and/or EHR

	Penalty	Market Basket (MB)	Market Basket Net of Productivity	Reduction (Percentage Points)	Update	Hospitals
No IQR	25% of the MB	3.4%	2.9%	-0.85	2.05%	90
No EHR	75% of the MB	3.4%	2.9%	-2.55	0.35%	82
No IQR/EHR	100% of the MB	3.4%	2.9%	-3.4	-0.5%	27

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2025 payments increasing 2.8 percent. Not all policy changes are reflected in this total. For example, the total does not include estimated changes in UCP and new technology add-on payments (NTAP). The factors that are included in this total are shown in the following table.

Contributing Factor	National Percentage Change
FY 2025 increase in payment rates	+2.9
Expiration of the MDH Program	-0.1[1]
Total	+2.8[2]

[1] MDH program is a temporary program that has been set to expire many times previously before being extended again by Congress—sometimes retroactively. The MDH program expires under current law on January 1, 2025. In the proposed rule, the impact table also referenced the expiration of temporary provisions of the LVH program that allow more hospitals to qualify than under regulations that were previously in effect. CMS does not discuss the LVH program separately here but its more permissive provisions are also set to expire on January 1, 2025. More discussion of the impact of the LVH program appears below.

[2] CMS targets 5.1 percent of IPPS payments as outliers but estimates that it will pay just under that percentage in FY 2024 (a difference of less than 0.05 percentage points).

Table I Impact Analysis

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

Hospital Type	All Final Rule Changes
All Hospitals	2.8%
Urban	2.8%
Rural	2.6%
Major Teaching	3.0%

To the extent the impact on a given hospital category deviates from the national average of 2.8 percent, it suggests that there is a factor(s) 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 largest deviation from the average increase of 2.8 percent is occurring from expiration of the MDH program. While the MDH program has been set to expire numerous times in its 30+ years of existence, Congress has always temporarily extended the program. Nevertheless, at this point in time, the MDH program is set to expire at the end of calendar year. CMS estimates that expiration of the MDH program will affect 117 hospitals and decrease spending $152 million for 9 months of FY 2025.

Other provisions having an impact include:

Rural Floor. The rural floor raises the wage index of 771 urban hospitals so that it is not below the wage index for the rural area of its state. CMS calculates a national rural floor budget neutrality adjustment factor of 0.977499 (-2.25 percent) applied to hospital wage indexes. CMS projects that rural hospitals in the aggregate will experience a 0.7 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in urban areas would experience a 0.1 average increase in payments; and urban hospitals in the Pacific region can expect a 2.3 percent increase in payments relative to the rural floor not being applied, primarily due to the application of the rural floor in California.

Imputed Floor, Frontier Floor and Outmigration. CMS shows the combined impact of three provisions in a single column: (1) The imputed floor establishes a statewide wage index floor in all urban states, Washington, DC, and Puerto Rico; (2) the frontier floor establishes a floor on the wage index of 1.0 in Montana, North Dakota, South Dakota and Wyoming; and (3) the outmigration adjustment increases the wage index for hospitals in counties where a high proportion of its workers commute to hospitals in adjacent counties with a higher wage index. None of these provisions are subject to budget neutrality.

The imputed floor provision is estimated to increase payment to 76 hospitals in Connecticut, Washington, DC, New Jersey, Puerto Rico and Rhode Island by $203 million. The frontier floor is estimated to increase payment to 41 hospitals by $55 million. The outmigration adjustment is estimated to increase payment to 203 hospitals by $65 million.

NTAP. NTAP payments are not subject to budget neutrality. CMS is continuing NTAP payments for 24 technologies that remain eligible for add-on payments in FY 2025 and estimates Medicare will pay $262.4 million for these products in FY 2025.

For alternative pathway applications (discussed further in section II.E), CMS is approving 11 alternative pathway applications (one for two indications) and estimates total expenditures of $171.5 million. An additional 5 NTAP applications are being approved under the traditional pathway (including 2 additional technologies that are considered substantially similar to a product already approved). These technologies are estimated to cost $335.6 million. In total, CMS expects to spend $769.5 million on NTAP in FY 2025 (about $274 million more than its estimates of FY 2024 NTAP).

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to decrease by $232.3 million or by 3.9 percent. Supplemental payments to Puerto Rico, Indian Health Service (IHS) and Tribal Hospitals are estimated to decrease another $3.3 million in FY 2025. The supplemental payments to hospitals in Puerto Rico and for IHS and Tribal Hospitals are analogous to uncompensated care payments for other hospitals and take into account unique issues with cost reporting that apply to these hospitals. More detail on these calculations is in section IV.

LVH. Special adjustments were established by the Affordable Care Act for LVHs. Subsequent legislation changed the criteria to allow more hospitals to qualify. However, those qualifying

criteria will expire on December 31, 2024 absent congressional intervention. CMS estimates changes to the qualifying criteria will result in 600 fewer hospitals receiving the LVH payment adjustment, resulting in lower spending of $267 million.

Graduate Medical Education (GME). As described in further detail in section V.F., Medicare subsidizes graduate medical education training based on a capped number of residents that a hospital may count. Section 4122 of the Consolidated Appropriations Act (CAA), 2023 authorized CMS to distribute an additional 200 residency positions above the caps effective July 1, 2026. As additional spending associated with the 200 residency positions is not effective until 2026, there will be no additional 2025 expenditures associated with these residents. However, CMS indicates this provision will result in additional expenditures of $10 million in FY 2026, $280 million for FY 2026 through FY 2030, and $740 million for FY 2026 through FY 2036.

End Stage Renal Disease (ESRD) Add-On. Hospitals that treat a high percentage of ESRD beneficiaries are eligible for an additional payment. CMS is making a change to how that additional payment is calculated, resulting in an estimated increase in payment of $10 million to 91 hospitals.

Maintaining Access to a Buffer Stock of Essential Medicines. CMS is proposing payment adjustments for the additional resource costs that small, independent hospitals incur in establishing and maintaining access to a 6-month buffer stock of one or more essential medicine(s) beginning October 1, 2024. CMS estimates that its proposal will provide payments to 500 eligible hospitals and cost Medicare about $0.3 million in FY 2025 (or about $620 per eligible hospital).

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2025 payments to an estimated 2,828 hospitals or 78.3 percent of all hospitals eligible to receive a readmissions penalty. The readmissions penalty is estimated to affect 0.42 percent of payments among all eligible hospitals. The impact section of the rule includes table I.G.7.-01 that illustrates the average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural) in FY 2025.

Hospital Value-Based Purchasing (HVBP) Program. The HVBP program is budget neutral but will redistribute 2 percent of base operating MS-DRG payments (about $1.67 billion) based on hospitals' performance scores. Table I.8.-01 in the impact section illustrates the average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural) in FY 2025.

Hospital Acquired Conditions (HAC) Reduction Program. The HAC reduction program reduces payment to hospitals that are among the highest quartile for HACs. The final rule includes an unnumbered table that shows the number of hospitals in the program and the number of hospitals receiving a penalty by hospital category.

Rural Community Hospital Demonstration Program. CMS estimates costs for the 22 hospitals participating in the Rural Community Hospital Demonstration Program at $49.9 million for FY 2025 using "as submitted" cost reports from FY 2019.

CMS used reconciled FY 2019 cost reports in the FY 2025 final rule in applying a final adjustment for budget neutrality to FY 2025 IPPS standardized amounts. In FY 2019, CMS estimated costs for the Rural Community Hospital Demonstration Program at $30.5 million more than its actual costs. As a result, CMS is subtracting this amount from the $49.9 million estimated to be paid for the demonstration in FY 2025. Based on costs of $19.4 million, CMS is applying a budget neutrality adjustment for FY 2025 of -0.02 percent.

C. IPPS Standardized Amounts

The following four rate categories continue in FY 2025 (before adjustments):

	Update
Full Update	2.9%
No IQR	2.05%
No EHR	0.35%
No EHR/IQR	-0.5%

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, 0.997190 (a decrease of 0.28 percent);
- MS-DRG recalibration cap, 0.999874 (a decrease of 0.01 percent);
- Wage index, 1.000114 (an increase of 0.01 percent);
- Geographic reclassification, 0.962791 (a decrease of 3.72 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.997157 or -0.28 percent;
- 5 percent cap on wage index reductions, 0.999173 or -0.08 percent;
- The outlier offset factor is 0.949 or -5.1 percent; and
- The rural community hospital demonstration program adjustment is 0.99981 or -0.02 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 2024 standardized amount before the FY 2025 adjustments are applied. The net increase in the standardized amount results as follows:

Factor	Net Change
Update	2.9%
DRG Recalibration	-0.28%
DRG Recalibration Cap	-0.01%
Wage Index	0.01%
Geographic Reclassification	-0.88%
25th Percentile	-0.02%
5% Cap on Wage Index Reductions	-0.05%

Factor	Net Change
Outlier	0.00%
Rural Community Hospital	0.03%
Net Change*	1.67%

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

The increase in the capital rate is 1.33 percent from $503.83 to $510.51. The combined increase in the operating standardized amount and the capital rate is 1.65 percent for FY 2025.

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.

STANDARDIZED AMOUNTS for FY 2025

	Full Update=2.9%	Reduced Update Failed IQR = 2.05%	Reduced Update Failed EHR =0.35%	Reduced Update Failed IQR and EHR = -0.5%
Wage Index >1.0				
Labor (67.6%)	$4,466.00	$4,429.11	$4,355.33	$4,318.44
Non-Labor (32.4%)	$2,140.51	$2,122.83	$2,087.47	$2,069.78
Wage Index <=1.0				
Labor (62%)	$4,096.04	$4,062.20	$3,994.54	$3,960.70
Non-Labor (38%)	$2,510.47	$2,489.74	$2,448.26	$2,427.52
National Capital Rate (All Hospitals)	$510.51			

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 $42,750 for FY 2024. 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 2025 outlier threshold. CMS is adopting an outlier threshold for FY 2025 of $46,152, an increase of just under 8 percent and $3,402 from the FY 2024 amount. CMS projects that the outlier threshold for FY 2025 will result in outlier payments equal to 5.1 percent of operating DRG payments and 4.23 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.957682 to the capital federal rate to fund operating and capital outlier payments respectively.

FY 2025 outlier threshold methodology. CMS is following past practice targeting total outlier payments at 5.10 percent of total operating DRG payments including the adjustment for outlier

reconciliation explained below (including outlier, all wage adjustments and UCP but continuing to exclude adjustments for value-based purchasing and the readmissions reduction program).

CMS' historical practice has been to calculate the outlier threshold based on the latest claims and cost report data. For FY 2025, the latest year of claims data is the March 2024 update to the FY 2023 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data is the March 2024 update of the Provider-Specific File (PSF).

Charge Inflation. CMS is continuing to use the same basic general methodology to inflate the charges that it has used historically (with exceptions for the 2020 through 2022 years of the COVID-19 pandemic when hospital charging practices were atypical). Under this methodology, CMS computes the 1-year average annual rate-of-change in charges per case, which is then applied twice to inflate the charges on the MedPAR claims by 2 years since CMS typically uses claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

These data are shown in the table below.

	Charges	Cases	Average Charge Per Case
FY 2023	$577,981,065,082	6,990,766	$82,677.79
FY 2024	$596,812,542,644	6,933,037	$86,082.41
Annual Rate of Increase			1.04118
Squared for 2 Years of Inflation			1.08406

CCRs. As it has done in the past, CMS is adjusting the CCRs from the March 2024 update of the PSF by comparing the percentage change in the national average case weighted operating CCR and capital CCR from the March 2023 update of the PSF to the national average case weighted operating CCR and capital CCR from the March 2024 update of the PSF.

These data are shown in the table below.

	March 2023 PSF	March 2024 PSF	% Change	Factor
Operating	0.24849	0.252248	1.51	1.015123
Capital	0.07716	0.017666	-0.28	0.997178

Public commenters raised concerns about the 15 percent increase in the proposed outlier threshold and attributed it to what they characterize as an anomalous increase in the CCRs during a period of rapid inflation in labor costs. These commenters suggested there is evidence that CCRs are declining and CMS should use a better projection of the change to CCRs than it is finding in the historical data.

As a precedent for deviating from its methodology, commenters reference CMS use of older CCR data for setting the FY 2023 outlier threshold because of concerns about anomalous data from the COVID-19 PHE that reflected an unprecedented increase rather than a decrease in CCRs. There were suggestions for other deviations from CMS' normal methodology as well to

mitigate the increase in the outlier threshold. These suggestions have been made in the past and rejected by CMS and are not further explained here.

CMS responded to the comments on the CCR noting the inflation factor of 1.015123 being used for the final rule is less than half the increase that was used for the proposed rule (1.03331). Further, it is difficult to know whether current conditions such as higher labor costs and inflation that are driving the increase in CCRs are an anomaly or part of a continuing pattern. It is unclear at this time whether change in average CCRs would return to being under 1.0 or remain above 1.0. For this reason, CMS is not making any changes to its methodology to avoid using a CCR inflation factor above 1.0.

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 2025 outlier threshold.

The original criteria for being subject to outlier reconciliation was that (1) the hospital's actual operating CCR for the cost reporting period fluctuates plus or minus 10 percentage points or more compared to the interim operating CCR used to calculate outlier payments when a claim is processed; and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. However, CMS has revised the instructions to the Medicare Administrative Contractors (MACs) for when they should undertake outlier reconciliation.

On March 28, 2024, CMS issued Change Request (CR) 13566 (R12558CP | CMS) that changed the criteria under which a MAC could reconcile outliers on a Medicare cost report when (1) the actual operating CCR is found to be plus or minus 20 percent or more from the operating CCR used during that time period to make outlier payments, and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. This change is effective October 1, 2024.

CMS received comments saying that the change to the outlier reconciliation criteria constitutes a substantive change to CMS' payment policy that cannot be adopted without going through notice and comment rulemaking. In response, CMS indicates that it established outlier reconciliation under §412.84(i)(4) effective for discharges on or after August 8, 2003, which makes all hospital outlier payments subject to reconciliation. CMS has not modified the outlier regulation. The instructions CMS has issued via CR 13566 have set forth an enforcement policy that determines when MACs will identify additional hospitals for reconciliation referral. They do not change the legal standards that govern hospital outlier reconciliation.

For the FY 2025 outlier threshold, CMS will use the historical outlier reconciliation amounts from the FY 2019 cost reports (cost reports with a beginning date on or after October 1, 2018, and on or before September 30, 2019). CMS indicates these are the most recent and complete set of cost reports which are finalized and/or approved by the MAC. For the FY 2025 final rule,

CMS is using the March 2024 extract of the Hospital Cost Report Information System (HCRIS) to determine the reconciliation amounts.

As the new methodology for reconciling outliers was not applicable during this cost reporting period, CMS is applying the new criteria to information on the FY 2019 cost reports to determine an estimate of reconciled outlier payments for FY 2025. CMS determined reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2019 for FY 2025). 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.

CMS estimates that FY 2019 reconciliation would result in hospitals being owed $36,439,127 or 0.04 percent of IPPS payments. As a result, CMS proposes adding 0.04 percentage points from 5.10 percent making the outlier target 5.14 percent. CMS will target 5.14 percent of operating payments as outliers assuming that 0.04 percentage points of that amount will be repaid to hospitals under the reconciliation process. Reconciliation will have the effect of slightly decreasing the outlier threshold (from $46,502 to $46,152) 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 -0.03 percent based $2,181,440 in reconciled capital outlier payments owed to hospitals.

FY 2023 Outlier Payments. CMS' current estimate, using available FY 2023 claims data, is that actual outlier payments for FY 2023 were approximately 5.27 percent of actual total MS-DRG payments or 0.16 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 2023 are equal to the projected 5.1 percent of total MS-DRG payments and the amount of the reduction in the standardized amounts.

FY 2024 Outlier Payments. CMS says that FY 2024 claims data are unavailable to estimate the percentage of total payments made as outliers in FY 2024. However, in the impact section of the final rule, CMS estimates that, using FY 2023 data, outlier payments will be slightly less than the 5.1 percent targeted and removed from the standardized amounts to fund outlier payments (less than 0.05 percentage points).

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

A. Adoption of the MS-DRGs

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies

according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. In FY 2008, CMS made significant changes to the prior DRG system expanding the number of DRGs from 538 to 755 to better recognize severity of illness. The new DRG system is known as the Medicare Severity or MS-DRGs. CMS refers readers to past rulemaking for more details about the MS-DRGs.

A perennial issue associated with implementation of the MS-DRGs in FY 2008 concerned a budget neutrality adjustment to account for improvements in documentation and coding that would increase spending without an increase in actual patient severity of illness. CMS believed its obligation under the law was to make a preemptive adjustment for documentation and coding to ensure spending did not increase due to adoption of the MS-DRGs.

Congress intervened several times with respect to application of the documentation and coding adjustment and specified how the adjustments were to occur over a period of years—both to recoup excess spending and restore rates to what they otherwise would be in the absence of the adjustments. Controversy has occurred over whether Congress did or did not require CMS to fully restore rates to what they otherwise would have been in the absence of the adjustments going forward.

Public comments have indicated that CMS made documentation and coding adjustments totaling -3.9 percentage points over the period FY 2013 to FY 2017 to recoup excess spending but has only restored 2.9588 percentage points of those reductions through FY 2023. CMS does not dispute these facts but argues that Congress specified the precise adjustments to make from FY 2018 through FY 2023 and that CMS is not authorized to make the additional adjustments requested by hospitals. Hospitals counter that the statute is explicit that CMS may not carry forward any documentation and coding adjustments applied in FY 2010 through FY 2017 into IPPS rates after FY 2023.

In response to these public comments, CMS reiterates its early responses that Congress was prescriptive in the level of adjustments the agency was directed to make. A lawsuit was recently filed against the Secretary of Health and Human Services over this issue.

B. Changes to Specific MS-DRG Classifications

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

Beginning with FY 2024, 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 notes in the discussion for MS-DRG classification changes which topics it will continue to consider in future rulemaking. Interested parties should submit any comments and suggestions for FY 2026 by October 20, 2024 via MEARIS at https://mearis,cms,gov/public/home.

As discussed in the proposed rule, CMS received the following requests to modify the GROUPER logic in a number of cardiac MS-DRGs under Major Diagnostic Category (MDC 05 (Diseases and Disorders of the Circulatory System):

- Modify the GROUPER logic of new MS-DRG 212 (Concomitant Aortic and Mitral Valve Procedures) to be defined by cases reporting procedure codes describing a single open mitral or aortic valve replacement/repair (MVR or AVR) procedure, plus an open coronary artery bypass graft procedure (CABG) or open surgical ablation or cardiac catheterization procedure plus a second concomitant procedure.
- Modify the GROUPER logic of MS-DRG 212 by redefining the procedure code list that describes the performance of a cardiac catheterization by either removing the ICD-10-PCS codes that describe plain radiography of coronary artery codes from the logic list or adding ICD-10-PCS procedure codes that involve CT or MRI scanning using contrast to the list. The requestor also suggested adding ICD-10-PCD codes that describe endovascular valve replacement or repair procedures into the GROUPER logic for this MS-DRG.
- Modify the GROUPER logic of new MS-DRGs 323-325 (Coronary Intravascular Lithotripsy with Intraluminal Device. The requestors suggested adding additional percutaneous coronary intervention (PCI) procedures such as percutaneous coronary rotational, laser, and orbital atherectomy to the GROUP logic for these MS-DRGs.

CMS noted for these requests, the complexity of the GROUPER logic for these MS-DRGs required more extensive analyses to identify and evaluate all of the data relevant to assess these potential modifications. CMS noted, its analysis continues to indicate that open cardiac valve replacement and supplement procedures are clinically different from endovascular cardiac valve replacement and supplement procedures in terms of technical complexity and hospital resource use (see discussion below at section 4). CMS also continued to believe that atherectomy is distinct from coronary lithotripsy in that each of these procedures are defined by clinically distinct definitions and objectives. CMS believed additional time is needed to review and evaluate extensive modifications to the structure of these new MS-DRGs.

To allow the public to better analyze and understand the impacts of its proposals, CMS posted a test version of the ICD-10 MS-DRG GROUPER Software, Version 42 on its website. CMS also made available a supplemental file in Table 6P.1a that includes the mapped Version 42 FY 2025

ICD-10-CM and ICD-10-PS codes and the deleted Version 41 FY 2024 ICD-10-CM codes fand V41.1 ICD-10-PCS 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.
In the 2024 OPPS/ASC final rule, CMS also finalized that beginning with FY 2025, it would no longer discuss the IPPS Medicare Code Editor (MCE) in rulemaking and to generally address future changes or updates to the MCE through instructions to the Medicare Administrative Contractors (MACs). Beginning with FY 2025, in association with the annual propose rule, CMS made available a draft version of the Definitions of MCE Manual to allow review of any changes that will become effective October 1 for the upcoming fiscal year. Any new and modified code updates approved after the annual spring ICD-10 Coordination and Maintenance Committee meeting will be included in the finalized Definitions of MCE Manual that will be made available in association with the final rule. Any questions, comments, or recommendations regarding the MCE should be sent to CMS at MSDRGClassificationChange@cms.hhs.gov.
The FY 2025 ICD-10 MS-DRG GROUPER and MCE Software Version 42, the ICD-10 MS-DRG Definitions Manual files Version 42 and the Definitions of MCE Manual Version 42 is available on the CMS website at https://www.cms.gov/medicare/payment/prospetive-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.

This section of the preamble discusses changes that CMS proposes to the MS-DRGs for FY 2025. CMS used claims data from the September 2023 update of the FY 2023 MedPAR file, which contains hospital bills received through October 1, 2022 through September 30, 2023 (referred to as the "September 2023 update of the FY 2023 MedPAR file").

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

In the FY 2021 IPPS final rule, CMS finalized its proposal to expand the existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) with a base MS-DRG to include the NonCC subgroup for a three-way severity level split.[1] CMS believes that this will better reflect resource stratification and promote stability in the relative weights by avoiding low volume counts for the NonCC level MS-DRGs. CMS noted that the application of the NonCC subgroup criteria may result in modifications to certain MS-DRGs that are currently split into three severity levels and result in MS-DRGs that are split into two severity levels.

In the FY 2022 IPPS final rule, due to the PHE, CMS delayed applying the NonCC subgroup criterion to existing MS-DRGs until FY 2023 or future rulemaking. Commenters recommended that a complete analysis of the MS-DRG changes in connection with the expanded three-way

[1] 85 FR 58448

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.
In the FY 2024 IPPS proposed rule,[2] CMS provided an alternate test version of the ICD-10 MS-DRG GROUPER Software, Version 41.A, reflecting the proposed GROUPER logic for FY 2024 as modified by the application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split.[3] In addition, CMS provided additional files, including an alternate Table 5, an alternate Length of Stay (LOS) Statistics file, an Alternative Case Mix Index (CMI) file, and an alternate After Outliers Removed and Before Outliers Removed (AOR_BOR) file.[4] CMS encouraged review of this information and welcomed feedback.

For FY 2024, CMS continued to apply the criteria to subgroups, including application of the NonCC subgroup criteria, in the annual analysis of MS-DRG classification requests. CMS continues this policy for FY 2025 MS-DRG classification requests. The table below, reproduced from the rule, illustrates all five criteria and how they are applied to each CC.

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

For analysis of requests to create a new MS-DRG, CMS evaluates the most recent year available of MedPAR claims data. For evaluation of requests to split an existing base MS-DRG into severity levels, CMS analyzes the most recent 2 years of 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

[2] 88 FR 26673 through 26676
[3] Available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Sortware.
[4] These files are available in association with the FY 2024 IPPS proposed rule on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.

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

Comments/Responses: Commenters supported CMS' decision to wait to propose extensive modifications to the structure of these MS-DRGs. Many commenters, however, reiterated the request to modify the GROUPER logic of new MS-DRG and suggested a wide range of modifications. Some commenters agreed with CMS that atherectomy is distinct from coronary lithotripsy and other commenters disagreed with CMS.

CMS reiterates that with the implementation of ICD-10, some types of requested changes to MS-DRG classifications require more extensive research to identify and analyze the relevant data. CMS notes that although many commenters believe that a modification to the logic of MS-DRG 212 may be warranted they differ greatly in the solution. CMS will continue to monitor impacts in MDC 05 and across the DRGs to appropriately capture the resource utilization and clinical coherences for these procedures and also avoid unintended consequences. Feedback and other suggestions may be directed to MEARIS at https://mearis.cms.gov/public/hone.

Numerous commenters supported the decision to delay application of the NonCC subgroup criteria to existing MS-DRGs with a three-way severity level split. In response to a request the related analysis from the FY 2023 MedPAR file, CMS includes this information in Table 6P.4 on the CMS website for this final rule. CMS appreciates a commenters' recommendation that it considers patient risk adjustment as a criterion for creating CC and MCC subgroups and will take it under consideration as it continues to consider feedback associated with application of the NonCC subgroup criteria.

2. Pre-MDC MS-DRG 018 Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies

As part of an ICD-10-PCS procedure code request for the autologous genetically engineered cell-based gene therapy prademagene zamikeracel (PZ), for the treatment of recessive dystrophic epidermolysis bullosa, CMS received a request to revise the title of Pre-MDC MS-DRG 018 to "Chimeric Antigen Receptor (CAR) T-cell and Other Autologous Gene and Cell Therapies". In the proposed rule, CMS did not agree with this revision because the logic for the MS-DRG includes other immunotherapies and is not restricted to CAR T-cell and autologous gene and cell therapies. CMS stated that "Other Immunotherapies" encompasses the group of therapies that are currently available and to enable appropriate MS-DRGs for any future therapies that may also fit into this category.

Commenters/Responses: A few commenters recommended that CMS not map cases reporting application of PZ to Pre-MDC MS-DRG 018 because it differs in terms of clinical coherence and resource utilization from other therapies mapped to MS-DRG 018. A commenter was concerned that if CMS continued to assign new, higher volume, lower cost therapies to this MS-DRG, it could potentially distort the relative weight of the MS-DRG and result in inadequate payments for CAR T-cell therapies. Another commenter requested that CMS map the new procedure codes describing the application of PZ to MS-DRG 018 and discussed how these procedures are similar to the methodology for developing CAR T-cell therapies.

In response to comments requesting CMS not map PZ to MS-DRG 018, CMS notes that the commenters did not offer any alternative suggestions. CMS also discusses the basic premise behind the MS-DRG classification which is based on the average pattern of resource intensity and clinical coherence. In addition, although the existing therapies currently mapped to MS-DRG 018 may be indicated for the treatment of cancer, the logic for case assignment of Pre-MDC MS-DRG 018 does not preclude the assignment of other therapies indicated in the treatment of patients that do not have a diagnosis of cancer. CMS notes that PZ is defined as an investigational genetically engineered investigational cell therapy and it is difficult to predict what the associated costs will be in the future for cell and gene therapies under development or in clinical trial.

CMS finalizes its proposal to maintain the existing title to Pre-MDC MS-DRG 018, "Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies" and finalizes the assignment of the eight procedure codes describing the use of PZ to MS-DRG 018 (see Table 6B.)

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

a. Logic for MS-DRGs 023 through 027

In the proposed rule, CMS reviewed its previous analysis of MS-DRGs 023 through 027. In the FY 2024 IPPS final rule, CMS discussed 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.[5] The requestor submitted a similar request for FY 2021. At that time, CMS concluded that further analysis of claims data would be necessary to support reassignment of cases involving the use of the RNS neurostimulator. In FY 2024, CMS again concluded that additional time is needed to evaluate these cases and CMS did not propose to reassign these cases or create a new MS-DRG. In the FY 2024 IPPS final rule, CMS also discussed the analysis of cases reporting laser interstitial thermal therapy (LITT) procedures performed on the brain or brain stem, which includes examination of the logic for case assignments 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

[5] 88 FR 58661 through 58667

their approach, clinical indications, and whether the procedure involves the insertion or implantation of a device.

In the FY 2025 proposed rule, CMS discussed two comments about its ongoing analysis of MS-DRGs 023-027. In response to this discussion, CMS received additional comments supporting its decision to continue to monitor the case logic for MS-DRGs 023-027.

b. Intraoperative Radiation Therapy (IORT)

CMS received a request to add ICD-10-PCS procedure codes for IORT (D0Y0CZZ and D0Y1CZZ) to the Chemotherapy Implant logic list in MS-DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator). The requestor stated that IORT for the brain is always performed as part of surgical removal of a brain tumor. Based on its own analysis, the requestor found fewer than 11 cases reporting IORT in MS-DRGs 025, 026,and 027.
In the proposed rule, CMS analyzed claims data for MS-DRGs 023-027 and for cases reporting excision of brain tumor and IORT. The data showed there were no cases reporting the use of IORT with brain tumor excision; CMS was unable to evaluate whether IORT directly impacts resource utilization (see table in the proposed rule). CMS proposed to maintain the current structure of these MS-DRGs.
Commenters supported CMS' proposal. For FY 2025, CMS finalizes its proposal to maintain the current structure of MS-DRGs 023-027.

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

a. Concomitant Left Atrial Appendage Closure and Cardiac Ablation

The manufacturer of the WATCHMAN™ Left Atrial Appendage Closure (LAAC) devise requested CMS create a new MS-DRG for concomitant LAAC and cardiac ablation for atrial fibrillation (AF). Among patients with AF, thrombus in the LAA is a primary source for thromboembolisms. The request highlighted a recent study indicating that when LAAC is performed concomitantly with cardiac ablation, the outcomes are comparable to patients who have these procedures separately.[6]

The requestor performed its own analysis using ICD-10- PCS procedure codes 02L73DK for the LAAC procedure and 02583ZZ for cardiac ablation and found the average costs of cases reporting concomitant procedures were consistently higher compared to the average costs of other cases within their respective MS-DRG. The requestor stated this could limit beneficiary access to these procedures performed concomitantly which could impact the health quality of beneficiaries.

In the proposed rule, CMS summarized its review of this request (see tables in the final rule). For its analysis CMS identified nine codes describing LAAC procedures and 27 codes to describe cardiac ablation. CMS examined claims data for all cases in MS-DRGs 273 and 274

[6] Piccini et al. LAA occlusion with the WATCHMAN FLZ and concomitant catheter ablation procedures. Heart Rhythm Society Meeting 2023, May 19, 2023; New Orleans, LA.

(Percutaneous and Other Intracardiac Procedures). Concomitant cases in MS-DRG 273 and 274 had higher average costs and slightly longer lengths of stay compared to all the cases assigned to these MS-DRGs. CMS also reviewed the clinical data and agreed that concomitant procedures can improve symptoms, prevent stroke, and reduce the risk of bleeding compared with oral anticoagulants.

For FY 2025, CMS proposed to create a new base MS-DRG for cases reporting a LAAC procedure and a cardiac ablation procedure – MS-DRG 317 (Concomitant LAAC and Cardiac Ablation). CMS evaluated the criteria to create subgroups but the data did not support any subdivision. CMS proposed to include the nine ICD-10-PCS codes that describe LAAC procedures and the 27 ICD-10-PCS codes for cardiac ablation in the logic for this new MS-DRG. CMS discussed a proposed modification of the surgical hierarchy (discussed below in section 14).

Comments/Responses. Many commenters supported the proposal to create a new base MS-DRG for cases reporting a LAAC procedure and a cardiac ablation procedure in MDC 05. Some commenters suggested that CMS devise a broader, supplemental payment mechanism to facilitate incremental payment when two major procedures are performed during the same hospital admission. CMS does not agree with a suggestion that CMS delay implementation of MS-DRG 317 because of safety, effectiveness, and workflow issues when these two procedures are performed concomitantly. CMS will continue to monitor the claims data and perform additional analysis if any evidence is presented to CMS regarding the clinical efficacy of concomitant left atrial appendage closure and cardiac ablation procedures.

Commenters highlighted a difference in case volume between the table in the proposed rule that CMS stated reflected cases reporting procedure codes describing concomitant LAAC and cardiac ablation in MS-DRGs 273 and 274 and the table in which illustrated the findings for all cases reporting procedure codes describing concomitant LAAC and cardiac ablation found in claims data from the September 2023 update of the FY 2023 MedPAR data. In response, CMS explains the discrepancies and explains that the table illustrating its findings for all 1,723 cases reporting procedure codes describing concomitant LAAC and cardiac ablation includes cases that are anticipated to potentially shift or be redistributed as a result of the proposal to (1) create a new base MS-DRG 317 and (2) the proposal to sequence the new MS-DRG above MS-DRG 275 and below MS-DRGs 231, 232, 233, 234, 235, and 236 in MDC 05 (surgical hierarchy).

In the final rule, CMS repeats this analysis and concludes the data supports creating new base MS-DRG describing concomitant LAAC and cardiac ablation. CMS believes the revisions to the surgical hierarchy creates a more coherent grouping and better reflects the clinical severity and resource use involved in these cases.

CMS disagrees with a comment suggesting that the nine ICD-10-PCS codes that describe LAAC procedures as non-O.R. procedures should be designated O.R. procedures. CMS believes that circumstances in which a patient is admitted for a principal diagnosis outside of MDC 05 and a LAAC is performed as the only surgical procedure in the same admission are infrequent. CMS believes the current designation of LAAC procedures as non-O.R. procedures that affect the assignment for MS-DRGs 273 and 274, and now MS-DRG 317, is clinically appropriate to

account for the subset of patients undergoing left atrial appendage closure specifically. CMS also believes that under n the same circumstances, when cardiac ablation is the only surgical procedure performed, the current designation of 02570ZK, 02573ZK, and 02574ZK are appropriately designated as non-O.R. procedures.

CMS agrees with a comment suggesting that ICD-10-PCS codes for the destruction of chordae tendineae (02590ZZ, 02593ZZ, and 02594ZZ) should be removed from the list of cardiac ablation procedures for MS-DRG 317. CMS' data analysis indicates that the chordae tendineae would not be ablated with cardiac ablation procedures and instead would be ablated with cardiac valve repair or replacement procedures. CMS also agrees with commenters noting that procedure code 02583ZF (Destruction of conduction mechanism using irreversible electroporation, percutaneous approach) to identify electroporation for cardiac ablation was finalized April 1, 2024 can be done concomitant with LAAC.

For FY 2025, CMS finalizes its proposal to create new MD-DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation) in MDC 05, effective October 1, 2024. Specifically, CMS modifies the proposed list of ICD-10- PCS codes that describe cardiac ablation in the Version 42 GROUPER logic of MS-DRG 317 by removing ICD-10-PCS codes 02590ZZ (Destruction of chordae tendineae, open approach), 02593ZZ (Destruction of chordae tendineae, percutaneous), 02594ZZ (destruction of chordae tendineae, percutaneous endoscopic approach) and add ICE-10-PCS code 02583ZF (Destruction of conduction mechanism using irreversible electroporation, percutaneous approach).

A table in the final rule lists the finalizes 25 ICD-10-PCS procedure codes that describe cardiac ablation that CMS finalizes in the logic for assignment of cases reporting a LAAC procedure and a cardiac ablation. CMS also finalizes the inclusion of nine ICD-10-PCS procedure codes that describe LAAC procedures listed previously in the logic for assignment of cases reporting a LAAC procedure and a cardiac ablation procedure for new MS-DRG, without modification. The finalized modifications to the surgical hierarchy are discussed below in section 14.

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

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

In the FY 2023 IPPS final rule[7], CMS discussed a request to reassign the ICD-10-PCD procedure codes describing the implantation of BAROSTIM from MS-DRGs 252 – 254 (Other Vascular Procedures) to MS-DRGs 222 – 225 (Cardiac Defibrillator Implant). The requestor stated that the subset of patients that have an indication for the BAROSTIM system also have indications

[7] 87 FR 48837 through 48843

for the implantation of implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy defibrillators (CRT-D) and cardiac contractility modulation (CCM) devices and all these devices require the permanent implantation of a programmable electrical pulse generator and at least one electrical lead. CMS concluded that the claims analysis did not have sufficient claims on which to base and evaluate any proposed changes to the current MS-DRG assignment. CMS was also concerned that comparing the implantation of a BAROSTIM system to the placement of ICD, CRT-D and CCM was not appropriate because the devices all differed in terms of technical complexity and anatomical placement of the electrical lead(s) and there was no intravascular component or vascular puncture involved with implanting a BAROSTIM system.

For FY 2025, CMS received a similar request to again review the MS-DRG assignment of the procedure codes that describe the implantation of the BAROSTIM system. The requestor acknowledged that implantation is predominated performed in the outpatient setting but that a significant number of severely sick patients with multiple comorbidities are treated in the inpatient setting.

In the proposed rule, CMS summarized its review of this request (see tables in the final rule). Using ICD-10-procedure codes for implantation of the BAROSTIM system (0JH60MZ in combination with 03HK3MZ or 03HL3MZ) CMS found only 23 cases describing the implantation of a BAROSTIM system in MS-DRGs 252-254. For these cases the average costs for the implantation of a BAROSTIM system were greater than the average costs of all cases in these MS-DRGs. Based on the small number of cases, CMS continued to believe there is not sufficient evidence to create a new MS-DRG for these cases.
CMS also evaluated claims data for MS-DRGs 25,276, and 277 and noted that the average length of stay (5.8 days) and average costs ($59,355) for BAROSTIM (23 cases) was similar to the 3,264 cases in MS-DRG 276 that had an average length of stay of 8.2 days and average costs of $52,993.

CMS reviewed the clinical issues and the claims data and although there is no intravascular component or vascular puncture involved when implanting a BAROSTIM system and the implantation of the BAROSTIM system is distinguishable from the placement of ICD, CRT-D, and CCM devices, CMS agreed that all these procedures all share an indication of heart failure (clinically coherent) and demonstrate comparable resource utilization. CMS proposed to reassign cases reporting procedure codes describing the implantation of a BAROSTIM system to MS-DRG 276, even if there is no MCC reported.

Commenters overwhelmingly supported these proposals.

For FY 2025, CMS finalizes its proposal to reassign all cases with one of the following ICD-10-PCS code combinations reporting the implantation of a BAROSTIM system to MS-DRG 276, even if there is no MCC reported:

- 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK3MZ (Insertion of simulator lead into right internal carotid artery, percutaneous approach); and

- 0JH60MZ in combination with 03HL3MZ Insertion of simulator lead into left internal carotid artery, percutaneous approach).

CMS also finalizes its proposal to change the title of MS-DRG 276 from "Cardiac Defibrillator Implant with MCC" to "Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator. CMS discusses a proposed modification of the surgical hierarchy in section II.C.15 of the final rule (discussed below in section 14).

c. Endovascular Cardiac Valve Procedures

The manufacturer of the SAPIEN™ family of transcatheter heart valves requested CMS to delete MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures) and move all cases reporting transcatheter aortic valve replacement or repair (TAVR) (supplement) procedures currently assigned to MS-DRGs 216-221 (Cardiac Valve & Other Major Cardiothoracic Procedures with and without Cardiac Catheterization). The requestor asserted that TAVR procedures are not profitable to hospitals and when patients are clinically eligible for both a TAVR and surgical aortic valve replacement (SAVR) procedure, factors beyond clinical appropriateness can drive treatment decisions. The requestor believed that sharing a single MS-DRG would eliminate any final incentive for hospitals to choose between the two procedures. CMS discussed similar prior requests from the FY 2015 and FY 2020 IPPS final rule.

In the proposed rule, CMS summarized its review of this request (see tables in the final rule). CMS stated the data analysis showed that cases in MS-DRG 266 and 267 with or without a cardiac catheterization have average lower costs and shorter average lengths of stay than cases reporting surgical valve replacement and supplement procedures with or without a cardiac catheterization.

CMS continued to believe that endovascular cardiac valve replacement and supplemental procedures are clinically coherent in their currently assigned MS-DRGs. CMS noted that the choice of SAVR versus TAVR should not be based on potential facility payment and it is not appropriate for facilities to recommend a specific type of therapy or treatment strictly because it may involve higher payment. CMS proposed to maintain the structure of MS-DRGs 266 and 267.

Many commenters expressed support for the proposal to maintain the structure of MS-DRGs 266 and 267. A commenter stated that while they believe that procedures such as TAVR should be paid at a rate that makes them efficacious for hospitals to perform, given CMS' analysis, the requested MS-DRG modification may not be appropriate. Another commenters stated it was unclear why the requestor implied that there is any type of bias in patient selection and stated the decision to perform endovascular or surgical cardiac valve replacement is typically made by the heart team based on the patient's characteristics and individualized risk-benefit. The requestor disagreed with the proposal.

For FY 2025, CMS finalizes its proposal to maintain the structure of MS-DRGs 266 and 267.

d. MS-DRG Logic for MS-DRG 215

CMS received a request to review the GROUPER logic for MS-DRG 215 (Other Heart Assist System Implant) to evaluate the assignment for the ICD-10- PCS procedure code describing the revision of malfunctioning devices with the heart via an open approach (02WA0JZ). The requestor also recommended that CMS consider expansion of the open heart structures to include the atrial or ventricular septum and heart valves.

In response to these requests, CMS clarified that the revision codes listed in the GROUPER logic for MS-DRG 215 specifically describe procedures to correct, to the extent possible, a portion of a malfunctioning heart assist device or the position of a displaced heart assist device. Although not explicitly stated, CMS thought this request was for consideration of the reassignment of the 18 procedure codes describing the open revision of devices in the heart valves, atrial septum, or ventricular septum (listed in the final rule) to MS-DRG from MS-DRGs 228 and 229 (Other Cardiothoracic Procedures).

In the proposed rule, CMS summarized its review of this request (see tables in the final rule). The analysis indicated that cases assigned to MS-DRG 215 have higher average cases than the cases reporting the open revision of devices currently assigned to MS-DRGs 228 and 229. Instead, these cases are more aligned with the average costs and average length of stay for all cases in MS-DRGs 228 and 229. In addition, CMS did not believe the procedures describing the open revision of services in the heart valves, atrial septum, or ventricular septum are clinically coherent with the procedure codes currently assigned to MS-DRG 215.
CMS proposed to maintain the GROUPER language for MS-DRG 215. Commenters agreed with this proposal.

For FY 2025, CMS finalizes its proposal to maintain the GROUPER language for MS-DRG 215.

5. MDC 06 (Diseases and Disorders of the Digestive System): Excision of Intestinal Body Parts

CMS identified a replication issue from the ICD-9 based MS-DRGs to the ICD-10 based MS-DRGs regarding the assignment of eight ICD-10-PCS codes that describe the excision of intestinal body parts by open, percutaneous of percutaneous endoscopic approach (see table in the final rule). ICD-9-CM procedure code 45.33 (Local excision of lesion or tissue of small intestine, except duodenum) was designated as an OR procedure and assigned to MS-DRGs 347-349 (Anal and Stromal Procedures). CMS also identified four additional ICD-10-PCS code (see table in the final rule) that provide more specificity than ICD-9-PCS code 45.33 that mapped to MS-DRGs 329-331 (Major Small and Large Bowel Procedures).

In the proposed rule, CMS summarized its review of its analysis for the eight ICD-10-PCS procedure codes assigned to MS-DRGs 347-349 and compared this information to claims data from MS-DRGs 329-331. CMS noted the data suggests that overall, cases reporting one of the eight procedure codes may be more appropriately aligned with the average costs of the claims in MS-DRGs 329-331. CMS noted that these eight procedure codes do not describe procedures on a stoma but are specific to intestinal anatomy and believed that these procedure codes are clinically

coherent with the four other procedure codes that describe excision of body parts assigned to MS-DRGs 329-331.

CMS proposed the reassignment of these eight procedure codes for anal and stromal procedures to MS-DRGs 329-331 (Major Small and Large Bowel Procedures). Commenters supported this proposal. For FY 2025,

CMS finalizes its proposal to reassign procedure codes 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB4ZZ, 0DCC0ZZ, 0DCC3ZZ, 0DBCC3ZZ, and 0DBC4ZZ from MS-DRGs 347-349 (Anal and Stromal Procedures) to MS-DRGs 329-331 (Major Small and Large Bowel Procedures).

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

a. MS-DRG Logic for MS-DRGs 456, 457, 458

CMS identified an inconsistency in the GROUPER logic for MS-DRGs 456-458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions) related to ICD-10-CM diagnosis codes describing deforming dorsopathies. A deforming dorsopathy is characterized by abnormal bending or flexion in the vertebral column.
In the proposed rule, CMS summarized its review of the second and third logic lists (see tables in the final rule) and believed the five diagnosis codes describing deforming dorsopathies of specific anatomic sites are clinically aligned with the diagnosis codes currently in the third logic list entitled "OR Secondary Diagnosis. CMS proposed to add diagnosis codes M43.8X4 - M43.8X8 to the "OR Secondary Diagnosis" logic for MS-DRGs 456-458.

Commenters agreed. For FY 2025, CMS finalizes its proposal to add diagnosis codes M43.8X4 - M43.8X8 to the "OR Secondary Diagnosis" logic for MS-DRGs 456-458.

b. Interbody Spinal Fusion Procedures

As discussed in the FY 2024 IPPS proposed and final rules,[8] 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. For FY 2024, CMS maintained the current structure of MS-DRGs 453-460 and stated it would continue to review this issue.

In FY 2024, CMS also implemented 12 ICD-10-PCS procedure codes to identify and describe spinal fusions using the aprevo customized interbody fusion device; CMS also revised the code titles to include "custom-made anatomically designed interbody fusion device" (see table in the proposed rule).

[8] 88 FR 26726 – 26729, 88 FR 58731 – 58735, and 88 FR 77211

As part of the FY 2024 request, the requestor discussed concerns that its analysis of claims data for the first half of FY 2022 indicated 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' analysis indicated that cases reporting a procedure utilizing an aprevo custom device reflect a higher consumption of resources. CMS was concerned about the reliability of the claims data and believed further review is warranted. For FY 2024, CMS maintained the current structure of MS-DRGs 453-460. For FY 2025, CMS summarized its extensive review of this issue (summarized in tables in the final rule). CMS updated its analysis of cases reporting spinal fusion using an aprevo customized interbody fusion device in claims data for MS-DRGS 453-460. CMS also reviewed the findings for cases identified based on the list of providers submitted by the manufacturer. This analysis did not confirm that the claims from these providers was miscoded. Based on its analysis and clinical review, CMS did not believe the reassignments for spinal fusion using an aprevo customized interbody fusion device is appropriate. CMS noted that MS-DRGs 453-455 and 458-459, cases using the aprevo device were low in volume and had higher average costs in comparison to all the cases in their respective MS-DRGs.

Because cases reporting spinal fusion procedures using the customized aprevo device have higher costs in MS-DRGs 453-455, 458, and 460, CMS further reviewed the data for these MS-DRGs. This analysis found that cases in these MS-DRGs had a wide range in the average length of stay and average costs. In its analysis of the claims data for MS-DRGs 453-455, CMS also identified logic issues related to cases that were "multiple level fusions". CMS' analysis of the data for MS-DRGs 453 and 454 also showed that cases reporting the aprevio device reported multiple MCC and CC conditions. CMS believed that this reporting with the aprevo device combined with the reported performance of multiple level fusions may be contributing to the increase in resource utilization for these cases. CMs provided a list of the top 5CC and MCC conditions, as well as the top 5 O.R. procedures (excluding discectomy) reported in MS-DRGs 453-455 that it believed may be contributing factors to the increase in resource utilization and complexity for these cases.

Based on these findings, CMS expanded its analysis to include all spinal fusion cases in MS-DRGs 453-460 to identify and examine the cases reporting multiple level fusions versus single level fusions, multiple MCCs or CCs, and other O.R, procedures. CMS believed that clinically, all these factors may contribute to increases in resource utilization, severity of illness, and technical complexity. CMS' analysis of MS-DRGs 453-355 indicated that the greater the number of spinal fusion procedures performed during a single procedure, the greater the consumption of resources expended. CMS believed many factors, including the use of interbody fusion cages, other types of spinal instrumentation, operating room time and comorbidities, may be contributing to resource utilization.

Based on this review, to more appropriately reflect utilization of resources, including those performed with the aprevo device, CMS believed new MS-DRGs were needed to differentiate between multiple level combined anterior and posterior spinal fusions except cervical; single level combined anterior and posterior spinal fusions except cervical; and combined anterior and

posterior cervical spinal fusions. CMS discussed its analysis of this proposal, including application of all five criteria to create subgroups for the base MS-DRG.

For FY 2025, CMS proposed to delete MS-DRGs 453-455 and create 8 new MS-DRGs:

- MS-DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC),
- MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC),
- MS-DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC),
- MS-DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC),
- MS-DRG 429 (Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC),
- MS-DRG 430 (Combined Anterior and Posterior Spinal Fusion Except Cervical without MCC),
- MS-DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC), and
- MS-DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC).

CMS also proposed to revise the title for MS-DRGs 459 and 460 to "Single Level Spinal Fusion Except Cervical with MCC and without MCC", respectively. CMS discusses a proposed modification of the surgical hierarchy discussed below in section 14.

For FY 2025, CMS proposed to maintain the current structure of MS-DRGs 456-458.

Comments/Responses: Several commenters supported the proposed restructuring for the spinal fusion MS-DRGs. Several commenters raised concerns about the proposal because it did not address the logic for all the spinal fusion MS-DRGs, specifically MS-DRGs 456-458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions) and MS-DRGs 471-473 (Cervical Spinal Fusion). CMS notes that as part of its ongoing analysis of this request, in the proposed rule, it discussed findings from the FY 2023 MedPAR file for MS-DRGs 456-458. In the proposed rule, CMS stated that it needed additional analysis before it considered any modification to the current structure of these MS-DRGs. CMS sought public comment and notes that other suggestions for future rulemaking can be submitted by October 20, 202 and directed to https://mearis.cms.gov/public/home. With respect to the MS-DRGs 456-458, the procedure codes describing a custom-made anatomically designed interbody fusion device are not listed in the logic for these MS-DRGs because they are specific for cervical vertebrae. CMS anticipates the manufacturer of the aprevo device will request a unique procedure code to describe the use of the technology for the cervical spine and request MS-DRG classification changes. CMS notes that suggestions for both of these groups of MS-DRGs and other suggestions for future rulemaking can be submitted by October 20, 202 and directed to https://mearis.cms.gov/public/home.

A few commenters requested additional time before implementing these proposals to allow hospitals time to access the impact of the proposed changes. CMS notes that before proposing

these changes for FY 2025, this topic was discussed in the FY 2024 rulemaking cycle and providers had the opportunity to consider how spinal fusion cases are reported in their respective facilities and submit request changes to the MS-DRGs for CMS to consider. In response to concerns about the spinal fusion episode accountability model under TEAM, CMS refers readers to the discussion of TEAM in the final rule (also discussed in this summary).
CMS discusses the comments provided by the manufacturer of the aprevo custom-made anatomically designed interbody fusion device. CMS provides additional analysis in the final rule to address the issues raised in the comment letter. CMS recognizes that with the requested reassignments the average length of stay for cases reporting a custom-made anatomically designed interbody fusion device varies from the average length of stay for all cases in the requested MS-DRGs. CMS continues to believe the length of stay is a factor in assessing clinical coherence, but because the technology is indicated for patients who have complicated spinal anatomy which require individualized treatment plans to precisely address alignment needs these clinical variability impacts length of stay.

A few commenters suggested that if CMS is going to finalize the proposed restructuring, it should consider deleting MS-DRGs 459 and 460 and create a new MS-DRG for single level spinal fusion except cervical with MCC and without MCC. CMS appreciates this suggestion and agrees with this suggestion.

After consideration of comments, CMS finalizes its proposal to delete MS-DRG 453, 454, and 455 and to create new MS-DRGs 426, 427, and 428, with modifications, for FY 2025. Specifically, CMS finalizes its proposed with modification to assign cases reporting the use of a custom-made anatomically designed interbody fusion device with a CC to MS-DRG 426. Conforming changes to the GROUPER logic are shown in Table 6P.2e associated with this final rule. The finalized MS-DRG titles are:

- MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interfusion Body Device),
- MS-DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and
- MS-DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC).

CMS finalizes its proposal to create new MS-DRGs 447 and 448, with modification, for FY 2025. Specifically, it is finalizing its proposal with modification to assign cases reporting the use of a custom-made anatomically designed interbody fusion device without an MCC to MS-DRG 447. Conforming changes to the GROUPER logic are shown in Table 6P.2e associated with this final rule. The finalized MS-DRG titles are:

- MS-DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device), and
- MS-DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC).

As discussed above, CMS agrees with commenters that the proposed revisions to the MS-DRG logic changed the types of cases that would be classified to MS-DRGs 459 and 460 and these

MS-DRGS are no longer necessary. For FY 2025, CMS deletes MS-DRGs 459 and 460 and finalizes the creation of MS-DRGs 450 and 451. The logic for case assignment to MS-DRGs 450 and 451 is comprised of the logic lists that were initially proposed for revised MS-DRGs 459 and 460, with modification. CMS also finalizes the assignment of cases reporting the custom-made anatomically designed interbody fusion device without an MCC to MS-DRG 450. Conforming changes to the GROUPER logic are shown in Table 6P.2e associated with this final rule. The finalized MS-DRG titles are:

- MS-DRG 450 (Single Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device) and
- MS-DRG 451 (Single Level Spinal Fusion Except Cervical without MCC)

CMS also finalizes its proposal to create new MS-DRG 402 and new MS-DRG 429 and 430, without modification, for FY 2025. Conforming changes to the GROUPER logic are shown in Table 6P.2e associated with this final rule. The finalized MS-DRG titles are:

- MS-DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC),
- MS-DRG 429 (Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC), and
- MS-DRG 430 (Combined Anterior and Posterior Spinal Fusion Except Cervical without MCC).

CMS will continue to monitor the data and consider if any future modifications may be warranted.

7. MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorder): Resection of Right Large Intestine

CMS identified an inconsistency in the MDC and MS-DRG assignment of procedure codes describing resection of the right large intestine and resection of the left large intestine with an open and percutaneous endoscopic approach (ICD-10-PCS codes 0DTG0ZZ and 0DTG4ZZ). CMS proposed to add procedure codes, ICD-10-PCS 0DTG0ZZ and 0DTG4ZZ, to MDC 10 in MS-DRGS 628-630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures). Commenters supported this proposal. For FY 2025, CMS finalized its proposal to add procedure codes, ICD-10-PCS 0DTG0ZZ and 0DTG4ZZ, to MDC 10 in MS-DRGS 628-630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures).

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

CMS received a request to review the GROUPER logic that determines the assignment of cases to MS-DRG 794 (Neonate with Other Significant Problems).
In the proposed rule, CMS summarized its review of this issue. CMS noted it has started to examine the GROUPER logic that determines the assignment of cases to the MS-DRGs in MDC 15, including MS-DRG 794 and 795. This examination was complicated because of the

extremely low volume of Medicare patients in these MS-DRGs. Any proposed modifications will be addressed in future rulemaking.

For FY 2025, CMS proposed to reassign ICD-10-CM diagnosis codes Q81.0, Q81.1, Q81.2, Q81.8 and Q81.9 from MS-DRGs 606 and 607 in MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast) and MS-DRG 795 (Normal Newborn) in MDC 15 to MS-DRGs 595 and 596 in MDC 09 and MS-DRG 794 in MDC 15. Commenters supported this proposal. CMS finalizes this proposal, effective October 1, 2024.

9. MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms): Acute Leukemia

CMS identified a replication issue from the ICD-9 based MS-DRGs to the ICD-10 based MS-DRGs regarding the assignment of six ICD-10-CM diagnosis codes that describe a type of acute leukemia (see table in the proposed rule). Under the ICD-9-CM, the diagnosis codes did not differentiate between the acuity of the diagnosis (e.g. acute versus chronic). These six ICD-10-CM diagnosis codes were assigned to surgical MS-DRGs 820-822 (Lymphoma and Leukemia with Major O.R. Procedures, surgical MS-DRGs 823-835 (Lymphoma and Non-Acute Leukemia with Other Procedures) and medical MS-DRGs 840-842 (Lymphoma and Non-Acute Leukemia). In the proposed rule, CMS summarized its review of this issue which includes discussion of other diagnosis codes that could be more appropriately grouped with the diagnosis codes describing types of acute leukemia. CMS concluded the data analysis showed that cases reporting a principal diagnosis code describing a type of acute leukemia with an ICD-10-PCS procedure code designated as O.R. procedure that is not listed in the logic list of MS-DRGs 820-822 have higher average costs and longer lengths of stay compared to all the cases in their assigned MS-DRG. CMS proposed a new MS-DRG for cases describing a type of acute leukemia with an O.R. procedure. CMS discussed its analysis of this proposal, including application of all five criteria to create subgroups for the base MS-DRG. For FY 2025, CMS is not proposing to subdivide the new MS-DRG.

For FY 2025, CMS proposed to create a new base surgical MS-DRG, MS-DRG 850 (Acute Leukemia with Other Procedures), for cases reporting a principal diagnosis describing a type of acute leukemia with an ICD-10-PCS code designated as O.R. procedure that is not listed in the logic list of MS-DRG 820-821.

- CMS proposed to add the 27 ICD-10-CM diagnosis codes listed in the logic list entitled "Principal Diagnosis" in MS-DRGs 834-836 and ICD-10-CM codes C94.20- C94.22, C94.41 and C94.42.
- CMS proposed to add the procedure codes from Current MS-DRGs 823-825 (Lymphoma and No-Acute Leukemia with Other Procedures) to the proposed MS-DRG 850.

CMS noted the current logic of MS-DRGs 823-826 includes 189 procedure codes describing stereotactic radiosurgery that are designated as non-O.R. procedures. Therefore, as part of the logic for the new MS-DRG 850, CMS proposed to designate these 189 codes as non-O.R. procedures affecting the MS-DRG.

CMS also proposed to revise the titles for MS-DRGs 834-836 from "Acute Leukemia without Major O.R. Procedures" to "Acute Leukemia". CMS believed this will better reflect the GROUPER logic that will no longer include ICD-10-PCS codes designated as O.R. procedures. Commenters supported CMS' proposal. A few commenters suggested that CMS reconsider the criteria for determining subgroups with small population MS-DRGs such as proposed new MS-DRG 850. CMS discusses why it has established the criterion that there are at least 500 or more cases in each subgroup for MS-DRG classification. This minimum case volumes were established to avoid overly fragmenting the MS-DRG system. CMS is concerned smaller volumes will yield stochastic (unpredictable) effects.

After consideration of comments, CMS finalizes its proposals.

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.

CMS did not receive any requests suggesting reassignment. For FY 2025, CMS finalizes its proposal not to move any cases in MS-DRGs 981 through 983 and MS-DRGs 987 through 989.

11. Operating Room (O.R.) and Non-O.R. Issues

CMS has a list of procedures that are considered O.R. procedures. CMS discussed 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 described 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 noted 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. Due to the PHE, CMS thought it would be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review. For FY 2024, CMS continued to believe additional time was necessary to develop the process and methodology. CMS received a comment suggesting factors to consider in evaluating O.R. designations. For FY 2025, CMS is continuing to review the process and methodology and encouraged comments on any other factors to consider in its refinement efforts to recognize and differentiate consumption of resources for the ICD-10 MS-DRGs.

Comments/Responses: Many commenters supported CMS' plan to continue to review the process and methodology. Several commenters recommended CMS provide detailed impact files prior to the adoption of changes to the designation of procedure codes in the ICD-10-PCS classification for review and comment. A few commenters recommended that CMS work closely with physician specialty societies and industry stakeholders to identify the most important drivers of complexity and resource use in the hospital setting. A commenter specifically recommended that CMS consider a technical expert panel to review methodologies for determining the designation of procedure codes in the ICD-10-PCS classification system. A few commenters provided additional suggestions for CMS to consider in their methodology. CMS acknowledges the support and suggestions. It continues to encourage comments on other factors to consider in its refinement efforts.

For FY 2025, CMS did not receive any requests to change the designation of specific ICD-10-PCS procedure codes as non-O.R. or O.R. procedures by the October 20, 2023 deadline. Based on its own internal review and analysis, CMS made proposals related to (1) laparoscopic biopsy of intestinal body parts and (2) laparoscopic biopsy of gallbladder and pancreas. After review of comments, CMS finalizes these proposals. The reader is referred to the final rule for a discussion of these finalized changes.

12. Changes to the MS-DRG Diagnosis Codes

Under the IPPS MS-DRG classification, CMS developed a standard list of diagnoses that are considered CCs. In the FY 2008 IPPS final rule[9], CMS described its process for establishing three different levels of CC severity into which it would subdivide the diagnoses codes: MCC, a CC, or a non-CC.

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.[10]

[9] 72 FR 47152 through 47171
[10] 84 FR 42150 through 42152

CMS developed nine guiding principles as meaningful indicators of expected resource use by secondary diagnosis:

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

Since the FY 2021 IPPS final rule, CMS has not received any additional feedback or comments on the nine guiding principles. For FY 2025, CMS proposed to finalize the nine guiding principles list above. CMS' evaluations to determine the extent to which the presence of a diagnosis as a secondary diagnosis results in increased hospital resource use will include a combination of mathematical analysis of claims data and the application of the nine guiding principles.

CMS plans to continue a comprehensive CC/MC analyses using a combination of the prior mathematical analysis of claims data in combination with the guiding principles. CMS has made available on the CMS website updated impact on resource use files for public review of the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2023 MedPAR files.[11] CMS continues to encourage commenters to provide a detailed explanation of how applying a suggested concept would ensure that the severity designation appropriately reflects resource use for any diagnosis code. CMS is also interested in how it can improve the reliability and validity of the coding data.

Many commenters supported CMS' decision to finalize the guiding principles. Other commenters expressed concerns with the guiding principles because they appeared to be open to interpretation or differences in clinical opinion and there was a lack of detailed definitions and criteria for applying the guiding principles. Several commenters stated it was unclear what impact the guiding principles would have.

CMS clarifies that the application of the guiding principles is not a departure from its historical approach of considering both mathematical analysis and clinical factors for determining CC/MCC designation. The guiding principles are intended to provide a framework for assessing relevant clinical factors to help denote if, and to what degree, additional resources are required

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

above and beyond those that are already being utilized to address the principal diagnosis or other secondary diagnoses that might also be present on the claim. CMS notes that additional information about this topic is available in the 2021 IPPS PPS final rule (85 FR 58550 through 58554).

CMS finalizes the nine guiding principles. CMS states its evaluations to determine the extent to which the presence of a diagnosis code as a secondary diagnosis results in increased hospital resource use will include a combination of mathematical analysis of claims data and the application of the nine guiding principles.

a. Proposed Changes to Severity Levels

1. SDOH – Inadequate Housing/Housing Instability

In the FY 2023 IPPS proposed rule, CMS requested public comments on how reporting of diagnosis codes in categories Z55-Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances) 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.

Comments/Responses: Many commenters continue to support CMS' efforts to encourage documentation and reporting diagnosis of SDOH diagnosis codes. Commenters encouraged CMS to finalize the evidence-based IQR Program measures "Screening for Social Drivers of Health" and "Screen Positive Rate for Social Drivers for Social Drivers of Health finalized in the FY 2023 IPPS final rule. CMS refers readers to the FY 2023 IPPS final rule for a discussion of these measures (87 FR 48867-48872). CMS expects the policies finalizes in the FY 2024 IPPS final rule which change the severity level for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness) and Z59.02 (Unsheltered homelessness) from NonCC to CC will increase documentation of SDOH.

In this proposed rule, CMS reviewed the data on the impact on resource use for the seven ICD-10-CM SDOH Z codes that describe inadequate housing/housing instability, currently designated as NonCC, when reported as a secondary diagnosis. The table below is an extract from the proposed rule.

ICD-10-CM SDOH for Inadequate Housing/Housing Instability		
ICD-10-CM Code	**Description**	**Total Count of Discharge Claims with the Secondary Diagnosis**
Z59.10	Inadequate housing, unspecified	227
Z59.11	Inadequate housing environmental temperature	74
Z59.12	Inadequate housing utilities	162
Z59.19	Other inadequate housing	987
Z59.811	Housing instability, housed, with risk of homelessness	165
Z59.812	Housing instability, housed, homelessness in past 12 months	141
Z59.819	Housing instability, housing unspecified	1,237

CMS discussed its analysis which showed inconsistencies in the resources used. When Z59.10, Z85.19 and Z59.811 are reported as a secondary diagnosis, the resources involved in caring for a patient supports increasing the severity level from a NonCC to CC. In contrast the analysis showed that for diagnosis codes Z59.11, Z59.12, Z59.812 and Z59.819 the resources involved are more aligned with a NonCC severity level. CMS noted that these diagnosis codes have recently become effective and believed the difference in resource use may be attributed to lack of use or knowledge about the newly expanded codes and the data may not yet reflect the full impact on resource use for these patients.

CMS discussed the use of the nine guiding principles to further assess the impact of inadequate housing and housing instability on the severity level. Inadequate housing is defined as an occupied housing unit that has moderate or severe physical problems. Patients living in inadequate housing may be exposed to health and safety risks and evidence associates poor housing conditions with increased morbidity from many health factors including infectious diseases, chronic illnesses and mental disorders. Housing instability encompasses a number of challenges including having trouble paying rent, overcrowding, moving frequently, or spending the bulk of household income on housing. Evidence suggests that housing instability is associated with higher prevalence of many health conditions including overweight/obesity, hypertension, diabetes, and cardiovascular disease.

After considering the impact on resource data and consideration of the nine guiding principles, for FY 2025, CMS proposed to change the severity level designation for the seven inadequate housing/housing instability from NonCC to CC.

Comments/Responses: Commenters expressed overwhelming supporting for this proposal. Many commenters noted an operational concern in that currently only 25 diagnoses are captured on the institutional electronic claim form and 19 diagnoses are captured on the paper bill. CMS thanks the commenters for their support. It notes that any proposed changes to the institutional claim form need to be submitted to the National Uniform Billing Committee (NUBC) for consideration at the NUBS develops and maintains the Uniform Billing (UB) 04 data set and form.

Many commenters recommended CMS examine other SDOH Z codes to determine the hospital resource use for these codes and consider severity designation changes in future rulemaking. Many commenters stated that research has found a strong association between food insecurity and chronic conditions and encouraged CMS to examine the severity designation of ICD-10-CM SDOH Z code Z59.41 (Food insecurity).

In response to these comments, CMS examined the severity designation of Z59.41 (Food insecurity). CMS found that the impact of resource use (C1) value is 0.9273. A C1 value generally closer to 1 suggests the resources involved in caring for patients experiencing food insecurity are more aligned with a NonCC severity level, as the code is currently designated, rather than a CC or an MCC severity level. CMS notes that this contrasts with the research conclusions and notes that Z59.41 was only reported on 6,634 claims in the FY 2023 MedPAR file. CMS will continue to follow this issue in future rulemaking.

Some commenters discussed the challenges for clinicians in documenting SDOH including the specificity of the codes, the lack of training for physicians and clinical staff about the importance of the SDOH codes, and the concern that patients are uncomfortable discussing these issues. Commenters thought all these issues could result in underreporting SDOH's. Some commenters suggested CMS should incentivize the reporting of SDOH codes. CMS notes that proposals for updates to the diagnosis codes should be directed to the ICD-10 Coordination and Maintenance Committee at nchsicd10CM@cdc.gov. Another resource that CMS cites is the American Hospital Association's *Coding Clinic for ICD-10-CM/PCS* which provides clarification on the appropriate documentation and use of Z codes.

For FY 2025, CMS finalizes its proposal to change the severity levels for diagnosis codes Z59.10, Z59.11, Z59.12, Z59.12, Z59.19, Z59.811. Z59.812, and Z59.819 from NonCC to CC. These diagnosis codes are included in Table 6J.1 – Additions to the CC List-FY 2015, associated with this final rule. CMS expects this policy will foster the increased documentation and reporting of SDOH. CMS will continue to monitor SDOH Z code reporting, including reporting based on SDOH screening performed as part of new quality measures. CMS may also consider proposing changes for other SDOH codes in the future. CMS continues to be interested in feedback on how it can foster the documentation and reporting of the diagnosis codes describing social and economic circumstances. Feedback and other suggestions may be submitted by October 20, 2024 through MEARIS.

2. Causally Specified Delirium

CMS received a request to change the severity level designations of the ICD-10-CM diagnosis codes that describe causally specified delirium from CC to MCC when reported as a secondary diagnosis. Causally specified delirium is delirium caused by a physiological effects of a medical condition, by the direct effects of a substance or medication (including withdrawal) or by multiple unknown factors. A table in the final rule lists that 37 ICD-10-CM diagnosis codes that describe causally specified delirium.

CMS summarized its review of this issue. CMS concluded that the data are mixed and do not consistently support a change in the severity level. On average, the data suggests that codes describing causally specified delirium are more similar to a NonCC. In considering the nine guiding principles, CMS noted that delirium is a diagnosis that can impede patient cooperation or management of care. Patients diagnosed with delirium can require a higher level of care by needing intensive monitoring and a greater number of caregivers.

After considering the impact on resource data and consideration of the nine guiding principles, for FY 2025, CMS proposed to maintain the severity designation of these 37 codes for causally specified delirium as CCs.

Commenters/Responses. Many commenters urged CMS to change the designation of the 37 ICD-10-CM diagnosis codes that describe causally specified delirium to MCC. Commenters discussed the issues associated with the accurate reporting of these diagnosis codes and that this issue confounded delirium as being preferentially coded as toxic or metabolic encephalopathy.

Another commenter stated its review of the September 2023 update of the FY 2023 MedPAR file generally supported the request to change delirium from a CC to an MCC.

CMS discusses its analysis of the MedPAR file. CMS notes that it recognizes that patients with delirium can utilize increased hospital resources but it continues to believe there is a lack of consistent claims data to support a severity level change of these diagnosis codes from CCs to MCC for FY 2025. In response to comments about incorrect coding, CMS recommends that entities seeking coding guidance on reporting casually specified delirium or encephalopathy submit any questions pertaining to correct coding to the AHA. CMS also consulted with the CDC's National Center for Health Statistics (NCHS) because NCHS has the lead responsibility for maintaining ICD-10-CM diagnosis codes. The NCHS' staff acknowledged the terms delirium and encephalopathy are differentiated in the classification system but it would consider further review of the classification for these two diagnoses.

FY 2025, CMS finalizes its proposal to maintain the severity designation of these 37 codes for causally specified delirium as CCs. CMS stated that while claims data does not support a severity level change from CCs to MCC, and actually supports a NonCC severity level, it recognizes that patients with delirium can utilize increased hospital resources and can be at a higher severity level.

b. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2025

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

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

c. CC Exclusions List for FY 2025

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.[12] CMS also identified excluded secondary diagnoses using the five following principle: (1) Chronic and acute manifestations of the same condition should not be considered CCs for one another; (2) Specific and nonspecific (NOS) diagnosis codes for the same condition should not be considered CCs for one another; (3) Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another; (4) Codes for the same condition in anatomically proximal sites should not

[12] 52 FR 33143

be considered CCs for one another; and (5) Closely related conditions should not be considered CCs for one another.

The ICD-10 MS-DRGs Version 41.1 CC Exclusion List is included as Appendix C in the ICD-10 MS-DRG Definitions Manual with is available on the CMS website link at https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/AcuteInpatientPPS/index.html and includes two list identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. A link is provided to a collection of diagnosis codes, which when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

Effective April 1, 2024, for the release of the ICD-10 MS-DRG Definitions Manual, Version 41.1, CMS has added a new section to Appendix C: Part 3: Secondary Diagnosis CC/MCC Severity Exclusions in Select MS-DRGs. Part 3 lists diagnosis codes that are designated as a CC or MCC and included in the definition of the logic for the listed MS-DRGs. When these diagnosis codes are reported as a secondary diagnosis and grouped to one of the listed MS-DRGs, the diagnosis is excluded from acting as a CC/MCC for severity in DRG assignment. CMS explains that each MS-DRG is defined by a particular set of patient attributes including principal diagnosis, specific secondary diagnosis, procedures, sex, and discharge status. Secondary diagnoses are used in the definition of the MS-DRG. For example, a secondary diagnosis of acute leukemia with chemotherapy is used to define MS-DRG 899. If a MS-DRG has secondary diagnosis logic, the suppression is activated regardless of the severity of the secondary diagnosis(s) codes for appropriate grouping and MS-DRG assignment.

The full list of MS-DRGs where suppression occurs is shown in the following table, reproduced from the final rule. CMS believes this additional information about the suppression logic may further assist users of the ICD-10 MS-DRG GROUPER software and related materials.

MS-DRG 008		*MS-DRGs 796-798
MS-DRG 010		*MS-DRGs 805-807
MS-DRG 019		*MS-DRGs 837-839
*MS-DRGs 082-084		MS-DRG 927
*MS-DRGs 177-179		*MS-DRGs 928-929
*MS-DRGs 280-282		MS-DRG 933
*MS-DRGs 283-285		MS-DRG 934
*MS-DRGs 456-458		MS-DRG 935
*MS-DRGs 582-583		MS-DRG 955
MS-DRG 768		MS-DRG 956
MS-DRG 790		*MS-DRGs 957-959
MS-DRG 791		*MS-DRGs 963-965
MS-DRG 792		*MS-DRGs 974-976
MS-DRG 793		MS-DRG 977
MS-DRG 794		
*The MS-DRG(S) contain diagnoses that are specifically excluded from acting as a CC/MCC for severity in MS-DRG assignment.		

In its review of the secondary diagnosis logic, CMS identified MS-DRGS 673-675 (Other Kidney and Urinary Tract Procedures) with three “Or Principal Diagnosis” logic and one “With

Secondary Diagnosis" logic list. CMS discussed its analysis which shows diagnosis codes N18.5 (Chronic kidney disease, stage 5) currently designated as a CC and diagnosis code N18.6 (End stage renal disease) currently designated as a MCC have inappropriate logic assignments. For FY 2025, CMS finalizes its proposal to correct the logic for case assignments to MS-DRGs 673-675 (Other Kidney and Urinary Tract Procedures) by adding suppression logic to exclude diagnosis code N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease) from the logic list entitled "With Secondary Diagnosis". This prevents these diagnosis codes from acting as a CC or an MCC, respectively, when reported as a secondary diagnosis with one of the 13 listed principal diagnosis codes (see table in the proposed rule) from the "Or Principal Diagnosis" logic lists in MS-DRGS 673-675 for MS-DRG assignment.

CMS also finalizes its proposal to refine how the suppression logic is displayed under Appendix C-Part C and not to display the MS-DRGs when the suppression logic has no impact on the grouping (this means the logic list for the affected MS-DRG contains diagnoses that are all designated as NonCC, or the MS-DRG is not subdivided by a severity split) as reflected in the draft Versions 42 ICD-10 MS-DRG Definitions Manual available on the CMS website in associated with this proposed rule.

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

- Table 6G.1 Secondary Disorders 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; and
- Table 6J Secondary Disorders Order Deletions to the CC Exclusion List.

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

For FY 2025, commenters requested that CMS designate the 16 new procedure codes that describe introduction of the AGENT™ Paclitaxel-Coated Balloon Catheter that is indicated to treat coronary in-stent restenosis in patients with coronary artery disease as operating room (O.R.) procedures, with assignment to surgical MS-DRGs. The ICD-10-PCS codes and surgical MS-DRGs are listed in the final rule. CMS disagrees with this request. CMS states that the use of the AGENT device to deliver the paclitaxel to the coronary vessel(s) cannot occur in the absence of a surgical vessel preparation, and therefore, it is the vessel preparation procedure that will determine the surgical MS-DRG assignment to one of the listed surgical MS-DRGs. CMS finalizes the designation of the 16 new procedure codes describing use of the AGENT Paclitaxel Coated-Ballon Catheter as non-O.R. for FY 2025.

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

Table 6A	New Diagnosis Codes
Table 6B	New Procedure Codes
Table 6C	Invalid Diagnosis Codes
Table 6D	Invalid Procedure Codes
Table 6E	Revised Diagnosis Title
Table 6G.1	Proposed Secondary Disorders Order Additions to the CC Exclusion List
Table 6G.2	Proposed Principal Disorders Order Additions to the CC Exclusion List

Table 6H.1	Proposed Secondary Disorders Order Deletions to the CC Exclusion List
Table 6H.2	Proposed Secondary Disorders Order Deletions to the CC Exclusion List
Table 6I.1	Proposed Additions to the MCC List
Table 6I.2	Proposed Deletions to the MCC List
Table 6J.1	Proposed Additions to the CC List
Table 6J.2	Proposed Deletions to the CC List

Tables 6A and 6B include the MDC and MS-DRG assignments. Table 6A also includes the new proposed severity level designations for the new diagnosis codes and Table 6B also includes the proposed O.R. status for the new procedure codes.

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

14. 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 final changes for FY 2025, CMS proposed to revise the surgical hierarchy for the MDC 05 (Diseases and Disorders of the Circulatory System); MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms) MS-DRGs.

CMS finalizes its proposals to revise the surgical hierarchy for MDC 05 and MDC 17 MS-DRGs (see tables in the final rule).

Based on the changes finalized for FY 2025, CMS finalizes its proposals to modify the existing surgical hierarchy for MDC 08 with modifications. The finalized surgical hierarchy for MDC 08 is shown in the following table reproduced from the final rule.

Surgical Hierarchy: MDC 08	
MS-DRGs 426-428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical
MS-DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical
MS-DRGs 429-430	Combined Anterior and Posterior Cervical Spinal Fusion
MS-DRGs 456-458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions
MS-DRGs 447-448	Multiple Level Spinal Fusion Except Cervical
MS-DRGs 450-451	Single Level Spinal Fusion Except Cervical
MS-DRGs 461-462	Bilateral or Multiple Major Joint Procedures of Lower Extremity
MS-DRGs 463-465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders
MS-DRGs 466-468	Revision of Hip or Knee Replacement
MS-DRGs 521-522	Hip Replacement with Principal Diagnosis of Hip Fracture
MS-DRGs 469-470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity
MS-DRGs 471-473	Cervical Spinal Fusion
MS-DRGs 474-476	Amputation for Musculoskeletal System and Connective Tissue Disorders

Surgical Hierarchy: MDC 08	
MS-DRGs 477-479	Biopsies of Musculoskeletal System and Connective Tissue
MS-DRGs 480-482	Hip and Femur Procedures Except Major Joint
MS-DRG 483	Major Joint or Limb Reattachment Procedures of Upper Extremities
MS-DRGs 485-489	Knee Procedures
MS-DRGs 518-520	Back and Neck Procedures Except Spinal Fusion
MS-DRGs 492-494	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur
MS-DRGs 495-497	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur
MS-DRGs 498-499	Local Excision and Removal of Internal Fixation Devices of Hip and Femur
MS-DRGs 500-502	Soft Tissue Procedures
MS-DRGs 503-505	Foot Procedures
MS-DRG 506	Major Thumb or Joint Procedures
MS-DRGs 507-508	Major Shoulder or Elbow Joint Procedures
MS-DRG 509	Arthroscopy
MS-DRGs 510-512	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures
MS-DRGs 513-514	Hand or Wrist Procedures, Except Major Thumb or Joint Procedures
MS-DRGs 515-517	Other Musculoskeletal System and Connective Tissue O.R. Procedures

15. 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.

Effective with discharges on and after April 1, 2024, CMS implemented 41 procedure codes including the insertion of a palladium-103 collagen implant into the brain, the excision or resection of intestinal body parts using a laparoscopic hand-assisted approach, the transfer of omentum for pedicled omentoplasty procedures and the administration of talquetamab into the ICD-10-PCS classification system. These codes, including their O.R. status and MDC and MS-DRG assignment are lists in a table in the final rule.

CMS notes that for FY 2024, there are 74,044 diagnosis codes and 78,638 procedure codes. For FY 2025, there are 74,260 diagnosis codes and 78, 948 total codes at this time, there are 252 new diagnosis codes and 41 new procedure codes finalized for FY 2025.

17. Replaced Devices Offered without Cost or with a Credit

In the FY 2008 final rule with comment period[13], 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,[14] 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. The table below, reproduced from the final rule, lists the MS-DRGs subject to this policy for FY 2025.

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
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

[13] 72 FR 47246 through 47251
[14] 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**
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
MDC 5	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without
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 or Carotid Sinus Neurostimulator
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 MedPAR (fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year) from the 2nd year preceding the rate-setting year (e.g., FY 2023 for FY 2025). It also uses Medicare cost report data from the 3rd year preceding the rate-setting year (e.g., FY 2022 for FY 2025).

In developing relative weights for FY 2025, CMS is using:

- FY 2023 MedPAR data: FY 2023 hospital claims received through March 31, 2024, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). Medicare Advantage (MA) claims and claims from facilities currently classified as CAHs are excluded. CMS used data from approximately 6,916,571 million Medicare discharges regrouped using the FY 2025 MS-DRG classifications.
- FY 2022 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2022 cost reporting periods, using the March 31, 2024 update of the FY 2022 HCRIS.

For FY 2025, CMS is not proposing any changes to its methodology and will calculate MS-DRG weights using national averages for the 19 CCRs. Accompanying the final rule, CMS posted the version of HCRIS cost report data file which it used to calculate the 19 CCRs for FY 2025, available at: FY 2025 IPPS Final Rule Home Page | CMS (Select file #4 under FY 2025 Final Rule Data and Supplemental Files, "FY 2025 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 2025, this will occur for MS-DRGs 016 and 017 (Autologous Bone Marrow Transplants), MS-DRGs 095 and 096 (Bacterial and Tuberculous Infections of the Nervous System), MS-DRGs 504 and 505 (Foot Procedures), MS-DRGs 797 and 798 (Vaginal Delivery with Sterilization).

National Average CCRs. The FY 2025 final CCRs in comparison to the FY 2024 CCRs are shown in the following table:

Group	Final FY 2024 CCR	Proposed FY 2025 CCR
Routine Days	0.417	0.418
Intensive Days	0.351	0.360
Drugs	0.18	0.178
Supplies & Equipment	0.303	0.297
Implantable Devices	0.269	0.259
Inhalation Therapy	0.153	0.162
Therapy Services	0.268	0.265

Group	Final FY 2024 CCR	Proposed FY 2025 CCR
Anesthesia	0.072	0.071
Labor & Delivery	0.416	0.381
Operating Room	0.16	0.160
Cardiology	0.086	0.088
Cardiac Catheterization	0.102	0.104
Laboratory	0.102	0.102
Radiology	0.128	0.127
MRIs	0.067	0.067
CT Scans	0.033	0.033
Emergency Room	0.153	0.153
Blood and Blood Products	0.245	0.246
Other Services	0.34	0.336

Relative Weight Calculation for CAR-T cell Therapy (MS-DRG 018). Beginning with FY 2021, CMS adopted a differential payment for clinical trial cases and expanded access use (also known as compassionate use) claims where the hospital does not incur the costs of the CAR-T product. For FY 2025, CMS proposed to continue its methodology for identifying clinical trial claims and expanded access use claims in MS-DRG 018 by excluding claims with the presence of condition code "90" and claims that contain ICD-10-CM diagnosis code Z00.6 without payer-only code "ZC."

Public commenters supported CMS' proposal. As the CAR-T products are very costly, some commenters requested that CMS continue to use a proxy of standardized charges of less than $373,000 to eliminate clinical trial cases from the relative weight calculation. While CMS acknowledged that there may be some cases with fewer than $373,000 in standard charges where the condition codes and diagnosis codes specified above are not used, CMS believes the availability of these codes to eliminate clinical trial cases from the methodology obviates the need to continue using the $373,000 proxy. CMS is finalizing its proposed policy without change.

CMS estimates that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($111,211) were 33 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($334,119). Accordingly, CMS is adopting a payment adjustor of 0.33 to the applicable clinical trial and expanded access use immunotherapy cases. Additionally, CMS will use an adjusted case count for these cases in determining the calculation of the relative weights and for purposes of 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 proposed to continue that policy for FY 2025. There were no comments presented in the rule on this proposal that CMS is finalizing without change. CMS is applying a budget neutrality adjustment of -0.01 percent for the 10 percent cap.

Other Issues. CMS normalizes the relative weights by an adjustment factor 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. The FY 2025 final rule normalization factor is 1.92336

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. This policy will apply to 8 MS-DRGs (7 for newborns and 1 for vaginal delivery with sterilization).

D. Add-on Payments for New Services and Technologies

1. Background

Sections 1886(d)(K) and (L) of the Act establish a process for identifying and ensuring adequate payment for new medical services and technologies under the IPPS. The Secretary is required to establish criteria used to determine if a medical service or technology is new.[15] 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[16]; 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.[17] 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.[18]

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[19]:

1. Whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome;

[15] Section 1886(d)(5)(K)(vi) of the Act
[16] 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).
[17] 84 FR 42292 through 42297; regulations at §412.87(c) and (d)
[18] 85 FR 58736
[19] 74 FR 43813 and 43814

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 service or technology is new; if CMS determines the medical service or technology is considered new, then it makes a determination as to whether the cost threshold and substantial clinical improvement criteria are met.

Cost Criterion. For purposes of the cost criterion, CMS includes the cost thresholds applicable to the next fiscal year, in the data files associated with the prior fiscal year. The MS-DRG thresholds applicable to FY 2025 are included in the data files associated with the FY 2024 final rule on the CMS website.[20]

For the FY 2026 threshold values, the final cost thresholds are included in the data files associated with the FY 2025 final rule, also available on the CMS website.

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[21], 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;

[20] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.
[21] 84 FR 42288 through 42292

        - Improvement in one or more activities of daily living;
        - Improved quality of life; or
        - Demonstrated greater medication adherence or compliance; or
        - The totality of the circumstances otherwise demonstrates substantially improvements, relative to available technologies, for the diagnosis or treatment of Medicare beneficiaries.
- Evidence from published or unpublished sources from the US or elsewhere may be sufficient to establish an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries includes the following sources: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated may have a low prevalence among Medicare beneficiaries.
- The service or technology may represent an advance that substantially improves, relative to available options, the diagnosis or treatment of a subpopulation of patients with the medical condition.

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

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

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

c. Additional Payment for New Medical Service or Technology

In the FY 2020 IPPS final rule[22], 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.[23]

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

In the FY 2024 IPPS final rule, CMS finalized that beginning with new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of the application submission, and must provide documentation of the FDA acceptance or filing to CMS when the application is submitted.[24] CMS also finalized that beginning with FY 2025 applications, an applicant must have received approval or clearance by May 1 instead of July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Applications submitted under the alternative pathway for certain antimicrobial products are excluded from the date change.

In the FY 2021 IPPS final rule, CMS finalized a policy 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.[25] Antimicrobial products that would otherwise meet the applicable add-on payment criteria would begin

[22] 84 FR 42297 through 42300
[23] 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.
[24] 88 FR 58948 through 58958
[25] 85 FR 58739 through 58742

receiving the new technology add-on payment, effective for discharges the quarter after the date of FDA marketing authorization instead of waiting to re-apply for the next fiscal year, provided FDA marketing authorization is received by July 1 of the year for which the applicant applied for new technology add-on payments.

e. New Technology Liaisons

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

f. Application Information for New Medical Services or Technologies

For FY 2026, complete application information, along with final deadlines for submitting an application, will be posted as it becomes available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. Once the application deadline has closed, CMS will also post the tracking forms completed by each applicant. At the time the proposed rule is posted, CMS will also post online the application, including the completed application forms, certain related materials, and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost, and other information identified by the applicant as confidential). This information is posted at https://mearis.cms.gov/public/publications/ntap. Applications that are withdrawn prior to the publication of the proposed rule are not publicly posted.

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

The Secretary is required to obtain public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of the proposed rule discussing these services or technologies.[26] On December 13, 2023, CMS held a town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" for pending new technology applications.[27] In their evaluation of individual applications, CMS considers the presentations made at the town hall meeting and written comments received by December 18, 2023. 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 are not summarized 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. CMS notes that after Section "X" codes have served their purpose, proposals to delete them and

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

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. Information about ICD-10-PCS codes is available at https://www.cms.gov/Medicare/Coding/ICD10.

4. FY 2025 Status of Technologies Approved for FY 2024 New Technology Add-On Payments

CMS discusses the final FY 2025 status of 31 technologies approved for FY 2024 new technology add-on payments. A medical service or technology may be considered new within 2 or 3 years after which data becomes available which reflects the inpatient hospital code assigned to the new service or technology. CMS' practice has been to begin and end new technology add-on payments on the basis of a fiscal year and it generally follows a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend an add-on payment for an additional fiscal year. In general, CMS extends add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the US market occurs in the latter half of the fiscal year (70 FR 47362).

Comments/Responses. A commenter restated a prior comment that the requirement for a manufacturer to submit information rebutting a presumption that the date of first availability is the date of FDA marketing authorization adds unnecessary burden and complexity to the application process. The commenter believed the newness period should begin with the date of the first claim, which they stated would be consistent with the definition of newness for the Transitional Pass-through status in the OPPS. CMS reiterates its prior response which discussed the differences between "newness" for the purpose of the IPPS new technology add-on payment and eligibility for the OPPS pass-through payment.[28] CMS notes it believes the commenter is not referring to "newness" but rather to the limited two-to-three year period of pass-through payment which begins on the date CMS makes its first pass-through payment for a drug, biological, or device (§§419.64(c)(2) and 419.66(g)). For new technology add-on payments, CMS believes its policy to begin the newness period on the date of FDA approval or clearance, or if later, the date of availability on the U.S. market is consistent with the statutory requirement to establish a mechanism for data collection of the costs of a new service or technology for a period of not less than two years and not more than three years beginning on the date on which an inpatient code is issued for the service or technology. In addition, CMS believes its regulations which allows new technology add-on payments for 2- to 3-years provides time for collection of cost data within MedPAR.[29] CMS continues to disagree that the appropriate policy would be for the newness period to begin with the date of the first claim.

The applicant for REZZAYO™ submitted a comment stating that its newness start date should not be March 22, 2023 but should be the date of availability on the U.S. market, July 26, 2023. The applicant explained the market delay was due to the need to comply with an FDA post-marketing commitment (PMC) protocol. The applicant stated the completed PMC requirements were submitted on July 19, 2023 and REZZAYO was made available on July 26, 2023. CMS states that an applicant may begin distribution of a drug product when FDA receives the required

[28] 86 FR 45136

[29] 1886(d)(5)(K)(ii)(II) of the Act, §§§412.87(b)(2), 412.87(c)(2), and 412.87(d)(2).

information, and absent additional information, it considers the beginning of the newness period to begin July 19, 2023.

Many commenters supported the proposed continuation of new technology add-on payments for the SAINT Neuromodulation System. The applicant requested CMS assign a newness date of April 5, 2024 and provided a summary and timeline of all the required activities prior to April 5, 2024 when the SAINT Neuromodulation System was available at two hospitals. In response, CMS notes that between October 1, 2022 and April 4, 2024, it identified 5 claims reporting the ICD-10-PCS code associated with this technology; three of those claims were made in FY 2024 and received new technology add-on payment. Based on this data, CMS continues to believe the beginning of the newness period began on September 1, 2022, the date of FDA marketing authorization for the indication covered by the Breakthrough Device designation.

The applicant foe DefenCath® updated its WAC on April 15, 2024 to $249.99 per 3ml vial instead of the $390 per 3ml vial in its application. CMS updated the new technology add-on payment amount for DefenCath. CMS notes that although the applicant stated the product was launched on April 15, 2024, it did not receive information about a documented delay in market availability, and continues to believe the newness period begins on November 15, 2023, the date of FDA marketing authorization for the indication covered by its QIDP designation. For FY 2025, the maximum new technology add-on payment amount is $3,656.10.

Continuation of Technologies. Table II.E.-01 in the final rule (see table extract below) lists the 24 technologies CMS finalizes to continue their new technology add-on payments for FY 2025 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 final maximum NTAP amount for FY 2025, codes used to identify cases eligible for NTAP, and previous related final rule citations. In addition, because CMS determines that ELREXFIO™ and TALVEY® are substantially similar to TECVAYLI®, for FY 2025 it is using a single cost for determining the new technology add-on payment for ELREXFIO, TALVEY, and TECVAYLI. For FY 2025, CMS calculated a case-weighted average cost of $19,845.52 for this technology with a maximum new technology add-on payment for a case of $12,899.59. (The FY 2025 applications for ELREXIO and TALVEY are discussed below in Section E.5.d).

Continuation of Technologies Approved for FY 2024 New Technology Add-On Payments Still Considered New for FY 2025 Because 3-Year Anniversary Date Occurs on or After April 1, 2025				
	Technology	**Newness Start Date**	**NTAP Start Date**	**3-year Anniversary Date of Entry onto US Market**
1	Thoraflex™ Hybrid Device	04/19/2022	10/1/2022	04/19/2025
2	ViviStim® Paired VNS System	04/29/2022	10/1/2022	04/29/2025
3	GORE® TAG® Thoracic Branch Endoprosthesis	05/13/2022	10/1/2022	05/13/2025
4	Cerament® G	05/17/2022	10/1/2022	05/17/2025
5	iFuse Bedrock Granite Implant System	05/26/2022	10/1/2022	05/26/2025
6	CYTALUX® (pafolacianine) (ovarian indication)	04/15/2022	10/1/2023	04/15/2025

Continuation of Technologies Approved for FY 2024 New Technology Add-On Payments Still Considered New for FY 2025 Because 3-Year Anniversary Date Occurs on or After April 1, 2025				
Technology		**Newness Start Date**	**NTAP Start Date**	**3-year Anniversary Date of Entry onto US Market**
7	CYTALUX® (pafolacianine) (lung indication)	06/05/2023	10/1/2023	06/05/2026
8	EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm)	05/19/2023	10/1/2023	05/19/2026
9	Lunsumio™ (mosunetuzumab)	12/22/2022	10/1/2023	12/22/2025
10	REBYOTA™ (fecal microbiota, live-jslm) and VOWST™ (fecal microbiota spores, live-brpk)	01/23/2023	10/1/2023	01/23/2026
11	SPEVIGO® (spesolimab)	09/01/2022	10/1/2023	09/01/2025
12	TECVAYLI™ (teclistamab-cqyv)	11/09/2022	10/1/2023	11/09/2025
13	TERLIVAZ® (terlipressin)	10/14/2022	10/1/2023	10/14/2025
14	Aveir™ AR Leadless Pacemaker	06/29/2023	10/1/2023	06/29/2026
15	Aveir™ Dual-Chamber Leadless Pacemaker	06/29/2023	10/1/2023	06/29/2026
16	Ceribell Status Epilepticus Monitor	05/23/2023	10/1/2023	05/23/2026
17	DETOUR System	06/07/2023	10/1/2023	06/07/2026
18	DefenCath™ (taurolidine/heparin)	11/15/2023	1/1/2024	11/15/2026
19	EchoGo Heart Failure 1.0	11/23/2022	10/1/2023	11/23/2025
20	Phagenyx® System	04/12/2023	10/1/2023	04/12/2026
21	REZZAYO™ (rezafungin for injection)	07/19/2023	10/1/2023	03/22/2026
22	SAINT Neuromodulation System	09/01/2022	10/1/2023	09/01/2025
23	TOPS™ System	06/15/2023	10/1/2023	06/15/2026
24	XACDURO® (sulbactam/durlobactam)	05/23/2023	10/1/2023	05/23/2026

Discontinuation of Technologies. Table II.E.-02 in the proposed rule (see table extract below) lists the 7 technologies CMS finalizes to discontinue their new technology add-on payments for FY 2025 because the 3-year anniversary date of entry into the U.S. market occurs prior to April 1, 2024. The complete table in the proposed rule also includes the proposed maximum NTAP amount for FY 2025, codes used to identify cases eligible for NTAP, and previous related final rule citations.

Comment/Response. The manufacturer of Intercept Fibrinogen Complex stated that due to manufacturing delays the majority of hospitals could not access this product and its add-on payment should be extended an additional year. CMS responds that a technology is not considered "new" once it is available on the U.S. market for more than 2 to 3 years, regardless of whether the technology's use in the Medicare population has been frequent or infrequent (88 FR 58802).

Proposed Discontinuation of Technologies Approved for FY 2024 New Technology Add-On Payments No Longer Considered New for FY 2025 Because 3-Year Anniversary Date Occurs Prior to April 1, 2025				
	Technology	**Newness Start Date**	**NTAP Start Date**	**3-year Anniversary Date of Entry onto US Market**
1	Intercept® Fibrinogen Complex (PRCFC)	05/05/2021	10/1/2021	5/05/2024
2	Rybrevant® (amivantamab)	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 (TLIF indication)	6/30/2021 (TLIF)	10/1/2021	6/30/2024 (TLIF)
5	Hemolung Respiratory Assist System (RAS) (non- COVID-19 related use)	11/15/2021 (other)	10/1/2022	11/15/2024 (other)
6	Livtencity™ (maribavir)	12/2/2021	10/1/2022	12/2/2024
7	Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System	10/04/2021	10/1/2023	10/04/2024

5. FY 2025 Applications for New Technology Add-On Payments: Traditional Pathway

CMS received 16 applications for new technology add-on payments for FY 2025 under the traditional pathway; one applicant was not eligible for consideration because it did not meet FDA marketing authorization requirements and three applicants withdrew their applications prior to the issuance of this proposed rule. Prior to the issuance of this final rule, two additional applications were withdrawn – odronextamab for the R/R DLBCL indication and odronextamab for the R/R FL indication.

The summary below provides a high-level discussion of the remaining 10 new technology assessment; readers are advised to review the final rule for more detailed information. CMS notes that the manufacturer for Casgevy™ submitted a single application, but for two separate indications, which are discussed separately. The publicly posted FY 2025 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 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 with the information posted on the CMS website.[30]

The following applications were approved for add-on payments:

- Casgevy™ for sickle cell disease (SCD) for recurrent vaso-occlusive crises (VOCs),
- HEPZATO™ for injection/hepatic delivery system, and
- Lyfgenia™ for SCD and a history of VOCs.

[30] 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.

As discussed below, because CMS considers ELREXFO and TALVEY as substantially similar to TECVAYLI, which was approved for new technology add-on payments for FY 2024 and is still considered "new" for purposes of add-on payments for FY 2025, ELREXFO and TALVEY are also eligible for the new technology add-on payment for FY 2025.

a. Casgevy™ (exagamglogene autotemcel) First Indication: Sickle Cell Disease (SCD)

Vertex Pharmaceuticals submitted an application for Casgevy, a modified CD34+ hematopoietic stem and progenitor cell (HSPC) cellular therapy approved for the treatment of sickle cell disease (SCD) in patients 12 years and older with recurrent vaso-occulsive crises (VOC). Using a CRISPR/Cas9 gene editing technique, the patients' CD34+ HSPCs are edited resulting in increased production of fetal hemoglobin (HbF) and occurrence of a natural clinically benign condition called hereditary persistence of fetal hemoglobin (HPFH) that reduces or eliminates SCD symptoms. Infusion of Casgevy induces increased HbF production in SCD patients. The new technology add-on payment for treating transfusion-dependent beta thalassemia (TDT) is discussed separately in section *b*.
The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP2310171VPTU.

Newness. The applicant stated that Casgevy was granted Biologics License Agreement (BLA) from the FDA on December 8, 2023 for treatment of SCD in patients 12 years of age or older with recurrent VOCs. Effective April 1, 2023, two ICD-10-PCS codes may be used to uniquely describe procedures involving the use of Casgevy: XW133J8 and XW143J8. The applicant provided an extensive list of ICD-10-CM diagnosis codes that may be used to identify the indication for Casgevy (see the online application posting); CMS believed that five ICD-10-CM codes identify the indication for Casgevy: D57.1 (Sickle-cell disease without crisis), D57.20 (Sickle-cell/Hb-C disease without crisis), D57.40 (Sickle-cell thalassemia without crisis), D57.42 (Sickle-cell thalassemia beta zero without crisis), D57.44 (Sickle-cell thalassemia beta plus without crisis), or D57.80 (Other sickle-cell disorders without crisis).

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated that Casgevy is not substantially similar to other currently available technologies because it is the first approved therapy to use CRISPR gene editing technology and no other approved technology uses the same or a similar mechanism of action. For the second criterion (same or different MS-DRG), the applicant stated that the ICD-10-PCS codes are assigned to MS-DRGs 016 and 017, DRGs currently used for autologous stem-cell transplants. For the third criterion (same or similar disease or patient population), the applicant stated that there are several approved therapies used to treat patients with SCD but no other approved single product acts as a stand-alone one-time treatment intended to permanently address the basis cause of SCD.

In the proposed rule, CMS noted that Casgevy may have the same or similar mechanism of action to Lyfgenia™ (the application for Lyfgenia is discussed below in section *i*). Casgevy and Lyfgenia are both gene therapies using modified autologous CD34+ hematopoietic stem and HSPC therapies administered via stem cell transplantation for the treatment of SCD. Lyfgenia was approved by FDA for the same indication as Casgevy on December 8, 2023. CMS noted that

both technologies extract CD34+ HSPCs for manufacturing the product and then patients undergo myeloablative conditioning using busulfan to deplete their bone marrow in preparation for the technologies' modified stem cells to engraft the patient's bone marrow. CMS believed that Casgevy and Lyfgenia also have the same or similar mechanism of action, reduction in the amount of sickling hemoglobin to reduce and prevent VOC associated with SCD. In addition, both technologies map to the same MS-DRGs and treat the same or similar disease (sickle cell disease) in the same or similar patient population (patients 12 years of age and older with a history of VOC).

CMS discusses comments it received from the manufacturer of Casgevy and the manufacturer of Lyfgenia explaining the unique mechanism of action of each treatment. Based on this additional information, CMS agrees that Casgevy and Lyfgenia do not have the same mechanism of action. CMS states that Casgecy modifies a patients' own HSPCs to increase HbF expression to subsequently reduce the expression of intracellular sickled hemoglobin concentration. In contrast, Lyfgenia modifies a patients' own HSPCs to increase^{T87Q} (modified adult hemoglobin). CMS concludes that Casgevy meets the newness criterion. It has a unique mechanism of action and is not substantially similar to existing treatment options for the treatment of SCD in patients 12 years or older with recurrent VOC.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. A table in the final rule, summarizes the cost analysis. CMS concludes that Casgevy meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Casgevy offers a substantial clinical improvement because it will expand patient eligibility for potentially curative SCD therapies, have improved clinical outcomes relative to available therapies, and avoid serious risks or side effects associated with other potentially curative treatment options for SCD. The applicant provided one study to support these claims and eight background articles about SCD treatments. A table in the final rule summarizes the applicant's assertions.

In the proposed rule, CMS discussed several concerns regarding whether Casgevy meets the substantial clinical improvement criterion. CMS noted that the only assessment of the technology was submitted from conference presentations that provided data on the ongoing CLIMB-121 trial, a phase 1/2/3 single-arm trial assessing a single dose of Casgevy in patients 12 to 35 years old with SCD and a history of 2 or more severe VOCs per year over 2 years. The applicant also noted a safety profile consistent with myeloablative busulfan and autologous hematopoietic stem cell transplantation (HSCT). CMS noted, however, that the provided evidence did not include peer-reviewed literature that directly assessed the use of Casgevy for SCD. CMS was also concerned that the small study population may limit generalizability to the Medicare population and the short follow-up duration was insufficient to assess improvements in long-term clinical outcomes.

The applicant responded to CMS' concerns and provided additional information from a published peer-review study which assessed Casgevy in patients 12 to 35 years of age with SCD who had at least two severe VOCs before the study. In response to concerns about sample size, the applicant stated that it believes the study sample size are appropriate given that SCD affects

an estimated 100,000 Americans. The applicant also stated that the study results are generalizable to the Medicare population as the population is consistent with CMS data indicating that more than 70 percent of Medicare fee-for-service beneficiaries are dual eligible and more than 80 percent of these beneficiaries with SCD are covered under Medicare disability benefits.

CMS also summarizes additional comments it received, including a comment from the manufacturer of Lyfgenia.

Based on the additional information provided, CMS concludes that Casgevy represents a substantial clinical improvement because it offers a treatment option for certain patients with SCD who are not eligible for bone marrow transplant due to a lack of HLA matching and who experience recurrent VOEs despite treatment with existing treatments.

CMS **finalizes that Casgevy meets all three criteria for new technology add-on payments** and approves add-on payments for FY 2025. Cases involving the use of Casgevy will be identified by the two ICD-10-PCS codes for transfusion of exagamglogene autotemcel in combination with one of the following ICD-10-CM codes for sickle-cell disease: D57.1, D57.20, D57.40 D57.42, D57.44 or D57.80. Based on information provided by the applicant, the estimated cost per patient is $2,200,000. As discussed below (section E.10), for FY 2025 CMS is revising the maximum new technology add-on payment percentage to 75 percent for a medical product that is a gene therapy indicated for the treatment of SCD. For FY 2025, the maximum new technology add-on payment for a case involving Casgevy is $1,650,000.

b. Casgevy™ (exagamglogene autotemcel) Second Indication: Transfusion-Dependent ß Thalassemia (TDT)

Vertex Pharmaceuticals also submitted an application for Casgevy for treating transfusion-dependent beta thalassemia (TDT).

Newness. The applicant stated that Casgevy was granted BLA from the FDA on January 16, 2024 for the treatment of TDT in patients 12 years of age or older. Two ICD-10-PCS codes may be used to describe procedure involving the use of Casgevy: XW133J8 and XW143J8. The applicant provided an extensive list of ICD-10-CM diagnosis codes that may be used to identify the indication for Casgevy (see the online application posting); CMS believed that three ICD-10-CM codes identify the indication for Casgevy for TDT: D56.1 (Beta Thalassemia), D56.2 (Delta-beta thalassemia), or D56.5 (Hemoglobin E-beta thalassemia).

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated that Casgevy is not substantially similar to other currently available technologies because it is the first approved therapy to use CRISPR gene editing technology and no other approved technology uses the same or a similar mechanism of action. For the second criterion (same or different MS-DRG), the applicant stated that the ICD-10-PCS codes are assigned to MS-DRGs 016 and 017, DRGs currently used for autologous stem-cell transplants. For the third criterion (same or similar disease or patient population), the applicant stated that

there are no other approved single that acts as a stand-alone one-time treatment intended to permanently address the basis cause of TDT.

In the proposed rule, CMS was concerned that Casgevy may be the same or similar to other gene therapies used to treat TDT, especially Zynteglo™. Zynteglo, approved for treatment of TDT on August 17, 2022, is a gene therapy that uses modified autologous CD34+ HSPC administered via stem cell transplantation for treatment of TDT. CMS discussed similarities between Casgevy and Zynteglo and believed these technologies may be substantially similar to each other. CMS noted that if Casgevy is substantially similar to Zynteglo for the treatment of TDT, the newness period for this technology would begin on August 17, 2022 (the BLA approval date for Zynteglo). CMS discusses comments it received from the manufacturer of Casgevy and the manufacturer of Zynteglo explaining the unique mechanism of action of each treatment. Based on this additional information, CMS agrees that Casgevy and Zynteglo do not have the same mechanism of action. CMS concludes that Casgevy meets the newness criterion. It has a unique mechanism of action and is not substantially similar to existing treatment options for the treatment of TDT in patients 12 years or older.

Cost. The analysis for the cost criterion is the same analysis discussed above for the SCD indication. CMS concludes that Casgevy meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Casgevy offers a substantial clinical improvement because it is expected to avoid serious risks or side effects associated with the existing approved gene therapy for TDT, Zynteglo. The applicant provided one study to support these claims as well as two package inserts. A table in the final rule summarizes the applicant's assertions.

In the proposed rule, CMS discussed several concerns regarding whether Casgevy meets the substantial clinical improvement criterion. CMS noted that the only assessment of the technology was submitted from conference presentations that provided data on the ongoing CLIMB-121 trial, a phase 1/2/3 single-arm trial assessing a single dose of Casgevy in patients 12 to 35 years old with TDT. This is the same study discussed for the SCD indication and CMS has similar concerns.

With regard to the claim of reduced serious risks or side effects, the applicant stated that Zynteglo utilizes gene transfer to use a modified, inert lentivirus to add working exogenous copies of the Beta-globulin gene to increase functional hemoglobin A which carries the risk of lentiviral vector (LVV)-mediated insertional oncogenesis after treatment. The applicant stated that the technology for Casgevy does not carry a risk for insertional oncogenesis; it does have the potential to produce off-target edits but this has not been observed. CMS notes that information is not provided about the frequency and related clinical relevance of LVV-mediated oncogenesis and also questions whether the follow-up duration of patients treated with Casgevy is sufficient to assess improvement in the rate of malignancy. CMS was interested in additional information on the overall safety profile comparison between Casgevy and Zynteglo, as well as any comparisons of Casgevy to other potentially curative treatments for patients with TDT.

CMS discusses the comments it received which included comments from the manufacturer of Casgevy and the manufacturer of Zynteglo. CMS continues to question whether there is evidence to demonstrate that Casgevy improves clinical outcomes relative to existing technologies because of the lack of comparison to exiting standard of care and potentially curative treatment options provided by allo-HSCT and Zynteglo. CMS also does not understand how the provided evidence supports the applicant's assertion that Casgevy improves clinical outcomes for TDT by avoiding the risk or insertional oncogenesis or the replication of competent lentivirus.
Based on the additional information provided, CMS concludes that it is unable to determine that Casgevy for TDT represents a substantial clinical improvement. For 2025, **CMS does not approve Casgevy for TDT** for new technology add-on payments.

c. DuraGraft® (Vascular Conduit Solution)

Marizyme submitted an application for DuraGraft®, an intraoperative vein-graft preservation solution used for vein graft harvesting and storage during coronary artery bypass graft (CABG) surgery.[31] The applicant also submitted an application for FY 2024 that it withdrew prior to the issuance of the FY 2024 IPPS final rule.[32]

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP231012EE9NW.
Newness. The applicant stated that the FDA granted a De Novo classification on October 4, 2023 for adult patients undergoing CABG and the device is indicated for flushing and storage of vascular grafts during CABG surgery for up to 4 hours. The applicant indicated that ICD-10-PCS code XY0VX83 would identify procedures using the DuraGraft® technology.

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated there are no other treatment options available with the same mechanism of action as DuraGraft®. DuraGraft directly interferes with the mechanisms of oxidative damage; common storage solutions are only salt solutions which have no ability to protect against ischemic injury. For the second criterion (same or different MS-DRG) the applicant stated that cases involving patients receiving treatment involving DuraGraft® would be assigned to the same MS-DRGs as patients receiving treatments involving heparinized blood, saline, and electrolyte solutions. For the third criterion (same or similar disease or patient population) the applicant indicated that heparinized blood, saline and electrolyte solutions involve treatment of the same disease process and the same patient population as DuraGraft®.
As in previous discussions, CMS was concerned that the mechanism of action of DURAGRAFT® may be the same or similar to other vein graft storage solutions such as various saline, blood, and electrolyte solutions.

CMS discusses comments it received, including comments from the manufacturer, supporting the unique mechanism of DURAGRAFT. The applicant asserted that by FDA definition of a De Novo request, there are no other legally marketed treatments or products intended for treating or storing vascular grafts. The applicant stated that while vascular grafts are placed in a liquid, such

[31] Somahlution submitted applications for DURAGRAFT® for FY 2018, FY 2019 and FY 2020, which were withdrawn. Marizyme Inc, acquired Somahlution in 2020.
[32] 88 FR 26795 through 26803

as Ringers Lactate, to keep them from drying out between harvesting and implantation, these liquids should not be considered similar to DuraGraft which prevents oxidative damage and maintains the structural and functional integrity of vascular conduits. In addition, the applicant cited the new ICD-10-PCS code, XYOVX83, to report DuraGraft when used in CABG procedures.

CMS concludes that DuraGraft meets the newness criterion. It has a unique mechanism of action as compared to other vein graft storage solutions because it creates a reducing environment for vascular grafts to prevent oxidative damage which occurs during ischemic storage of grafts. CMS notes the applicant indicated that DuraGraft should be available near the end of the second quarter of 2024. CMS considers the newness date for this technology to be October 4, 2023, the date it was granted De Novo classification from FDA.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. In the proposed rule, CMS noted that although DuraGraft replaces solutions currently used for flushing and storage, the applicant did not remove any charges for prior technology. The applicant conducted two new cost analyses to address CMS' concerns. CMS concludes that DuraGraft met the cost criteria.

Substantial Clinical Improvement. The applicant stated that DuraGraft® significantly reduces clinical complications associated with vein graft following coronary artery bypass grafting (CABG) surgery. The applicant asserted there is no other product or technology that reduces the incidence of peri-operative myocardial infarction. The applicant provided four studies to support its assertions and 47 background articles about reducing adverse cardiac events (MACE). A table in the proposed rule summarizes the applicant's assertions.

In the proposed rule, CMS discussed concerns with the information provided, many of them similar to prior concerns discussed in the FY 2024 PPS proposed rule. It was concerned that some of the studies (Szalkiewicz and Perrault) used a relatively small sample size (166 and 125 patients respectively) as compared to the number of potentially eligible patients. As provided by the applicant, about 400,000 CABG surgeries are performed annually and approximately 60% will be performed on Medicare beneficiaries. CMS was also concerned about the relatively short follow-up periods in these studies (4 days and 12 months respectively). CMS noted that both authors indicated limitations with these studies and that larger cohorts and longer-term evaluation was needed. CMS questioned whether similar clinical results would have been achieved with a larger patient sample and over a longer follow up period. In addition, CMS noted that the studies predominately included white males and CMS questions whether the results from studies could be generalized to other patient groups. CMS noted that male patients account for only two-thirds of Medicare beneficiaries who underwent CABG surgery.

CMS discusses the comments it received which included comments from the manufacturer of DuraGraft. CMS continues to question whether the patient samples in the studies are representative of the Medicare population and the extent to which the results could be generalized to the Medicare population. CMS continues to be concerned that the studies focus on predominately white men and did not include sufficient women and minorities.

Based on the additional information provided, CMS concludes that it is unable to determine that DuraGraft represents a substantial clinical improvement over existing treatments. For FY 2025, **CMS does not approve DuraGraft** for new technology add-on payments.

d. ELREXFIO™ (elranatamab-bcmn) and TALVEY™ (talquetamab-tgvs)
In the proposed rule, CMS discussed these applications as two separate technologies. After further consideration and review of comments, CMS concludes that ELREXFIO and TALVEY are substantially similar and evaluates both technologies as one application.

Pfizer submitted an application for ELREXFIO™, a heterodimeric humanized full-length bispecific antibody against B-cell maturation antigen (BCMA) on myeloma cells and cluster of differentiation (CD)3 on T cells. ELREXFIO bridges the BCMA cell-surface antigen and the extracellular CD3 subunit expressed on T cells and activates the T cell to release cytokines that kill multiple myeloma (MM) cells. An application was submitted for FY 2024, but the technology did not meet the July 1, 2023 deadline for FDA approval and was not eligible for consideration for new technology add-on payments for FY 2024.[33]

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP2310176PV9B.
Johnson & Johnson Health Care Systems submitted an application for TALVEY, the first and only approved G protein-coupled receptor, class c, group 5, member 5 (GPRC5D) target therapy (a bsAb) approved for the treatment of adults with RRMM who have received at least four prior lines of therapy (4L+RRMM) including a PI, an IMiD, and an anti-CD38 mAb. GPRC5D is an orphan receptor expresses at significantly higher level on MM cells than on normal plasma cells.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP2310163HW2V.

Newness. The applicant stated ELREXFIO was granted BLA approval from the FDA on August 14, 2023 for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-cluster of differentiation 38 (anti-CD38) monoclonal antibody (mAB). The applicant stated patients could be admitted to receive the first dose cycle in the inpatient setting. The applicant indicated CD-10-PCS code XW01L9 describes procedures using ELREXFIO.

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated there are no other treatment options available for patients with RRMM who have received 4 prior lines of therapy including a PI, IMiD, and mAB that uses a humanized IgG2a antibody for the mechanism of action. In addition, the applicant stated it is also the only BCMA-directed bispecific antibody (bsAb) therapy with a clinical study in its prescribing information supporting use in patients who have received prior BCMA-directed therapy. Specifically, the applicant stated that current treatment options (XPOVIO®, BLENREP, ABECMA®, CARVYKTI™, and traditional chemotherapy agents) are not bispecific antibodies.

[33] 88 FR 26803 through 26809

The applicant discusses differences between ELREXFIO and two other bsAbs approved for patients with RRMM, TECVAYLI®, and TALVEY™.

Newness. TALVEY was granted BLA from FDA on August 9, 2023 for the treatment of adult patients with 4L+RRMM who have received four prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb. The ICD-10-PCS procedure code for TALVEY infusion is XW01329. The applicant stated that MM ICD-10-CM codes C90.00 and C90.02 may be used to identify the indication for TALVEY.

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated that TALVEY has a unique mechanism of action because it is a CD3 T-cell engaging bsAb targeting GPRC5D. The applicant stated that TALVEY has a different mechanism of action from TECVAYLI and ELREXFIO because it binds to different receptors; TALVEY is the only bsAb for RRMM that target GPRC5D on myeloma cells.

In the proposed rule, CMS was concerned that ELREXFIO may be substantially similar to TALVAY and both may also have a similar mechanism of action as TECVAYLI. CMS noted that per the applications for ELREXFIO and TALVEY both are bispecific antibodies approved for treatment of adults with RRMM and who have received at least four lines of prior therapy including a PI, IMiD and an anti-CD38 mAB. CMS acknowledges that these technologies bind to different proteins on the tumor cell but does not understand how that results in a different mechanism of action. CMS also notes that these technologies would be assigned to the same MS-DRG and treat the same or similar patient population.

CMS also believed that ELREXFIO and TALVEY may be substantially similar to TECVAYLI, which was approved for new technology add-on payments for FY 2024 for treatment of patients with RRMM who have received at least four prior lines of therapy, including a PI, IMiD, and an anti-CD38 mAb. TECVAYLI is a bsAb that use binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor.

CMS discusses the comments it received. The applicant for ELREXFIO agreed that based on CMS' newness criteria, that all three technologies are all substantially similar. The applicant stated that CMS should extend the new technology add-on payment status to ELREXFIO. The applicant for TALVEY did not agree that TALVEY has a similar mechanism of action due to the targeting of different antigens on the surface of malignant plasma cells. While GPRC5D and BCMA may have similar expression on plasma cells, the applicant stated that the pattern of expression of GPRC5D and BCMA are independent of each other, making GPRC5D a distinct clinical target. The applicant also asserted that TALVEY could be used to treat patients who have progressed on or did not respond to TECVAYLI.

CMS continues to believe that ELREXFIO, TALVEY, and TECVAYLI use the same or a similar mechanism of action, map to the same MS-DRG, and treat the same patient population. 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 these technologies. CMS considers the beginning of the newness period for ELREXFI and TALVEY to be November 9, 2022, the date TECVAYLI became commercially available. Because these technologies are

substantially similar to TECVAYLI, CMS does not address the cost and substantial clinical improvement for ELREXFI and TALVEY.

Cases involving the use of ELREXFIO will be identified by ICD-10-PCS code XW013L9 and cases involving the use of TALVEY will be identified by ICD-10-PCS code XW01329. The manufacturer of ELREXFIO estimated the cost per patient is $15,112. The manufacturer of TALVEY estimated the cost per patient is $26,164.44 per patient. Because ELREXFIO and TALVEY are substantially similar to TECVAYLI, CMS believes a single cost for determining the new technology add-on payment amount is appropriate. To determine the maximum new technology add-on payment, CMS calculated a weighted average of the cost of these technologies based upon the projected number of cases involving each technology. The case-weighted average cost for these technologies is $19,845.52. For FY 2025, the maximum new technology add-on payment for a case involving the use of ELREXFIO, TALVEY, or TECVAYLI is $12,899.59.

e. FloPatch FP120

Flosonics Medical submitted an application for FloPatch FP120, a wireless, wearable continuous wave Doppler ultrasound device that adheres over peripheral blood vessels and assesses blood flow. The applicant stated that FloPatch FP120 will optimize clinical workflow.
The online application posting is available at https://mearis.cms.gov/public/publications/mtap/NTP231017D56F4.

Newness. The applicant stated that FloPatch FP120 received 510(k) clearance from the FDA on May 3, 2023 for use for the noninvasive assessment of blood flow in the carotid artery. The applicant also indicated a more recent 510(k) submission included a proposed indication for use in peripheral vessels. In the proposed rule, CMS stated that because documentation of FDA acceptance or filing of the marketing authorization request indicating that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA was not provided with the application, FloPatch FP120 is only eligible for the noninvasive assessment of blood flow in the carotid artery.

CMS discussed three prior FDA 510(k) clearances for the FloPatch FP120, with the same indication for use for the noninvasive assessment of blood flow in the carotid artery. CMS noted the 2020 clearance was based on substantial equivalence to the FloPatch FP110 device.
In addition, the applicant stated that FloPatch FP120 was commercially available on January 1, 2023, before FDA clearance, and CMS requested additional information on the market availability date for the device.

The applicant submitted a request for a unique ICD-10-PCS procedure code for FloPatch FP120. The online posting provides a complete list of ICD-10-CM codes provided by the applicant.
As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant asserted that FloPatch 120 is not substantially similar to other currently available technologies because it offers real-time, non-invasive monitoring of hemodynamic changes of both arterial and venous blood flow, improving fluid decisions. The applicant does not believe the technology is assigned to the same MS-DRGs as existing technologies and does

not involve treatment of the same/similar disease or same/similar patients as existing technologies.

CMS was concerned that all of the FloPatch FDA-cleared devices, as well as the FP110 version, have an identical mechanism of action and have the same indications for use. CMS questioned if the device constitutes a difference mechanism of action because it is Doppler ultrasound technology. CMS also believed the device would be assigned to the same MS-DRGs as those involving existing technologies used for measurement of blood flow and involves treatment of the same or similar type of disease or patient population when compared to existing technologies.

CMS states that it appears that the May 3, 2023 FDA 510(k) clearance and prior FDA 510(k) clearances for FloPatch FP120 may be substantial similar to each other. Under this assumption, CMS believed the newness period for this technology would begin on March 24, 2020, the earliest FDA 510(k) clearance date for FloPatch FP 120. Therefore the 3-year anniversary date of the technology onto the U.S. market occurred in FY 2023 (March 24, 2023) and the technology would no longer be considered new and would not be eligible for new technology add-on payments for FY 2025.
A commenter stated CMS should deny the application because the many previous FDA clearances place the technology outside the FY 2025 eligibility period and the technology is not new.

Based on the information submitted, **CMS concludes that FloPatch PF120 is not eligible for new technology add-on payments** because it does not meet the newness criteria because it meets all three of the substantial similarity criteria.

f. HEPZATO™ KIT (melphalan for injection/hepatic delivery system)

Delcath System submitted an application for HEPZATO™ KIT, a drug/device combination product consisting of melphalan and the Hepatic Delivery System (HDS) indicated as a liver-directed treatment for patients with uveal melanoma with unresectable hepatic metastases.
The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP2310160RLLX.

Newness. The applicant stated that HEPZATO KIT was granted approval as a New Drug Application (NDA) from FDA on August 23, 2023, for liver-directed treatment in patients with uveal melanoma with unresectable hepatic metastases affecting less than 50 percent of the liver and no extrahepatic disease or extrahepatic disease limited to bone, lymph nodes, subcutaneous tissues, or lung that it amenable to resection or radiation. Because manufacturing did not begin until after FDA approval, the technology became available for sale on January 8, 2024. ICD-10-PCS code XW053T9 describes procedures involving the use of HEPZATO KIT. The online posting provides a complete list of ICD-10-CM codes provided by the applicant.

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated that HEPZATO KIT offers the first liver-directed treatment option for patients with liver-dominant metastatic ocular melanoma (mOM) who may be poor

candidates for liver resection and/or who may have difficulty tolerating systemic chemotherapy. CMS questioned whether reformatting the delivery mechanism for a drug represents a new mechanism of action for drug-device combination technologies.

The applicant submitted a comment explaining the unique mechanism of action for HEPZATO KIT. The applicant stated that the technology is the only FDA-approved product that saturates the entire liver with high-dose chemotherapy and allows complete treatment of liver metastases. In addition, melphalan was not approved by FDA to treat liver metastases from uveal melanoma until the approval of HEPZATO KIT.

Based on review of comments and the additional information provided by the applicant, CMS agrees that HEPZATO KIT has a unique mechanism of action because it is the only FDA-approved product that isolates the liver circulation and allows for a delivery of a high concentration of a chemotherapeutic agent to liver tumors while limiting systemic exposure. CMS concludes HEPZATO KIT meets the newness criterion and determines the newness period began on January 8, 2024 when HEPZATO KIT became available for sale.

In the proposed rule CMS also sought feedback about what factors it should consider when determining new technology add-on payments for technologies that may use a drug or device component that is no longer new in combination with a new drug or device component. The applicant stated that CMS should consider whether the combination either offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments or significantly improves clinical outcomes relative to available technologies. Another commenter stressed the need to include substantial clinical improvement as part of the newness criterion. The commenter also stated that the mechanism of action should be evaluated for the treatment provided by the drug-device combination, as a whole. Additionally, the commenter stated that if the drug device combination provides meaningful treatment to the same patients treated with existing drug or device components that is not new, but the combination provides a new treatment option for patients that do not respond well to the existing treatment options, it should not be considered substantially similar to existing treatments.

In response to comments, CMS states it will continue to consider issues related to the mechanism of action for technologies involving a drug-device combination. It does not however believe it should evaluate clinical improvement when assessing the newness criterion.

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

Substantial Clinical Improvement. The applicant stated that HEPZATO KIT represents a substantial clinical improvement over existing technologies because it offers a minimally invasive, targeted, effective and safe treatment options for a subset of patients with liver-dominant mOM. The applicant provided 11 studies and one background article. A table in the final rule summarizes the applicant's assertions.

In the proposed rule, CMS discussed concerns with the information provided that included seven peer-reviewed cohort studies, summary material from an unpublished study, and one randomized

controlled clinical study. CMS noted that the cohort studies provide a range of overall survival from 9.6 months to 27.4 months and it believed that additional information comparing HEPZATO KIT to currently available treatments would be helpful. CMS also noted that several of the studies were small, non-randomized studies without comparators or controls. CMS discussed the results from presentation material but stated it is unable to verify the methods, results, and conclusions because of inadequate information provided. CMS was interested in additional evidence supporting the assertion that HEPZATO KIT substantially improves survival over other treatments.

CMS discusses the applicant's responses to CMS's concerns. The applicant asserted that HEPZATO KIT is the only FDA-approved therapy for the approximately 55 percent of patients with mOM who are not eligible for KIMMTRAK or whose disease has progressed despite using other therapies. The applicant provided additional information about the studies provided in the application and provided additional evidence about survival of patients treated with HEPZATO KIT. CMS notes it received several additional comments in support of the application and one comment that did not support approval of HEPZATO KIT.

Based on review of the information submitted, CMS concludes that HEPZATO KIT offers a substantial clinical improvement for adult patients with uveal melanoma with unresectable hepatic metastasis who are ineligible for existing therapies because they may be poor candidates for liver resection or who may have difficulty tolerating systemic chemotherapy and are HLA-A*02:01-negative and therefore ineligible for KIMMTRAK.

CMS **finalizes that HEPZATO KIT meets all three criteria for new technology add-on payments** and approves add-on payments for FY 2025. Cases involving the use of this technology will be identified by XW053T9. Based on information provided by the applicant, the estimated cost per patient is $182,500 per inpatient stay. For FY 2025, the maximum new technology add-on payment for a case involving HEPZATO KIT is $118,625.

g. Lantidra™ (donislecel-jujn (allogenic pancreatic islet cellular suspension for hepatic portal vein infusion))

CellTrans submitted an application for Lantidra™, an allogeneic pancreatic islet cellular therapy, used with concomitant immunosuppression therapy, for treatment of adults with Type 1 diabetes with repeated episodes of severe hypoglycemia despite intensive management. The applicant stated that the primary mechanism of action is the secretion of insulin by the beta cells within the infused allogeneic islet of Langerhans cells, the cells responsible for regulating blood glucose levels.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP231017H5N2T.

Newness. According to the applicant, Lantidra was granted approval for a BLA from FDA on June 28, 2023 for treatment of adults with Type 1 diabetes (T1D) who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. The technology was not commercially available until

January 8, 2024. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code.

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated that Lantidra uses the same mechanism of action as solid pancreas transplant but the procedure to infuse Lantidra is distinct and would be assigned to a different MS-DRG as the existing treatment.

CMS noted that under national coverage determination (NCD) 260.3.1 Islet Cell Transplantation in the Context of a Clinical Trial, Medicare will pay for the routine costs as well as the transplantation and appropriate related services, for beneficiaries participating in an NIH-sponsored clinical trial. Coverage may include the costs of the acquisition and delivery of the pancreatic islet cells. CMS stated that because Lantidra may be covered by Medicare when used in the setting of a clinical trial, it will evaluate whether Lantidra is eligible for a new technology add-on payment for FY 2025. CMS noted that any payment would be contingent on CMS' coverage of the item and any restrictions on the coverage would apply.

The applicant submitted a comment clarifying that Lantidra treats a new patient population because it addresses an unmet need for patients with hard-to-control T1D complicated by severe hypoglycemia who cannot receive a whole pancreas transplant due to medical or surgical risk. CMS notes there are other technologies for patients with hard-to-control T1D, including continuous glucose monitors and automated insulin delivery systems. CMS does not agree that Lantidra meets an unmet need. CMS does agree, however, that the underlying mechanism of action of Lantidra is similar to whole pancreas transplant and is different from continuous glucose monitors and automated insulin delivery systems.

CMS concludes that Lantidra has a unique mechanism of action when compared to existing insulin delivery therapies and technologies and meets the newness criterion. CMS considers the beginning of the newness period as January 8, 2024, when Lantidra became commercially available.

Cost. In the proposed rule, CMS noted that the cost analysis only included MS-DRG 639 (Diabetes without CC/MCC) and was interested in information as to whether cases in other MS-DRGs would be potentially eligible for Lantidra and included in the cost analysis. CMS also raises other concerns about charges related to prior technology and the inflation factor of 10.00 percent applied to the standardized charges.

CMS summarizes the updated cost analysis provided by the applicant. CMS concludes Lantidra meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that Lantidra represents a substantial clinical improvement because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. The applicant asserted that pancreas transplant is associated with greater surgical and post-procedural risk than pancreatic islet transplantation. The applicant provided two patient testimonials, one study combining results of

a Phase 1/2 study and a Phase 3 clinical study to support these claims, and one background article. A table in the proposed rule summarizes the applicant's assertions.

In the proposed rule, CMS discussed concerns with the information provided and requested information on clinical outcomes based on comparison of Lantidra with currently available treatments, including whole pancreatic transplant or FDA-approved glucose monitoring and insulin delivery systems. CMS was concerned about the small number of patients evaluated at year 6 and noted that although the applicant states the trials had over 10 years of extended follow-up, the specific results on long-term efficacy appear to be up to 6 years post the last transplant. CMS was also interested in data demonstrating that Lantidra improves clinical outcomes including reduced mortality.

CMS discusses the additional information provided by the applicant in response to CMS' concerns. Another commenter also supported the application and cited unpublished results from a NIH-funded Phase 3 safety and efficacy study for islet cell transplantation as evidence to support clinical outcomes of islet cell transplantation.

CMS continues to have concerns as to whether Lantidra meets the substantial clinical improvement criterion. CMS states it is not clear from the additional evidence provided that patients eligible for treatment with Lantidra could not be appropriately managed with available diabetes management systems. CMS is also concerned that the evidence does not demonstrate that Lantidra improves clinical outcomes as compared to current technologies.

Based on the information submitted, CMS concludes it is unable to determine that Lantidra represents a substantial clinical improvement for existing technologies. For FY 2025, **CMS does not approve new technology add-on payments for Lantidra**.

h. AMTAGVI™ (lifileucel)

Iovance Biotherapeutics submitted an application for AMTAGVI, a one-time, autologous tumor-infiltrating lymphocyte (TIL) immunotherapy for treatment of patients with unresectable or metastatic melanoma. TIL therapy involves the adoptive cell transfer of autologous T-cells directly isolated from the tumor tissue and expanded *ex vivo* without any prior selection or genetic modification. Tumor antigen-specific T-cells are located within tumor lesions, where a dysfunctional state and low numbers prevent them from effectively eradicating the tumor. By isolating autologous TIL from the tumor microenvironment and expanding them, the manufacturing process produces large numbers of reinvigorated T-cells. Following the infusion of AMTAGVI, the TILs migrate back into the tumor, including metastases, where they trigger specific tumor cell killing upon recognition of tumor antigens. CMS notes the applicant submitted prior applications for FY 2022 and FY 2023 and the applications were drawn prior to the issuance of the respective final rules.[34]

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP231012V8Y9J.

[34] 86 FR 25272 through 25282 and 87 FR 28244 through 28257

Newness. The applicant stated that AMTAGVI was granted BLA approval from FDA on February 16, 2024 for treatment of adult patients with unresectable or metastatic melanoma previously treated with a programmed cell death protein 1 (PD-1) blocking antibody, and if B-raf proto-oncogene (BRAF) V600 mutation positive, a BRAF inhibitor with or without a mitogen-activated extracellular signal-regulated kinase (MEK) inhibitor. The applicant stated that AMTAGVI has been granted Regenerative Medicine Advanced Therapy (RMAT), Orphan Drug and Fast Track designations. The applicants expects AMTAGAVI to be commercially available 30-45 days after FDA approval due to the various requirements related to developing the treatment, including resection of the tumor and the TIL manufacturing process. CMS was interested in additional information about the delay in the technology's market availability. Two unique ICD-10-PCS codes identify the administration of AMTAGVI (XW033L7 and XW043L7).

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated AMTAGVI uses a novel and distinct mechanism of action which delivers a highly customized, personalized, and targeted treatment for unresectable or metastatic melanoma. The applicant stated that AMTAGVI is the first and only TIL immunotherapy approved for the treatment of advanced (unresectable or metastatic) melanoma. The applicant discussed the difference between this therapy and current treatments, including CAR T-cell therapies. For the second criterion (same or different MS-DRG), the applicant stated that cases would be assigned to Pre-MDC MS-DRG 018 (CAR T-cell and Other Immunotherapies). For the third criterion (same or similar disease or patient population), the applicant stated that upon FDA approval, AMTAGVI will be the first and only cell therapy indicated for this patients with unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy.

The applicant provided additional information about the technology's market availability. AMTAGVI was immediately available for providers to order after FDA approval on February 16, 2024 but initially it took 34 days for turnaround time. The first AMTAGVI shipment to a treatment center was March 28, 2024 and the first patient was treated on April 4, 2024. The applicant requested April 4, 2024 as the start of the newness period.

CMS concludes that AMTAGVI meets the newness criterion. CMS considers the newness period to begin on the date AMTAGVI was available for sale, which was February 16, 2024, the day it was granted BLA approval from FDA.

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

Substantial Clinical Improvement. The applicant stated that AMTAGVI represents a substantial clinical improvement because the efficacy and safety profile of the treatment provides a treatment option for patients with advance melanoma who lack effective or approved treatment options after being treated with immune checkpoint inhibitors (ICI) treatment. The applicant also asserted that AMTAGVI also improves clinical outcomes over published outcomes for chemotherapy. The applicant provided four studies and 22 background articles. A table in the proposed rule summarizes the applicant's assertions.

In the proposed rule, CMS discussed concerns about the information provided and noted that these are similar to concerns previously raised. CMS remained concerned about the methodology used to assess the efficacy and safety in the C-144-01 study and the use of a surrogate endpoint which combines the results of complete and partial responders. CMS was also concerned that the study population was not representative of the Medicare population. CMS was interested in additional information comparing AMTAGVI to existing treatments. CMS was also concerned that it is not clear how the impact of high-dose IL-2, which has been used to treat metastatic melanoma and is given as a post-treatment to AMTAGVI, impact the treatment effects and adverse effects reported for AMTAGVI.
CMS discusses the comments provided by the applicant to respond to its concerns. CMS is still concerned that the evidence does not demonstrate that the use of AMTAGVI significantly improves clinical outcomes over existing treatments and whether AMTAGVI TIL immunotherapy offers a treatment option for a patient population unresponsive to, or ineligible for, current treatments. CMS is also concerned that there is no comparison of AMTAGVI to other FDA approved treatments for unresectable or malignant melanoma. CMS acknowledges that the therapy was approved under FDA's accelerated approval pathway for oncology and hematology uses, but reiterates that it does not rely on FDA criteria in its evaluation of substantial clinical improvement for new technology add-on payments. CMS remains concerned that the study population lacks the disease burden that includes the comorbidities generally found in the Medicare population and that the study results can be generalized to the Medicare population.

Based on the information submitted, CMS concludes it is unable to determine that AMTAGVI represents a substantial clinical improvement for existing technologies. For FY 2025, **CMS does not approve new technology add-on payments for AMTAGVI.**

i. LYFGENIA™ (lovotibeglogene autotemecel)

Bluebird bio submitted an application for Lyfgenia, an autologous hematopoietic stem cell-based gene therapy for patients with SCD and a history of vaso-occlusive events (VOE). LYFGENIA consists of an autologous cluster of CD34+ cells from patients with SCD that contains hematopoietic stem cells (HSC) transduced with BB305 lentiviral vector (LVV) encoding the ß-globulin gene ($ß^{A\text{-}787Q\text{-}globin\ gene}$). The applicant explained that Lyfgenia adds functional copies of a modified form of the ß-globulin gene into a patient's HSC, which allows their red blood cells to produce an anti-sickling adult hemoglobin (HbA^{787Q}) to reduce or eliminate downstream complications of SCD.

The online application posting for Lyfgenia is available at https://mearis.cms.gov/public/publications/ntap/NTP231013X3AK8

Newness. Lyfgenia was granted BLA approval from FDA on December 8, 2023 for the treatment of patients 12 years of age or older with SCD and a history of VOEs. The application anticipates that Lyfgenia will become available on April 16, 2024; CMS was interested in additional information regarding the delay. There are two ICD-9-PCS procedure codes to identify the intravenous administration of Lyfgenia (XW133H9 and XW143H9). The online application posting contains the complete list of ICD-10-CM codes.

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated Lyfgenia has a distinct mechanism of action which converts SCD at the genetic, cellular, and physiologic level to a non-sickling phenotype through the expression of the gene therapy-derived antisickling ß-globulin gene. The applicant stated that Lyfgenia is not substantially similar to other currently available therapies indicated for SCD or to any drug therapy assigned to any MS-DRG.

As previously discussed above, in the proposed rule, CMS believed that Lyfgenia may have the same or similar mechanism of action as Casgevy. CMS discusses comments it received from the manufacturer of Casgevy and the manufacturer of Lyfgenia explaining the unique mechanism of action of each treatment. Based on this additional information, CMS agrees that Casgevy and Lyfgenia do not have the same mechanism of action. CMS states that Casgecy modifies a patients' own HSPCs to increase HbF expression to subsequently reduce the expression of intracellular sickled hemoglobin concentration. In contrast, Lyfgenia modifies a patients' own HSPCs to increase^{T87Q} (modified adult hemoglobin).
CMS concludes that Lyfgenia meets the newness criterion. Absent additional information, CMS considers the beginning of the newness period as December 8, 2023, when Lyfgenia was granted BLA approval from the FDA for the treatment of patients 12 years of age or older with SCD and a history of VOEs.

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

Substantial Clinical Improvement. The applicant stated that Lyfgenia is a substantial clinical improvement because it is a one-time administration that uniquely impacts the pathophysiology of SCD at the genetic level and offers the potential for stable, durable production of anti-sickling hemoglobin HbA ^{787} resulting in complete resolution of severe VOEs in patients with SCD. The treatment is an important option for patient's ineligible for allo-HSCT or without a matched related donor and significantly improves health-related quality of life. The applicant provided seven studies and 22 background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

In the proposed rule, CMS was concerned the information provided did not support the applicant's claim that Lyfgenia presents an acceptable risk-benefit profile for patients with SCD while allowing clinically meaningful improvements in quality of life. CMS requested additional information regarding the risk-benefit profile of Lyfgenia compared to existing therapies, including clarification about what is an acceptable risk-benefit profile for patients with SCD. CMS was also concerned that the safety and efficacy information based on 34 patients being evaluated for efficacy and 47 patients for safety (median age 23 years) is generalizable to the Medicare population.

CMS summarizes the applicant's response to CMS' concerns. Based on its review of all the information, CMS concludes that Lyfgenia represents a substantial clinical improvement over existing technologies because it offers a treatment option for certain patients with SCD who

experience recurrent VOEs and who have not been able to achieve adequate control with existing treatments and are ineligible for allo-HSCT due to a lack of a matched donor or other reasons. CMS finalizes that **Lyfgenia meets all three criteria for new technology add-on payments** and approves add-on payments for FY 2025. Cases involving the use of Lyfgenia will be identified by the two ICD-10-PCS codes for transfusion of lovotibeglogene autotecel. Based on information provided by the applicant, the estimated cost per patient is $3,100,000. As discussed below (section E.10), for FY 2025 CMS is revising the maximum new technology add-on payment percentage to 75 percent for a medical product that is a gene therapy indicated for the treatment of SCD. For FY 2025, the maximum new technology add-on payment for a case involving Lyfgenia is $2,325,000.

j. Quicktome Software Suite (Quicktome Neurological Visualization and Planning Tool)

Omniscient Neurotechnology submitted an application for Quicktome Software Suite, a cloud-based software that uses artificial intelligence (AI) tools and the scientific field of connectomics (understanding how individual neurons are connected to one another to form functional networks) to analyze millions of data points derived from a patients MRI. The applicant asserted that the technology using resting-state functional MRI (rs-fMRI) to see the brain's network architecture or functional connectome by mapping blood oxygen level depend (BOLD) signals across brain parcels. This information allows clinicians to quickly and accurately access the functional connectivity and structural layout of a patient's brain.
The online application posting for Quicktome Software Suite is available at https://mearis.cms.gov/public/publications/ntap/NTP23101722NQE.

Newness. The applicant stated the Quicktome Software Suite received FDA 510(k) clearance on May 30, 2023. The Quicktome Software is composed of a set of modules intended for the display of medical images and other health care data. The FDA clearance was based on substantial equivalence to the legally market predicate device, StealthViz Advanced Planning Application with Steath Diffusion Tensor Imaging (DTI)™ Package. In addition, the technology, under the trade name Quicktome, received FDA 510(k) clearance on March 9, 2021 based on substantial equivalence to StealthViz. StealthViz received FDA 510(k) clearance on May 16, 2008 for use in two and three-dimensional surgical planning and image review and analysis.

The applicant submitted a request for approval for a unique ICD-10-PCS procedure code and was granted approval for the 00K0XZ1 effective October 1, 2024. The online application posting contains the complete list of ICD-10-CM codes.

As summarized in a table in the final rule, for the first criterion (same or similar mechanism of action), the applicant stated that Quicktome Software Suite is the first and only FDA-cleared platform to enable connectomic analysis an individual level using learning and tractographic techniques to create personalized maps of the human brain and is also the first cleared neurological planning tool to offer rs-fMRI capabilities.

CMS was concerned that according to the 510(k) application, the Quicktome Software Suite may be equivalent to StealthViz, its predicate device. CMS was interested in additional information to support that The Quicktome Software Suite does not use the same or similar mechanism of action as StealthViz to achieve a therapeutic outcome, including information about capabilities

of Quicktome Software Suite that are not found in StealthViz and how these capabilities are the result of a new mechanism of action.

In the proposed rule, CMS also noted there are several existing FDA-approved or cleared technologies that analyze fMRI and other medical imaging data to create 3-D maps of a patient's brain and questions whether other FDA-cleared neurosurgical planning and visualization technologies integrate rs-fMRI. CMS was interested in more information on the relevant current standard of care and technologies utilized for neurosurgical planning and how the mechanism of action of the Quicktome Software Suite compares to existing technology.

CMS also observed that the applicant stated that the Quicktome Software Suite does not treat a new disease type or patient population, but does provide new information for the treatment of existing populations. CMS stated that the provision of new information for the treatment of existing patient populations does not mean that the technology treats a new disease type or patient population. CMS was interested in information to support whether and how Quicktome Software Suite may involve the treatment of a different type of disease or patient population. CMS received a few comments describing the mechanism of action for Quicktome Software Suite and how it is different from StealthViz. Commenters stated that unlike conventional methods, Quicktome Software Suite leverages AI algorithms to analyze complex structural and functional brain data that enable the creation of comprehensive brain network maps. The commenters also stated that the unique processing of rs-fMRI underscores Quicktome Software Suite's potential to revolutionize neurosurgical planning and improve patient outcomes for all Medicare patients.

In response, CMS states it remains concerned that the technology is not different from the mechanism of action of existing technologies that analyze medical imaging data to create 3D maps of a patient's brain. CMS agrees with commenters that Medicare patients who suffer from cognitive or motor impairments and cannot cooperate with task-based protocols would represent a patient population that could not utilize existing technologies for neurologic planning. CMS concludes that Quicktome Software Suite does not treat the same or similar type of disease and patient population as existing technologies.

CMS believes that Quicktome Software Suite meets the newness criterion. The beginning of the newness period will be May 30, 2023, when Quicktome Software Suite received FDA market authorization.

In the proposed rule, CMS sought feedback on how to determine newness for technologies that use AI. A commenter stated that AI, algorithm, or software do not represent the mechanism of action and are components of a technology, not the technology itself. The commenter stated these technologies should be evaluated for newness the same way as CMS evaluates any other medical device. Another commenter thought CMS should establish an alternative pathway for high-value AI technology. CMS appreciates these comments and welcomes additional comments as it continues to determine newness and mechanism of action for these technologies.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS noted that the cost analysis is limited to MS-DRGs for brain tumor resection (MS-DRGs 025-027) and is interested in whether the technology would map to other MS-DRGs.

In addition, CMS questions if every case within the MS-DRGs would be eligible for the technology.

CMS did not receive any comments on the cost analysis. CMS concludes that Quicktome Software Suite meets the cost criterion.

Substantial Clinical Improvement. The applicant asserted that Quicktome Software Suite is a substantial clinical improvement because it supports the visualization and brain mapping that improves clinical outcomes and reduces the risk of unplanned readmissions for craniotomy patients by reducing new postoperative neurological deficits that are caused by damage to brain networks. The applicant submitted three published studies, one unpublished study and four background articles; CMS noted that one of the articles submitted as a study using the technology does not directly assess the use of Quicktome Software Suite and should be considered a background article. A table in the final rule summarizes the applicant's assertions. In the proposed rule, CMS discussed concerns with the information provided. CMS did not believe that the information provided supports the applicant's claim that the Quicktome Software Suite improves clinical outcomes relative to services or technologies already available by avoiding or reducing damage to the brain networks during surgery. CMS was interested in additional information demonstrating the direct impact of using the Quicktome Software Suite on reducing neurological or cognitive deficits post-surgery. CMS also questioned whether the findings are generalizable to the Medicare population.

A few commenters discussed their experiences using Quicktome Software Suite and how it provides a substantial clinical improvement over existing technologies. CMS continues to have concerns as to whether this technology demonstrates substantial clinical improvement and questions whether Quicktome Software Suite improves clinical outcomes. Although commenters stated they have noted improved clinical outcomes with this technology they did not provide any evidence.

Based on the information submitted, CMS concludes it is unable to determine that Quicktome Software Suite represents a substantial clinical improvement for existing technologies. For FY 2025, **CMS does not approve new technology add-on payments for Quicktome Software Suite.**

7. FY 2025 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.
In the FY 2024 IPPS final rule, CMS finalized that beginning with new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of the application submission, and must provide documentation of the FDA acceptance or filing to CMS when the application is submitted.[35] CMS also finalized that beginning with FY 2025 applications, an applicant must have received approval or clearance by May 1 instead of July 1

[35] 88 FR 58948 through 58958

of the year prior to the beginning of the fiscal year for which the application is being considered. Applications submitted under the alternative pathway for certain antimicrobial products are excluded from date change.

CMS received 23 applications for new technology add-on payments under the alternative pathway. Seven applications were not eligible for consideration because they did not meet the requirements and two applicants withdrew their applications (including DefenCath which had received conditional approval and subsequently received FDA approval in November 2023 and was eligible for new technology add-on payments beginning with discharges on or after January 1, 2024). Prior to the issuance of this final rule, three additional applicants withdrew their respective applications for restor3d TIDAL™ Fusion Cage, Transdermal GFR Measurement System utilizing Lumitrace, and cefepime-taniborbactam.

Of the remaining 11 applications, CMS approves 12 new technology add-on payments for FY 2025. CMS approves two separate new technology add-on payments for ZEVTERA™. Ten of the technologies received a Breakthrough Device designation from FDA and one application was designated as a QIDP. There were no applications for technologies approved through the LPAD pathway from FDA.

For the Breakthrough Devices Program, the new technology add-on payment is the less of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case. For QIDPs and LPADs, the new the new technology add-on payment is the less of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS-DRG payment for the case.

In addition, the publicly posted FY 2025 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 final 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.[36]

a. Annalise Enterprise Computed Tomography Brain (CBT) Triage – Obstructive Hydrocephalus (OH)

Annalise-Ai Pty submitted an application for the Annalise Enterprise CTB Triage-OH, a medical device software application used to aid in the triage and prioritization of studies with features suggestive of OH. The device analyzes studies using an AI algorithm to identify suspected OH findings in non-contrast computed tomography (NCCT) brain scans and makes study-level output available to an order and imaging management system for worklist prioritization or triage. The online application posting is available at https://mearis.cms.gov/public/publciations/ntap/NTP231017D5AA7.

[36] 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.

The applicant indicates the technology received Breakthrough Device designation on February 17, 2023 for use in the medical care environment to aid in triage and prioritization of studies with features suggestive of OH. The device became commercially available on October 10, 2023. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code and was granted approval for XXE0X1A, effective October 1, 2024. The online posting provides a complete list of ICD-10-CM codes.

In the proposed rule, CMS summarized the analysis provided to demonstrate the technology meets the cost criterion. CMS was concerned that the diagnosis codes used by the applicant to identify eligible cases included non-neurologic diagnosis codes and whether using only neurologic diagnosis codes would more accurately identify eligible cases.

In response to CMS' concern, the applicant stated it intentionally included cases with non-neurological diagnosis codes to reflect patients who may have received the test based on presenting symptoms in the Emergency Department. The applicant believed that removing cases would undercount the inpatient stays and underestimate potential volume. The applicant conducted an additional sensitivity analysis by removing the non-neurological cases and determined the technology meets the cost criterion.

The applicant anticipates the total cost of the Annalise Enterprise CTB Triage – OH to the hospital to be $371.37 per patient. The applicant noted that given the limited experience with the technology, it used all IPPS hospitals to calculate cost per case instead of limiting the analysis to current subscribers. With time, the applicant indicated that it may make sense to limit the cost per case analysis to hospitals that are current subscribers.

CMS **approves the Annalise Enterprise CTB Triage – OH** for new technology add-on payments for FY 2025. The newness period will begin October 10, 2023, the date the technology became commercially available for the Breakthrough Device designation. For FY 2025, the maximum new technology add-on payment for a case involving the use of the technology will be $241.39. Cases involving the technology will be identified by ICD-10-PCS XXE0X1A.

b. ASTar® System

Q-linea submitted an application for the ASTar System, a fully automated system for rapid antimicrobial susceptibility testing (AST). The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP231013T7Y5F.

The applicant stated that the ASTar System consists of the ASTar Instrument and the ASTar BC G- Kit. The ASTar BC G- Kit is a multiplexed, *in vitro*, diagnostic test used on positive blood cultures confirmed positive by only gram stain for gram-negative bacilli and tests antimicrobial agents with nonfastidious and fastidious bacterial species. The technology received a Breakthrough Device designation from the FDA on April 7, 2022 and the applicant received FDA 510(k) clearance on April 26, 2024. The applicant submitted a request for an ICD-10-PCS code for the technology and procedure code XXE5X2A will be effective October 1, 2025. The online posting provides a complete list of ICD-10-CM codes.

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

CMS **approves the ASTar System** for new technology add-on payments for FY 2025. The newness period will begin on April 26, 2024, the date of FDA clearance. The applicant anticipates the operating cost of the system to be $150 per patient, based on the operating component cost for the ASTar BC G- Kit. The applicant did not include the capital costs for the ASTar Instrument. For FY 2025, the maximum new technology add-on payment for a case involving the use of the technology will be $97.50. Cases involving the technology will be identified by ICD-10-PCS XXE5X2A.

c. Edwards EVOQUE™ Tricuspid Valve Replacement System (Transcatheter Tricuspid Valve Replacement System)

Edwards Lifesciences submitted an application for the EVOGUE Tricuspid Valve Replacement System (EVOQUE System), a transcatheter treatment option for patients with at least severe tricuspid regurgitation. The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP231013MRRBG.

The EVOGUE System received Breakthrough Device designation from FDA on December 18, 2019 for the treatment of patients with symptomatic moderate or above tricuspid regurgitation. The applicant stated the technology received FDA approval on February 1, 2024 for a narrower indication for use; it is indicated for the improvement of health status in patients with symptomatic severe tricuspid regurgitation despite optimal medical therapy, for whom tricuspid valve replacement is deemed appropriate by the heart team. CMS agrees with the applicant that this indication is within the scope of the Breakthrough Device designation. The applicated submitted a request for a unique ICD-10-PCS code and was granted approval for X2RJ3RA, effective October 1, 2025. The ICD-10-CM codes 107.1 (Rheumatic tricuspid insufficiency), 107.2 (Rheumatic tricuspid stenosis and insufficiency), 136.1 (Nonrheumatic tricuspid insufficiency), and 136.2 (Nonrheumatic tricuspid stenosis with insufficiency) may be used to identify cases.

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

CMS **approves the EVOQUE System** for new technology add-on payments for FY 2025. The newness period will begin on February 1, 2024, the date the technology received its FDA marketing authorization for the indication covered by its Breakthrough Device designation. The applicant stated the total cost of the system will be $49,000 per patient. For 2025, the maximum new technology add-on payment for a case involving the EVOQUE system will be $31,850. Cases will be identified by ICD-10-PCS code X2RJ3RA.

d. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)

W.L. Gore & Associates submitted an application for the TAMBE Device, used for endovascular repair in patients with pararenal abdominal aortic aneurysms (PAAA) who have appropriate

anatomy. The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP231016DYQQX.

The TAMBE Device received Breakthrough Device designation from FDA on October 1, 2021, for endovascular repair of thoracoabdominal (TAAA) and pararenal aneurysms in the aorta in patients who have appropriate anatomy. The applicant stated the TAMBE Device received premarket approval (PMA) from FDA on January 12, 2024 for a slightly narrower indication – for TAAA and high-risk surgical patients with PAAA who have appropriate anatomy. CMS agrees with the applicant that this indication is within the scope of the Breakthrough Device designation. The applicant stated that the TAMBE Device isn't available for sale due to the required lead time to train physicians on the device and the first commercial device will only be implanted May1, 2024 or later. The applicated submitted a request for a unique ICD-10-PCS code. The ICD-10-CM codes are listed in the online application posting.

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

CMS proposed to approve the TAMBE Device for new technology add-on payments for FY 2025.

In a public comment, the applicant reiterated it anticipated the device would be available for sale in early May 2024 and that the first implant was conducted on May 10, 2024 by the leading clinical investigator. The technology became commercially available on May 10, 2024 to U.S. physicians who had completed the necessary training; the FDA-approved Instructions for Use requires the TAMBE device should only be used by physicians who have completed the training. CMS responds that it is unclear from the information provided when the technology first became available in the U.S. market.

CMS **finalizes approval of the TAMBE Device** of new technology add-on payments for FY 2025. The newness period will begin on January 12, 2024, the date the technology received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated the TAMBE Device has a number of required components and the actual type and number of components used varies by the patient's anatomy and the extent of the aneurysm. The applicant determined the number and types of components that were used in an average patient based on a multicenter pivotal clinical trial and calculated the case cost per component; the total cost per case is $72, 675. For FY 2025, the maximum new technology add-on payment for a case involving the TAMBE Device is $47,238.75. Devices eligible for new technology add-on payment will be identified by ICD-10-PCS code X2VESA.

e. LimFlow™ System

LimFlow submitted an application for the LimFlow System, a single-use medical device intended for patients with no-option chronic limb-threatening ischemia (CLTI) of the lower extremities who are at risk of major amputation.[37] The online application is available at

[37] The applicant submitted an application for a FY 2024 new technology add-on payment but the LimFlow System did not meet the applicable deadline of July 1, 2023 for FDA approval (88 FR 58919).

https://mearis.cms.gov/public/publications/ntap/NTP23101627LSC.

The LimFlow system received Breakthrough Device designation on October 3, 2017 for use in patient with CLTI with no suitable endovascular or surgical revascularization options and are at risk of major amputation. The applicant stated the technology was granted PMA from FDA on September 11, 2023 for patients who have chronic limb-threatening ischemia with no suitable endovascular or surgical revascularization options and are at risk of major amputation. The applicant stated that the technology became commercially available on November 1, 2023; time was needed to develop inventory and ramp up for commercial sales. The list of ICD-10-PCS codes and ICD-10-CM codes are available on the online posting.

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

CMS **approves the LimFlow System** for new technology add-on payments for FY 2025. The newness period will begin on November 1, 2023, the date the technology became commercially available for the indication covered by its Breakthrough Device designation. The applicant anticipated the total cost to the hospital to be $25,000 per patient. For FY 2025, the maximum new technology add-on payment for a case involving the LimFlow System will be $16,250. The final rule includes a list of the eight ICD-10-PCS codes that will identify cases eligible for the add-on payment.

f. Paradise™ Ultrasound Renal Denervation System

ReCor Medical submitted an application for the Paradise Ultrasound Renal Denervation System, an endovascular catheter-based system that delivers SonoWave 360 ultrasound energy circumferentially, thermally ablating and disrupting overactive renal sympathetic nerves. This treatment lowers blood pressure in patients 22 years of age or older who may be inadequately responsive to or intolerant to anti-hypertensive medications. The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP23101722HBQ.

The Paradise Ultrasound Renal Denervation System received Breakthrough Device designation from FDA on December 4, 2020 for reducing blood pressure in adults 22 years of age or older with uncontrolled hypertension, who may be inadequately responsive to, or intolerant to anti-hypertensive medications. The applicant received FDA PMA for the technology on November 7, 2023 for reducing blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. The applicant stated that ICD-10-PCS code X051329 uniquely describes procedures using the technology. The applicant indicated the following ICD-10-CM related hypertension codes may be used to identify cases: 110, 115.1,115.8,115.9, and 11A.0.

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

CMS **approves the Paradise Ultrasound Renal Denervation System** for new technology add-on payments for FY 2025. The newness period will begin on November 7, 2023, the date the technology received FDA marketing authorization for the indication covered by its Breakthrough

Device designation. The applicant indicated the cost per case of the technology is $23,000 per patient. For FY 2025, the maximum new technology add-on payment for a case involving the technology will be $14,950. Cases involving the use of the technology will be identified by the ICD-10-PCS code X051329.

g. PulseSelect™ Pulse Field Ablation (PFA) Loop Catheter

Medtronic submitted an application for the PulseSelect PFA Loop Catheter, a technology used to perform pulmonary vein isolation in cardiac catheter ablation to treat atrial fibrillation. The applicant states that PulseSelect uses non-thermal irreversible electroporation to induce cell death in cardiac tissue at the target site. The applicant noted that the PulseSelect PFA System consists of two primary elements: the PMA Loop Catheter and the Generator system but the Generator system is capital equipment and not included in this application. The online application is available at https://mearis.cms.goc/public/publications/ntap/NTP231017BMQKQ.

The applicant stated the PulseSelect PFA System, which includes the PulseSelect PFA Loop Catheter, received Breakthrough Device designation from FDA on September 27, 2018 for the treatment of drug recurrent symptomatic atrial fibrillation. The applicant indicated the catheter is also intended to be used for cardiac electrophysiological (EP) mapping (stimulation and recording). The PulseSelect PFA System received PMA on December 13, 2023 for a slightly narrower indication – for cardiac EP mapping (stimulation and recording) and for treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation or persistent atrial fibrillation (episode duration < 1 year). Procedure code 02583ZF (Destruction of conduction mechanism using irreversible electroporation, percutaneous approach) describes the procedure. The list of ICD-10-CMS diagnosis codes that may be used to identify cases is available on the online application.

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

CMS proposed to approve the PulseSelect PFA Loop Catheter for new technology add-on payments for FY 2025. The applicant anticipated the total cost to the hospital would be $9,750 per patient for the PFA Loop Catheter and $800 per patient for the Catheter Interface Cable. CMS notes that the applicant included the interface cable as a component of the Generator Reusable Accessories and it does not believe this cost should be included in the calculation in the new technology add-on payment.

In a public comment, the applicant requested the cost of the PulseSelect PFA Catheter Interface Cable ($800) be included as an operating cost instead of a capital cost. The cable is a sterilized, one-tie use connector between the PulseSelect PFA Loop Catheter and the PulseSelect PFA Generator System. CMS states that the submitted application was for the PulseSelect PFA Loop Catheter and not for the PulseSelect PFA System. Since the PulseSelect PFA Interface Cable is not a component of the PulseSelect PFA Loop Catheter, CMS concludes the PulseSelect PFA Catheter Interface Cable is not eligible to be included in the new technology add-on payments. The applicant also requested clarity on how eligibility for the new technology add-on payment would be properly determined on hospital claims. The applicant discussed that under the

traditional policy a technology that is substantially similar to an existing technology approved for new technology add-on payment also qualifies for new technology add-on payment within the eligibility period, even if a specific application for that technology was not submitted (82 FR 38110). Under the alternative new technology add-on payment pathway for Breakthrough Devices, CMS considers devices that are part of the FDA's Breakthrough Device Program as not substantially similar to an existing technology (87 FR 48915). The applicant stated this establishes that Breakthrough Devices approved for new technology add-on payment under the alternative pathway cannot be considered substantially similar to any other technology. The applicant requested clarification on how a new technology add-on payment approved for Breakthrough Device as well as other devices (which may or may not have Breakthrough Device status) would be distinguished on hospital claims when the same ICD-10-PCS code could be used to describe procedures using devices that had not been approved under the alternative pathway for new technology add-on payment.

CMS acknowledges that under the alternative pathway, a medical device designated under the FDA's Breakthrough Devices Program that has received FDA marketing authorization will be considered not substantially similar to an existing technology and will not need to meet the substantially improvement criterion. However, CMS notes that procedure codes under the ICD-10-PCS are not manufacturer specific. If after consulting current official coding guidelines a hospital determines that an ICD-10-PCS code associated with a new technology add-on payment describes the technology used in the procedure, the hospital may report the code and may be eligible to receive the additional payment. CMS states an entity seeking coding guidance may contact the AHA's Central Office on ICD-10-CM systems for advice.[38]

CMS **approves the PulseSelect PFA Loop Catheter** for new technology add-on payments for FY 2025. The newness period will begin on December 13, 2023, the date the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. Based on the information provided in the application, the cost per case of the PulseSelect PFA Loop Catheter is $9,750 per inpatient stay. For FY 2025, the maximum new technology add-on payment for a case using this technology is $6,337.50. Cases that are eligible for add-on payments will be identified by ICD-10-PCS code 02583ZF.

i. Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter

Medtronic submitted an application for the Symplicity Spyral Multi-Electrode Renal Denervation Catheter for delivering targeted radiofrequency energy to the renal nerves which disrupts overactive sympathetic signaling between the kidneys and brain as a treatment for uncontrolled hypertension. The Symplicity Spyral™ Multi-Electrode Renal Denervation System includes the t Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter and the Symplicity G3 Generator. The online application is available at: https://mearis.cms.gov.public/publications/ntap/NTP2310161U617.

The Symplicity Spyral™ Multi-Electrode Renal Denervation System received Breakthrough Device designation from FDA on March 27, 2020 for the reduction of blood pressure in patients with uncontrolled hypertension despite the use of anti-hypertensive medications or in patients

[38] https://www.aha.org/websites/2017-12-17-aha-central-office

who may have documented intolerance to anti-hypertensive medications. The technology received PMA approval on November 17, 2023 for reducing blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure. The applicant submitted a request for a unique ICD-10-PCS code. The online application posting contains the complete list of ICD-10-CMS codes provided by the applicant.

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

CMS proposed to approve the Symplicity Spyral Multi-Electrode Renal Denervation Catheter for new technology add-on payments for FY 2025. The applicant did not provide an estimate for the cost of the technology; CMS expected the cost information prior to the final rule.

A commenter was concerned that the cost information was not provided in the proposed rule. The commenter acknowledged that there was precedent not to disclose cost information prior to FDA marketing authorization but given that the technology was immediately available after it received FDA marketing authorization on November 17, 2023, the commenter believed that the applicant could have provided this information prior to the December 18, 2023 deadline for submitting additional information for a new technology add-on payment application. CMS responds that it frequently does not have cost information on applications discussed in the proposed rule; it expects that the applicant will submit cost information prior to the final rule. CMS will continue to consider the commenter's concerns.

CMS **approves the Symplicity Spyral Multi-Electrode Renal Denervation Catheter** for new technology add-on payments for FY 2025. The newness period will begin on November 17, 2023, the date the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. Based on the information provided by the applicant, the cost per case of the PulseSelect PFA Loop Catheter is $16,000. For FY 2025, the maximum new technology add-on payment for a case using this technology is $10,400. Cases that are eligible for add-on payments will be identified by ICD-10-PCS code X05133A.

j. TriClip™ G4

Abbott submitted an application for the TriClip G4 intended for treatment of patients with symptomatic, severe tricuspid valve regurgitation, whose symptoms and tricuspid regurgitation (TR) persists despite medical therapy. The TriClip G4 System consists of the TriClip G4 Implant, Clip Delivery System, and Steerable Guide. The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP231016N52MH.

The TriClip G4 System received Breakthrough Device designation from the FDA on November 19, 2020 for treatment of patients with symptomatic, severe tricuspid valve regurgitation, whose symptoms and TR severity persist despite optimal medical therapy. The technology received FDA premarket approval on April 1, 2024 with an indication for improving the quality of life and functional status in patients with severe tricuspid regurgitation despite optimal medical therapy, who are at immediate or greater risk for surgery and in who transcatheter edge-to-edge

valve repair is clinically appropriate and is expected to reduce tricuspid regurgitation severity to moderate or less, as determined by a multidisciplinary heart team. This indication is covered by its Breakthrough Device designation.ICD-10-PCS code 02UJ3JZ can be used for this technology; the applicant noted that there are no FDA-approved technologies using this procedure code. The applicant identified two ICD-10-CM codes for tricuspid insufficiency that would identify appropriate cases: 107.1 and 136.1.

CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS agrees that the TriClip G4 meets the cost criterion.

CMS **approves the TriClip G4** for new technology add-on payments for FY 2025. The newness period will begin on April 1, 2024, the date the technology received market authorization for the indication covered by its Breakthrough Device designation. The applicant indicated the total cost of the TriClip G4 to the hospital to be $40,000 per procedure. The applicant stated that all the components are sold together for a single operating cost. For FY 2025, the maximum new technology add-on payment for a case involving the technology will be $26,000 for FY 2025. Cases eligible for add-on payment will be identified by the ICD-10-PCS code 02UJ3JZ.

j. VADER® Pedicle System

Icotec Medical submitted an application for the VADER Pedicle System that is used for standard posterior fixation of the spinal column to provide stabilization of infected spinal segments after debridement of infectious tissues. The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP231016MGH3.

The VADER Pedicle System received Breakthrough Device designation from FDA on July 31, 2023 for stabilizing the thoracic and/or lumbar spinal column as an adjunct to fusion in patients with an active spinal infection who are at risk of spinal instability, spinal deformity or neurologic compromise, following surgical debridement. The technology received 510(k) clearance on February 26, 2024 for an indication consistent with the Breakthrough Device designation. CMS notes that the VADER Pedicle System has received FDA 510(k) clearance for multiple indications since 2019 but only the approved indication consistent with the FDA Breakthrough Device designation is applicable for the new technology add-on payment.

The applicant submitted a request for approval for a unique ICD-10-PCD code. The online application posting includes an extensive list of applicable ICD-10-CM codes. Based on the Breakthrough Device designated indication, CMS believes the relevant codes would be include in category M46 (Other inflammatory spondylopathies) under the ICD-10-CM classification in subcategories: M46.2- through M46.5, M46.8- and M46.9.

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

CMS **approves the VADER Pedicle System** for new technology add-on payments for FY 2025. The newness period will begin on February 26, 2024, the date the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on available information, the total cost of the VADER Pedicle System to be $43,450 per patient. For FY 2025, the maximum new technology add-on payment for a case involving the technology would be $28,242.50 for FY 2025. CMS reiterates that only the use of the VADER Pedicle System to stabilize the thoracic and/or lumbar spine as an adjunct to fusion in patients with spinal infection, the FDA Breakthrough Device Designation, are eligible for new technology add-on payments. Tables in the final rule list the ICD-10-PCS codes and ICD-10-CM diagnosis codes that will identify eligible cases.

n. ZEVTERA™ (ceftobiprole medocaril)

Basilea Pharmaceutical International submitted an application for ZEVTERA, an advanced cephalosporin antibiotic designed to treat infections caused by antibiotic resistant pathogens. The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2310161DBB8.

ZEVTERA received QIDP designation for community-acquired bacterial pneumonia (CABP) on July 20, 2015; for acute bacterial skin and skin structure infections (ABSSSI) on August 7, 2015; and for Staphylococcus aureus bacteremia (SAB) on December 8, 2017. The applicant anticipates an NDA decision from FDA consistent with all the QIDP designations by July 1, 2024. The applicant submitted a request for approval for a unique ICD-10-PCS code. The online posting contains a list of the code ICD-10-CMS codes. CMS believes the relevant combination of ICD-10-CMS codes to identify SAB would be R78.81 (Bacteremia) in combination with codes for Methicillin susceptible or resistant Staphylococcus aureus (B95.61 or B95.62).

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

Subject to the technology receiving FDA marketing authorization as a QIDP by July 1, 2024, CMS proposed to approve ZEVETRA for new technology add-on payments for FY 2025. ZEVETRA was eligible for conditional approval, if the technology did not receive FDA marking authorization by July 1, 2024, provided it received FDA marketing authorization before July 1, 2025.

ZEVETRA received NDA approval from FDA on April 3, 2024 with indications for the treatment of: adults with SAB, including those with right-sided infective endocarditis; adults with ABSSSI; and adults and pediatric patients three months to less than 18 years old with CABP.

CMS **approves ZEVETRA** for new technology add-on payments for FY 2025. The newness period will begin on April 3, 2024, the date the technology received FDA marketing authorization for the indications covered by its QIDP designation. Based on available information the average inpatient cost per case for the SAB indication is $11,500 and the cost per case for the ABSSSI and CABP indications is $3,7500. For FY 2025, the maximum new technology add-on payment for a case of ZEVETRA for FY 2025 would be $8,625 for SAB and $2,812.50 for ABSSSI and CABP (75% of the average cost of the technology). Cases for the indications of ABSSSI and CABP that are eligible for add-on payments will be identified by ICD-10-PCS codes XW0335A and XW0435A.). Cases for the SAB that are eligible for add-on

payments will be identified by ICD-10-PCS codes XW0335A or XW0435A in combination with ICD-10-CM code R78.81 in combination with B95.61 or B95.62.

7. Other Comments

CMS acknowledges receipt of comments requesting changes to the new technology add-on payment policies including creating additional alternative pathways, expanding the conditional approval process, moving to a biannual process, and requiring MA plans to provide new technology add-on payments. These comments are outside the scope of the proposals included in the proposed rule and CMS is not addressing the in this final rule.

8. Changes to the Method for Determining Whether a Technology Would be Within its 2- to 3-Year Newness Period when Considering Eligibility for New Technology Add-on Payments

CMS discusses its policy to pay the new technology add-on payment for technologies for the first 2 to 3 years that a product comes on the market, the period when the costs of the new technology are not yet fully reflected in the DRG weights. In general, CMS uses the FDA marketing authorization date at the time when a technology begins to become available on the market; CMS may recognize a later date when an applicant demonstrates a delay in availability. CMS' practice has been to begin and end new technology add-on payments on the basis of a fiscal year and has generally followed a guideline that uses a 6-month window (April 1) to determine whether to extend the payment for an additional fiscal year. In general, CMS extends payments for an additional year only if the three-year anniversary date of the product's entry onto the market occurs in the latter half of the fiscal year (after April 1).

In the FY 2024 IPPS final rule, CMS finalized that beginning with FY 2025 applications; in order to be eligible for consideration for new technology add-on payments for the upcoming fiscal year, an applicant must have received FDA approval or clearance by May 1 (instead of July 1) of the year prior to beginning of the applicable fiscal year (except for an application submitted under the alternative pathway for certain antimicrobial products). In the FY 2024 final rule, CMS discussed comments that asserted this policy change would prevent a 3-year new technology add-on payment duration for almost all applicants because only those technologies that received FDA marketing authorization in April would be eligible for 3 years of payment because of the shortened window from 3 months under the former policy (April 1 to July 1) to just 1 month (April 1 until May 1) (88 FR 58954).

After further consideration of comments, CMS agreed that the change in the FDA marketing authorization deadline from July 1 to May 1 may limit the ability of new technology add-on payment applicants to be eligible for 3 years of new technology add-on payments. CMS proposed that beginning with new technology add-on payments in FY 2026, effective for new technology add-on payments initially approved in FY 2025 or a subsequent year, CMS will use the start of the fiscal year (October 1) instead of April 1 to determine whether a technology is within its 2- to 3-year newness period and approve a new technology add-on payment for that fiscal year. For new technology add-on payments first approved prior to FY 2025 (including technologies determined to be substantially similar to those technologies), CMS would continue to use the midpoint of the upcoming fiscal year (April 1) for determining whether a technology would still be considered "new" for purposes of new technology add-on payments.

Comments/Responses. Commenters were supportive of CMS' proposal. Commenters stated the proposal would provide a more balanced and appropriate evaluation of the duration of the new technology add-on payment. Commenters stated this would allow more innovative technologies to receive new technology add-on payment for a third year. Commenters also requested CMS guarantee a third year of add-on payment for all technologies regardless of when they receive FDA market authorization. Some commenters requested CMS guarantee a third year of add-on payments for specific technologies, such as CAR-T cell therapies or gene therapies; a commenter requested CMS create a five-year add-on payment period for autologous gene and cell therapies. Other commenters stated the proposal did not adequately address underfunding of gene therapies and breakthrough drugs. Some commenters wanted the proposal effective immediately and apply to technologies receiving new technology add-on payments expiring in FY 2024.

Commenters raised other concerns with this proposal. Some commenters were concerned the proposal would result in unreliable claims data for rate-setting because new technology with only 2 years of add-on payment status would not have sufficient claims volume. A few commenters stated the statute did not mention the FDA approval date, nor was there a statutory preclusion from granting all products three years of add-on payments. One commenter recommended starting the newness period with the effective date of the ICD-10-PCS code describing the technology.

CMS does not agree that it should guarantee a third year of new technology add-on payment for all technologies regardless of when they receive FDA marketing authorization. The intent of the proposed policy was not to ensure a third year of payment but how the change in the FDA marketing authorization deadline for FY 2025 applications, may limit the ability for a third year of new technology add-on payments under its practice for determining whether to extend the add-on payment for an additional fiscal year. In addition, the proposal was to address concerns in the change in the deadline for FDA marketing authorization from July 1 to May 1 that became effective for FY 2025 applications and does not impact prior year new technology add-on payments.

CMS reiterates that the newness period does begins when the technology is available on the market, which is when data becomes available (69 FR 49003). CMS also notes it does not consider how frequently the technology has been used (70 FR 47349). In addition, CMS does not believe that 2 years' work of data is insufficient for inpatient rate setting and that the proposed policy would result in unreliable claims data.

CMS **finalizes** its proposal:

- Beginning with new technology add-on payments for FY 2026, in assessing whether to continue new technology add-on payments
  for technologies that are first approved for new technology add-on payments in FY 2025 or a subsequent year, CMS will extend add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year.
- For technologies that were first approved for new technology add-on payments prior to

FY 2024, including technologies that CMS determined to be substantially similar to those technologies, CMS will continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered "new" for purposes of new technology add-on payments.

9. Change to the Requirements Defining an Active FDA Marketing Application for the Purpose of New Technology Add-On Payment Application Eligibility

In the FY 2024 final rule, CMS finalized that to be eligible for consideration for the new technology add-on payment, an applicant must have already submitted an FDA market authorization request before submitting an application for new technology add-on payments. For this policy, submission of a request for market authorization by the FDA means the applicant has submitted a complete application to FDA, and that the application has an active status with the FDA (such as not in a Hold status or have received a Complete Response Letter).[39]

In the proposed rule, CMS discussed that applications for FDA marketing authorization may go in and out of a hold status at various stages of the FDA process for various reasons and the hold may vary from days to several months. After further consideration, based on the variability in the timing and reasons for the hold status with FDA, CMS believed it is appropriate to propose an update of this policy.

CMS proposed that beginning with new technology add-on payment applications for FY 2026, it would no longer consider a hold status to be an inactive status for purposes of eligibility for the new technology add-on payment. CMS would continue to consider an application to be in an inactive status when it is withdrawn, the subject of a Complete Response Letter, or the subject of a final decision from FDA refusing to approve the application.

Comments/Responses. Commenters overwhelming supported CMS' proposal to no longer consider a hold to be an inactive status for the purposes of new technology add-on payment eligibility. Many commenters requested CMS reverse other aspects of the policy finalized in the FY 2024 IPPS final rule including the requirement for a complete and active FDA marketing authorization request at the time of the application, the FDA documentation requirement, and moving the FDA marketing deadline from May 1 to July 1. The commenters stated these requirements are delaying beneficiary access to innovative technologies. Some commenters suggested CMS provide an alternative deadline for providing the necessary FDA information, such as within 60 days after the application submission, the December supplemental information deadline, or no earlier than March 1.

In response to comments, CMS reiterates that patient access to these technologies should not be affected if a technology does not qualify to receive a new technology add-on payment as CMS continue to pay for new technologies through the regular MS-DRG methodology. In addition, the costs incurred by the hospital for a case are evaluated to determine eligibility for an additional payment as an outlier payment which protects the hospital from large financial losses due to unusually expensive cases.

[39] 88 FR 58948 through 58958

CMS also discusses the reasons it implemented this policy which included the increasing complexity and volume of applications lacking critical information needed to determine whether the technology meets the eligibility criteria.[40] CMS will continue to require documentation demonstrating that FDA has determined the marketing authorization request is sufficiently complete to allow for substantive review by FDA (e.g., documentation of FDA acceptance or FDA filing, depending on the type of FDA marketing authorization application the applicant has submitted to FDA) at the time of submission of the new technology add-on payment application. CMS has not accepted and will not accept documentation in which the date that FDA made the determination to accept (for a 510(k) premarket submission or De Novo Classification request) or file (for a PMA, NDA, or BLA) when the request occurred after the submission of the application. CMS does not agree with commenters suggestion that CMS provide mitigating interventions for technologies that were found ineligible for new technologies add-on payments related to these new policies that were effective for FY 2025 applications.

In response to a comment, CMS clarifies the requirements for a "complete and active" FDA market authorization request. As discussed in the FY 2024 IPPS final rule, CMS considers an FDA marketing authorization application to be "complete" when the full application has been submitted to FDA (including all modules or all information following a rolling review or real-time oncology review (RTOR), where relevant) and FDA has provided documentation of acceptance (for a 510k application of De Novo Classification request) or filing (for a PMA, NDA, or BLA) to the applicant indicating that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA. Applicants are required to provide this documentation of FDA acceptance or filing of the request to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. Additionally, CMS considers an FDA marketing authorization application to be in an "active" status when the application has been determined by FDA to be sufficiently complete to permit substantive review by FDA. CMS continues to consider an application to be in inactive status where it is withdrawn, the subject of a Complete Response Letter, or the subject of a final decision from FDA to refuse to approve the application.

CMS **finalizes its proposal** that beginning with new technology add-on payment applications for FY 2026, it will no longer consider an FDA hold to be an inactive status for the purposes of eligibility for the new technology add-on payment for technologies that are not already FDA market authorized for the indication that is the subject of the application. CMS notes it ay reassess this policy for future years.

10. Change to the Calculation of the New Technology Add-On Payment for Gene Therapies Indicated for Sickle Cell Disease (SCD)

CMS believes that it is important to balance the need to maintain under the IPPS the incentive for hospitals to be cost-effective and also encourage the development and use of new technologies. CMS discusses its policies in limiting the new technology add-on payment percentage provided to hospitals. In the FY 2020 IPPS final rule, CMS adopted a general increase in the new technology add-on payment from 50 percent to 65 percent and an increase to 75 percent for QIDPs. In the FY 2021 IPPS final rule, CMS expanded the alternative pathway for

[40] 88 FR 58953

QIDPs to include LADP and finalized the maximum new technology add-on payment percentage for LADP products to 75 percent.

CMS believes that facilitating access to gene therapies for Medicare beneficiaries with SCD may have the potential to improve the health of impacted beneficiaries and lead to long-term Medicare savings. Consistent with its new technology add-on payment policy for products designated by the FDA as QIDP and LPAD, CMS believes the payment percent for gene therapies indicated and used for the treatment of SCD should be increased to 75 percent.

CMS proposed that, subject to its review of the new technology add-on payment eligibility criteria, for certain gene therapies approved for new technology add-on payments in the FY 2025 final rule for the treatment of SCD, effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period, to increase the payment percentage from 65 to 75 percent. CMS noted that if finalized, this policy would be temporary; these payment amounts would only apply to any gene therapy indicated and used specifically for the treatment of SCD that CMS approves for FY 2025 new technology add-on payments.

Comments/Responses. Some commenters were supportive of this proposal. Most commenters supporting the policy also requested CMS modify the proposal to extend the policy to other technologies, increase the payment percentage to 100 percent, and not limit the policy only to FY 2025 new technology add-on payments. Commenters recommended that all technologies should receive a payment percentage of 75 percent and other suggested other specific therapies that should be eligible for the 75 percentage including regenerative medicine advanced therapy (RMAT), therapies with Breakthrough designation, and CAR-T therapies. Commenters were concerned that CMS was making a value judgment that some technologies or medical conditions were more important than others.

CMS responds that the proposed policy aligns with the Administration-identified commitment to improve outcomes for patients with SCD by facilitating access to gene therapies that treat SCD and balance the need to maintain the incentives inherent in the prospective payment system. CMS acknowledges that for SCD gene therapies, due to the inherent design of the IPPS, even a 100 percent payment rate for the new technology add-on payment would not fully cover a hospital's costs. CMS believes that an add-on payment percentage of 100 percent would limit the incentive for cost-effective behavior inherent to a perspective payment system. CMS also believes it is premature to adopt a permanent increase in the new technology add-on payment as it wants to encourage value-based care and lower prices of costly therapies.

CMS **finalizes its proposal** that subject to its review of the new technology add-on payment eligibility criteria, for certain gene therapies approved for new technology add-on payments in the FY 2025 final rule for the treatment of SCD, effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period, to increase the payment percentage from 65 to 75 percent. This policy will only apply to Casgevy and Lyfgenia when indicated and used specifically for the treatment of SCD. CMS will continue to assess this policy and may propose changes in the future.

For FY 2025, CMS continues the new technology add-on payment for 24 technologies. Based on the applicant's estimates at the time they submitted their original application, CMS estimates the aggregated total FY 2025 payments for these new technology add-on payments would be approximately $262.4 million.

For FY 2025, CMS approves 11 technologies under the alternative pathway and 12 new technology add-on payments. Based on information from the applicants, CMS estimates that the total payment for these technologies would be approximately $171.5 million. Total estimated FY 2025 payments for QIDP designated new technologies are approximately $5.6 million and the total estimated FY 2025 payments for Breakthrough Device designated new technologies are approximately $165.9 million.

For FY 2025, CNS approves new technology add-on payment for 3 technologies that applied under the traditional pathway. CMS is also providing new technology add-on payments for 2 technologies that were evaluated as one application due to substantial similarity and which are also considered substantially similar to a technology that was approved for new technology add-on payments in FY 2024. Based on information provided by the applicants, CMS estimates that the total payment for these 5 technologies will be approximately $335.6 million.

For FY 2025, CMS estimates the total costs for new technology add-on payments will be $769.5 million.

FY 2025 Estimates for New Technology Add-on Payments	
Category	**Estimated Total FY 2025 Impact**
Technologies Continuing NTAP in FY 2025	$262,400,516.03
Alternative Pathway Application	$171,543,003.00
Traditional Pathway Application	$335,587,107.36
Aggregate Estimated Total FY 2025 Impact	**$769,530,626.39**

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

A. Background

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.

B. Revised Labor Market Area Delineations

Hospitals are assigned to labor market areas and the wage index reflects the average hourly wage reported on Medicare cost reports. CMS uses Office of Management and Budget (OMB) Core-Based Statistical Area (CBSA) 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.

On July 21, 2023, OMB released Bulletin No. 23-01. Bulletin No. 23-01 reflects changes to CBSA delineations based on the 2020 Standards for Delineating Core Based Statistical Areas (86 FR 37770 through 37778) and the application of those standards to Census Bureau population and journey-to-work data (e.g., the 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). CMS proposed to use these revised delineations to calculate the IPPS wage index beginning in FY 2025.

Public comments were broadly supportive of CMS's proposed update to the IPPS wage index with the revised OMB delineations and the continuation of the policy to cap wage index decreases that a hospital can experience in a given year. MedPAC cited its June 2023 report to Congress, which recommended that Congress repeal the existing Medicare wage index statutes, including current exceptions (geographic reclassification) and replace it with a system based on a system that includes all-employer, occupation-level wage data and other features.

One commenter indicated that CBSAs are not intended for any non-statistical uses. Consistent with OMB guidance and the Metropolitan Areas Protection and Standardization (MAPS) Act, CMS must fully explain why reliance on the updated CBSAs as set forth by OMB is appropriate for purposes of the FY 2025 wage index adjustments.

CMS responded to MedPAC's comments by citing its 2012 Report to Congress: Plan to Reform the Medicare Wage Index. This report concluded that any potential changes to the wage index must be considered in conjunction with the statutorily required geographic reclassifications and other adjustments. These provisions would complicate the implementation of the modifications to the current wage index framework described in MedPAC's June 2023 report to Congress.

With respect to the MAPS Act, CMS provided a detailed response citing the FY 1985 IPPS final rule (50 FR 24375 through 24377), the FY 1995 IPPS final rule (60 FR 29218 through 29220) and the FY 2005 rule (69 FR 49027 through 49028) for a history of outreach, consultation, and discussion of the challenges faced in defining appropriate labor market areas for purposes of the wage index methodology. There was no consensus among the interested parties on a choice for new labor market areas. CMS concluded the adoption and continuation of a metropolitan statistical area (MSA) based framework was the most prudent course of action. None of the alternative labor market areas that were studied provided a distinct improvement over the use of MSAs.

Unless specified otherwise, CMS is following all of the following policies:

Micropolitan Areas. A "Micropolitan Statistical Area" is defined as an area associated with at least one urban area that has a population of at least 10,000, but less than 50,000. CMS proposed to continue the policy established in the FY 2005 IPPS final rule and include hospitals located in Micropolitan Areas in each state's rural wage index.

Metropolitan Divisions. A metropolitan division is a county or group of counties within an MSA with a population of at least 2.5 million. Thus, MSAs may be subdivided into metropolitan divisions. In the FY 2005 IPPS final rule (69 FR 49029), CMS finalized a policy to use the metropolitan divisions where applicable under the CBSA definitions.

Under the current delineations, 11 MSAs are subdivided into a total of 31 metropolitan divisions. The revised OMB delineations have subdivided two additional existing MSAs into metropolitan divisions. Under the proposed delineations, 13 MSAs (the 11 currently subdivided MSAs plus two additional MSAs) are subdivided into 37 metropolitan divisions. CMS proposed to continue using metropolitan divisions as separate CBSAs for wage index purposes.

Connecticut County Equivalents. OMB Bulletin No. 23–01 replaced the 8 counties in Connecticut with 9 new "Planning Regions." Planning regions now serve as county-equivalents within the CBSA system. CMS proposed to adopt the planning regions as county equivalents for wage index purposes. The final rule includes an unnumbered table that shows the current county for each provider number in Connecticut, its current county and CBSA and its planning area and CBSA.

Urban Counties Becoming Rural. CMS' analysis shows a total of 53 counties (and county equivalents) and 33 hospitals that are currently part of an urban CBSA become rural beginning in FY 2025 under the revised OMB delineations. Other than "Lugar" hospitals (explained in the next paragraph) CMS proposed that the wage data for these hospitals will be used to calculate their respective state's rural wage index.

Seventeen of these counties are "Lugar" counties which means they are deemed urban to the adjacent county where the plurality of their workers commute. For purposes of calculating the wage index, these hospitals are treated as geographically reclassified to the urban area where the county is deemed.

When an urban hospital becomes rural, its DSH payments are affected. Existing regulations will result in a phase-down of any reductions in DSH payments to a hospital in this situation over three years where payment is based on 2/3 of the urban DSH adjustment and 1/3 of the rural adjustment in the first year; 1/3 of the urban DSH adjustment and 2/3 of the rural adjustment in the second year and 100 percent of the rural DSH adjustment in the third year.

Rural Counties Becoming Urban. CMS' analysis shows a total of 54 counties (and county equivalents) and 24 hospitals that are currently rural become part of an urban CBSA beginning in FY 2025 under the revised OMB delineations. CMS proposed that the wage data for these

hospitals will be used to calculate the urban CBSA wage index where these hospitals are now located.

Any Critical Access Hospitals (CAHs) in rural counties that are becoming urban will lose their CAH status unless they apply for an urban to rural reclassification. Existing regulations provide for a two-year period for CAHs to apply for an urban to rural reclassification in order to maintain CAH status.

Other special hospital designations (such as Sole Community Hospital (SCH) and MDH) that require rural status may also end if the hospitals do not apply for an urban to rural reclassification. These hospitals should apply for urban to rural reclassification before October 1, 2024 to avoid a termination of their special status (that is, unlike CAHs, these hospitals are not provided with a two year window to regain rural status before their special designation is terminated).

Urban Counties Moving to a Different Urban CBSA. If hospitals move from one CBSA to another under the revised OMB delineations, there may be impacts, both negative and positive, on their wage index values. The change from one urban area to another also creates issues for how to handle hospital reclassifications approved under the current CBSAs when adopting the new CBSA. These issues are addressed below in section III.F.3.

Transition. In the past, CMS has adopted new CBSA delineations over a 3-year period for any urban hospital that became rural to mitigate the negative impact on the hospital's wage index in any single year. Beginning in FY 2023, CMS adopted a policy to apply a 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. CMS believes this policy will adequately address reductions in the wage index for urban hospitals that are becoming rural as a result of the new CBSA delineations. It did not propose any additional transition for these hospitals.

A commenter requested that in addition to the permanent cap policy, CMS implement a 3-year wage index transition period consistent with prior updates to the CBSA delineations. CMS does not believe an additional transition beyond the 5 percent cap on reductions to the wage index is necessary noting the prior transitions were 2years only (except for hospitals moving from rural to urban areas). Further, less than 4 percent hospitals will be subject to the cap that did not also receive the cap for FY 2024. CMS also notes that a much larger number of urban and rural hospitals within the same state (nearly 60 percent) receive identical wage index values (prior to the application of other policies) as a result of policies it adopted for FY 2024.

C. Worksheet S-3 Wage Data

The final rule wage index values are based on data from FY 2021 submitted cost reports. CMS did not propose any changes to the categories of included and excluded costs for FY 2025 relative to prior years.

CMS notes that the wage index data that it is using for the FY 2025 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 and FY 2021 data than in prior years. However, CMS indicates that it is not apparent whether any changes due to the COVID-19 PHE differentially impacted the wages paid by individual hospitals (e.g., only a differential change due to the COVID-19 PHE would affect the wage index). Even if there were differential impacts, it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data.

One commenter requested CMS use data from FY 2022 cost reports for the wage index—the same cost report data that is used, in part, to calculate the relative weights. Another commenter requested CMS provide further information in a tabular format that would allow public commenters to validate its conclusions about the effect of the COVID-19 PHE on the wage index. CMS responded to the first comment that the FY 2021 wage index data are the latest audited data available to use for the wage index. The data the second commenter requested is available with the public use files CMS makes available with the proposed and final rules.

The final rule calculations of the FY 2025 wage index are based on wage data of 3,074 hospitals. The data file used to construct the final wage index includes FY 2021 data submitted to CMS as of May 29, 2024. The wage data includes the wage data for facilities that were IPPS hospitals in FY 2021, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any edits for reasonableness.

CMS does not include the data of facilities that were IPPS hospitals in FY 2021 that have since converted to CAH or Rural Emergency Hospital (REH) status as of January 24, 2024. CMS removed 11 hospitals that converted to CAHs and 19 hospitals that converted to REHs from calculation of the FY 2025 wage index.

General wage index policies are unchanged from prior years. CMS notes that it proposed to exclude 69 providers due to aberrant wage data that failed edits for accuracy. But these hospitals may be included in the final FY 2025 wage index if data aberrancies for these providers are resolved timely. CMS is including 8 hospitals in the final FY 2025 wage index whose wage data was excluded from the proposed rule. It is excluding an additional 3 hospitals with aberrant data from the final wage index.

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 final rule describes this process in great detail including when data files were posted and deadlines for hospitals to request corrections or revisions to audit adjustments. A hospital that fails to meet the procedural deadlines does not have a later opportunity to submit wage index data corrections or to dispute CMS' decision on requested changes.

CMS posts the wage index timetable on its website including all of the public use files made available during the wage index development process. All deadlines are eastern standard time. For the FY 2026 wage index timetable go to: FY 2026 Wage Index Home Page | CMS.

D. Method for Computing the Unadjusted Wage Index

For the FY 2025 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 $55.03.

E. 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. Hospitals were required to submit 2022 occupational mix survey data to CMS by July 1, 2023. The 2022 occupational mix survey data from 2022 will be used for the occupational mix adjustment applied to the FY 2025 through FY 2027 IPPS wage indexes.

CMS compares the impact of using the 2016, 2019 and 2022 occupational mix survey to not using it. These results are largely consistent across each survey.

Comparison of Occupational Mix Adjusted to Unadjusted Wage Index			
	2016 Survey (FY 2021 Wage Index)	2019 Survey (FY 2024 Wage Index)	2022 Survey (FY 2025 Wage Index)
Number of Urban Areas Wage Index Increasing	238 (57.77%)	231 (56.07%)	248 (60.19%)
Number of Rural Areas Wage Index Increasing	20 (42.55%)	27 (57.45%)	28 (59.57%)
Number of Urban Areas Wage Index Increasing 1%<= and <5%	114 (27.67%)	125 (30.34%)	148 (35.92%)
Number of Urban Areas Wage Index Increasing >5%	7 (1.7%)	5 (1.21%)	6 (1.46%)
Number of Rural Areas Wage Index Increasing 1%<= and <5%	9 (19.15%)	12 (25.53%)	17 (36.17%)
Number of Rural Areas Wage Index Increasing >5%	0 (0%)	0 (0%)	0 (0%)
Number of Urban Areas Wage Index Decreasing	173 (41.99%)	179 (43.45%)	163 (39.56%)
Number of Rural Areas Wage Index Decreasing	26 (55.32%)	20 (42.55%)	19 (40.43%)
Number of Urban Areas Wage Index Decreasing 1%<= and <5%	80 (19.42%)	78 (18.93%)	85 (20.63%)
Number of Urban Areas Wage Index Decreasing >5%	1 (0.24%)	3 (0.73%)	1 (0.24%)
Number of Rural Areas Wage Index Decreasing 1%<= and <5%	8 (17.02%)	8 (17.02%)	6 (12.77%)
Number of Rural Areas Wage Index Decreasing >5%	0 (0%)	0 (0%)	0 (0%)
Largest Positive Impact for an Urban Area	6.46%	7.17%	8.43%
Largest Positive Impact for a Rural Area	3.89%	4.07%	3.85%
Largest Negative Impact for an Urban Area	-5.91%	-5.56%	-6.16%
Largest Negative Impact for a Rural Area	-1.79%	-2.56%	-4.17%
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	1 (0.24%)	2 (0.49%)	1 (0.24%)
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	1 (2.13%)	0 (0%)	0 (0%)

CMS reports having occupational mix data for 96 percent of hospitals (2,956 of 3,074) used to determine the FY 2025 final rule wage index. Consistent with the statute, CMS will apply the 2022 occupational mix survey data to the FY 2025 wage index. The FY 2025 national average hourly wage, adjusted for occupational mix, is $54.73.

F. Geographic Reclassifications

This section describes three different types of geographic reclassifications where a hospital is considered to be in a different area than the area where it is located. These reclassifications are: 1) Urban to rural reclassifications for all IPPS purposes; 2) Medicare Geographic Classification Review Board (MGCRB) reclassifications only for the wage index; and 3) "Lugar" reclassifications where a hospital is in a rural county adjacent to an urban county where a plurality of its workers commute.

1. Urban to Rural Reclassification. 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 wage data comparison for whether its wages are higher than other hospitals in its geographic wage area is applied to other rural hospitals within the same state, not to other hospitals in the area where the hospital is geographically located.

When a multi-campus hospital reclassifies from urban to rural, the reclassification applies to all of the hospital's campuses. In addition, if a multi-campus urban hospital is reclassified as rural, the rural status will apply to all of its campuses for such policies as SCH, MDH or Rural Referral Center (RRC) status.

Under current policy, CMS requires a hospital that reclassifies from urban to rural to retain that status for at least 1 year before canceling that status. The purpose of this provision was to prevent hospitals canceling rural reclassification before the calculation of the rural wage index and then obtaining a new rural reclassification without its wage data being included in the rural wage index calculation.

One commenter indicated that this policy is no longer necessary due to a policy change (in response to adverse litigation against CMS) that makes the rural floor and the rural wage index a single calculation. This comment was out-of-scope to any proposal, but CMS responded that it still believes the one-year minimum waiting period is applicable as a hospital could still cancel an urban to rural reclassification to avoid its wage data lowering the rural wage index and then reclassify as rural to obtain a higher wage index and other benefits of an urban to rural reclassification.

The criteria for a hospital to reclassify from urban to rural are based, in part, on "Rural-Urban Commuting Area (RUCA)" designations maintained by the Health Resources and Services Administration (HRSA). Based on an area's RUCA designation, a hospital may be located in a rural census tract of an urban county. If so, the hospital is eligible to reclassify from urban to rural. CMS proposed a minor technical change to the regulations to ensure that its policy always

links to the latest HRSA update of the RUCA designations. There were no comments on this proposal that CMS is finalizing without modification.

CMS also proposed that when a hospital's Claims Certification Number (CCN) is terminated, the hospital's urban to rural reclassification ends for purposes of calculating the wage index. As these hospitals are now considered rural for the wage index calculation, termination of a hospital's CCN when that hospital has reclassified from urban to rural may be more likely to affect the calculation of the rural wage index than it had in the past. CMS noted in the proposed rule that its policy is only for purposes of the wage index and does not affect other policies dependent on rural status (such as SCH, CAH or REH designations). The rural reclassification status would remain in effect for any period that the original PPS hospital remains in operation with an active CCN. Public comments supported this proposal that CMS is finalizing without modification.

2. Geographic Reclassification. Geographic reclassification is a process where hospitals apply to use another area's wage index. To use another area's wage index, the applying hospital must be within a specified distance (15 miles for urban hospitals and 35 miles for rural hospitals) and have wages that are different than its own area and comparable to the wages of the requested area:

- Urban Hospitals: Average hourly wage that is at least 108 percent of other hospitals in its own 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.

CMS received two comments that were out-of-scope to any proposals. One commenter requested that a newly merged campus of a hospital be able to use its prior owner's wage data to support a geographic reclassification application. Under current policy, such a provider would be unable to reclassify for four years until it has its own wage data. CMS may consider this policy in future rulemaking.

The other commenter requested that CMS allow waterways navigated by ferry boat to be considered travel over an improved road for purposes of applying the reclassification proximity criteria. This commenter indicated that prior reclassification applications have been denied in this situation but overturned on administrative appeal. CMS agreed with making this change in future rulemaking to reduce future administrative appeals on this issue.

There are 470 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2025. There are 256 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2023 that will continue for FY 2025. There are 352 hospitals approved for wage index reclassification in FY 2024 that may continue for FY 2025. CMS indicates that there will be 1,078 hospitals in MGCRB reclassification status for FY 2025 (with 237 of these hospitals

reclassified back to their home area). This figure constitutes 32.5 percent of IPPS hospitals.

Applications for FY 2026 reclassifications are due to the MGCRB by September 1, 2024. This is also the current deadline for canceling a previous wage index reclassification withdrawal or termination for the FY 2025 cycle.

One commenter submitted an out-of-scope comment asking that there be a minimum time between release of the January wage index public use file and MGCRB decisions to allow hospitals ample time to submit documentation of rural reclassification, SCH and RRC status or to submit withdrawals. Further, to alleviate the burden of hospitals appealing MGCRB decisions, the commenter requested CMS require the MGCRB to issue requests for additional information rather than deny applications due to incomplete information or if the MGCRB maps distance for proximity differently than the hospital's submission.

CMS does not agree with this comment indicating that hospitals could avoid a denial due to incomplete information or avoid an administrative appeal by submitting a complete application at the time of filing, rather than relying on the MGCRB's current practice of accepting supporting documentation up until the date of review. Hospitals wishing to withdraw an MGCRB reclassification based on the January PUF can still withdraw after the MGCRB's decision.

MGCRB reclassifications are effective for 3 fiscal years. Hospitals that have been reclassified beginning in FY 2023, 2024, or 2025 were reclassified based on the current labor market delineations, not the revised one from OMB that CMS will be using beginning in FY 2025. CMS detailed its policies in the proposed rule for how it will assign reclassified hospitals based on the new CBSA delineations in the FY 2025 final rule:

Urban Counties Becoming Rural or Rural Counties Becoming Urban. CMS indicates that some rural hospitals are reclassified to an area where they are now geographically located under the new CBSA delineations. In this case, CMS is maintaining the hospital's geographic reclassification even though it does not need to reclassify to receive the area wage index of the urban area to which it is reclassified. Conversely, if a hospital had a home area reclassification but its county became rural and it is no longer part of the urban area to which it had a reclassification, CMS will maintain that hospital's geographic reclassification but no longer consider it to be a home area reclassification.

CMS identified six hospitals that are reclassified to an urban area that became rural under the new CBSA delineations. CMS indicates there is no comparable area to where these hospitals could be reclassified, and it proposed to terminate their reclassification status (although one would be a home area reclassification and its wage index would be unaffected).

One commenter indicated that this latter policy was unfair as it denies a previously approved 3-year MGCRB reclassification by CMS without any alternative even though eligibility for that reclassification is not evaluated once approved. The commenter provided several alternatives including assigning the reclassification to their "home" geographic area, the next closest CBSA, or another CBSA to which the hospital can demonstrate it would meet reclassification criteria.

CMS responded that there is no comparable CBSA to the one where these hospitals were reclassified, and it does not have authority to substitute another CBSA to which to reclassify the hospitals regardless of whether it meets the geographic reclassification criteria. The response further notes that the wage indexes for these six hospitals are increasing between FY 2024 and FY 2025 (albeit not as much had they continued to be reclassified). CMS is finalizing its policies as proposed.

Hospitals Reclassified to a CBSA Subsumed by Another CBSA. By law, the wage index for hospitals located in a geographic area cannot be reduced by the inclusion of reclassified hospitals. Therefore, hospitals reclassified into the area receive a wage index inclusive of their own data. Hospitals geographically located in an area receive a wage index that is exclusive of reclassified hospitals to the same area.

CMS proposed that in the case of a CBSA where all urban counties in the CBSA are subsumed by another CBSA, MGCRB reclassifications approved to the FY 2024 CBSA would be assigned the revised FY 2025 CBSA, and all of the hospitals data would be used to determine the wage index of the new CBSA (that is, the wage data for the hospitals in the CBSA that has been subsumed will now be part of the wage index for the new CBSA instead of being part of a wage index for hospitals reclassified to the area). CMS did not receive any comments on this proposal that it is finalizing without modification.

Hospitals Reclassified to CBSAs where One or More Counties Move to a New or Different Urban CBSA. CMS proposed that hospitals approved for MGCRB reclassification to the geographic area they are located in effective for FYs 2023, 2024, or 2025 would continue to be assigned a reclassification to their geographic "home area."

For other hospitals, CMS proposed to determine the best alternative location to assign current reclassifications for the remaining 3 years generally using the most proximate county that: (1) is located outside of the hospital's FY 2025 geographic labor market area, and (2) is part of the original FY 2024 CBSA to which the hospital is reclassified. For county-wide group reclassifications, CMS proposed to use the county to which the majority of hospitals in the group reclassification are geographically closest.

CMS did not receive any comments on any of these proposals although it did receive five requests for hospitals to be reassigned to a different eligible CBSA than the one selected by CMS. Four of these five requests were approved. One hospital was among the six described above that requested reclassification to an area where it was ineligible to be reclassified. CMS denied the request.

Hospitals Reclassified to CBSAs Reconfigured Due to the Migration to Connecticut Planning Regions. As there was significant reconfiguration of the CBSAs due to the transition from counties to planning regions in Connecticut, CMS proposed to adopt a similar assignment policy for hospitals reclassified to CBSAs that currently include Connecticut counties as for hospitals reclassified to CBSAs where one or more counties move to a new or different urban CBSA.

CMS did not receive any comments on this proposal, but it did receive two requests for assignment to a different reclassified CBSA. Both requests were approved.

Under current policy, the deadline for withdrawing or terminating a reclassification is 45 days from publication of the proposed rule in the *Federal Register*. For FY 2026 reclassifications, CMS proposed to change the deadline to 45 days from proposed rule display on the Office of the Federal Register website. The proposed change to the deadline is consistent with the current deadline for withdrawing a "Lugar" reclassification and making a decision about the outmigration adjustment (discussed in #3 below).

CMS had maintained the later deadline for withdrawing or terminating an MGCRB reclassification because of concerns that the deadline could fall before a hospital would know a decision on its appeal to the CMS Administrator of an MGCRB reclassification denial. However, MGCRB decisions are now occurring earlier and the deadline for the Administrator to make a decision on an appeal will be before the proposed deadline to make a reclassification decision for the following fiscal year.

Several public comments opposed this proposal noting that hospitals would have less time to analyze their reclassification options and make appropriate elections following the release of the final rule wage index public use file that was released this year on April 29. If the proposed rule is on public display as early as the statutory deadline of April 1 (historically, CMS has never met this deadline), hospitals could have less than 2 weeks to make a reclassification decision.

While CMS was sympathetic to hospital's concerns about having less time to make a decision, it responded that hospitals would still have sufficient information upon which to withdraw or terminate a reclassification decision. CMS is finalizing its proposal without modification.

3. "Lugar" Counties and Hospitals. 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 by May 24, 2024 that it is declining its Lugar reclassification).

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

- Waiving deemed urban status results in the Lugar hospital being treated as rural for all IPPS purposes.

- Waiving deemed urban status can be done once for the 3-year period that the outmigration adjustment is effective.
- If a Lugar hospital waives its reclassification for 3 years, it must notify CMS to reinstate its Lugar status within 45 days of the IPPS proposed rule publication for the following fiscal year.

In some circumstances, a Lugar hospital may decline its urban reclassification to receive an outmigration adjustment that it would no longer qualify for once it is reclassified as rural. In these circumstances, CMS will decline the Lugar hospital's request and continue to assign it a higher urban wage index (which itself could result in the county requalifying for the outmigration adjustment based on data in the final rule).

CMS received five timely requests for hospitals to accept the county outmigration adjustment in lieu of a Lugar reclassification. These hospitals complied with all of the procedural rules to receive the outmigration. CMS granted their request.

Under the new CBSA delineations, 22 Lugar counties will become urban and no longer be considered Lugar counties. In most cases, these counties are becoming part of an urban area or a substantially similar one to which they were previously deemed. Hospitals in these counties will now be considered urban for purposes of the wage index and all other IPPS purposes.

CMS also proposed to use updated data from the 2020 Census to revise the commuting thresholds for determining whether a county is a Lugar county. Based on the revised data, CMS proposed that 17 of 53 counties that that were previously urban qualify to be Lugar counties. CMS proposed to remove Lugar status for 33 rural counties (11 hospitals) where the counties no longer meet the commuting thresholds or adjacency criteria to qualify for Lugar status.

There were no comments on any of these proposals that CMS is finalizing. There are tables in the final rule showing counties that are either gaining or losing Lugar status as a result of either the new CBSA delineations or applying the revised commuting data from the 2020 census.

G. Wage Index Floors and Outmigration Adjustment

Rural Floor. The rural floor is a provision of statute that prevents an urban wage index from being lower than the wage index for the rural area of the same state. CMS estimates that the rural floor will increase the final rule FY 2025 wage index for 771 urban hospitals requiring a budget neutrality adjustment factor of 0.977499 (-2.25 percent) applied to hospital wage indexes.

CMS did not propose any new policies with respect to calculation of the wage index when an urban hospital is reclassified as urban. It does note that an urban to rural reclassified hospital is consider to be geographically rural for calculation of the pre-reclassified wage index. If that urban to rural reclassified hospital further reclassifies under the MGCRB reclassification provisions, the hold harmless provisions with respect to the rural wage index will apply.

There were a number of public comments on the rural floor despite the fact that there were no proposals. Most of these comments either requested clarification of application of CMS' policies

or raised issues that have been addressed in prior rules. Of particular note was concern about the magnitude of the final rule budget neutrality adjustment for application of the rural floor (more than doubling over the past decade).

CMS responded that it expects that the number of IPPS hospitals assigned their state's rural wage index will increase in future years as hospitals strategically obtain an urban to rural reclassification to obtain a higher wage index. For FY 2025, 58 percent of geographically urban hospitals are receiving a wage index equal to their state's rural floor, imputed floor, or frontier floor prior to any outmigration, low wage index hospital, or 5 percent decrease cap adjustments.

As substantially more hospitals receive the rural floor, there will be a consequently greater budget neutrality impact. CMS states that this result is unavoidable given the statutory requirement to treat an urban to rural reclassified hospital as being located in the rural area of its state and other statutory requirements that a uniform, national budget neutrality adjustment be applied in implementing the rural floor.

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

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

CMS did not make any proposals regarding application of the imputed floor but received comments both supporting and opposing the policy—the latter concerned that the imputed floor continues to unfairly manipulate the wage index to benefit a handful of only-urban states and territories. In response, CMS indicates that application of the imputed floor is a requirement of statute.

Frontier Floor Wage Index. The Affordable Care Act requires a wage index floor for hospitals in the low population density states of Montana, Nevada, North Dakota, South Dakota and Wyoming. CMS indicates that 41 hospitals will receive the frontier floor value of 1.0000 for FY 2022. As all hospitals in Nevada have a wage index of over 1.0, the provision will have no effect on Nevada hospitals. This provision is not budget neutral, and CMS estimates an increase of approximately $55 million in IPPS operating payments due to the frontier floor.

Outmigration Adjustment. CMS proposed to apply the same policies for the FY 2025 outmigration adjustment that it has been using since FY 2012. However, as noted earlier, CMS is

updating the counties and therefore, the hospitals within those counties, that qualify for the outmigration adjustment. CMS estimates the outmigration adjustment will increase IPPS payments by $65 million to 203 hospitals in FY 2025. This provision is not budget neutral.

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. In the FY 2024 IPPS rule, CMS indicated that it only had one year of data under the low-wage index policy to determine whether the policy has successfully resulted in hospital raising wages in order to get a higher wage index. For this reason, CMS adopted a policy to continue the low-wage index policy for FY 2024. CMS proposed to continue this policy in FY 2025 for an additional 3 years considering an analysis of this policy in the context of the COVID-19 PHE.

CMS indicates that the COVID-19 PHE complicates its ability to evaluate the low wage policy and its ability to determine whether low wage hospitals have been provided a sufficient opportunity to increase employee compensation. The proposed rule indicated that hospitals reported $31.1 billion in COVID-19 related funding on FY 2020 cost reports—$3.6 billion to hospitals subject to the low wage index policy. CMS states that these additional funding sources likely overwhelmed the $230 million provided by the low wage index policy making it difficult discern whether the low wage index policy is working.

The analysis further indicated that CMS' inability to isolate the wage data changes due to the COVID-19 PHE and disentangle them from changes due to the low wage index hospital policy makes isolating and evaluating the impact of the low wage index hospital policy challenging. CMS analyzed the distribution of the changes in the average hourly wages of the low wage index hospitals and non-low wage index hospitals and found a similar distribution of the changes in the average hourly wages. The similarity in the two distributions indicates that, based on the audited wage data, the policy has generally not yet had the effect of substantially reducing the wage index disparities that existed at the time the policy was promulgated. Also, to the extent that wage index disparities for a subset of low wage index hospitals has diminished, it is unclear to what extent that is attributable to the low wage index hospital policy given the effects of the COVID-19 PHE and additional funding provided to hospitals.

The COVID-19 PHE ended in May of 2023 (during FY 2023) and CMS has already extended the policy by 1 year through FY 2024. CMS is extending the policy for 3 more years through FY 2027. This policy will allow for a 4-year lag period between the end of the COVID-19 PHE and the time wage data will first become available for use under the FY 2028 IPPS reflective of the effect of the low wage index policy on hospital average hourly wages. For FY 2025, the 25th

percentile wage index value across all hospitals is 0.9007. CMS is applying a budget neutrality adjustment of -0.28 percent for this policy.

The low wage index hospital policy and the related budget neutrality adjustment are the subject of litigation, including in *Bridgeport Hospital, et al., v. Becerra*. The district court in *Bridgeport* held that the Secretary did not have authority to adopt the low wage index hospital policy. On July 23, 2024, D.C. Circuit Court held that the Secretary lacked authority to adopt the low wage index hospital policy and related budget neutrality adjustment. The Circuit Court vacated CMS' policy. As of the date of final rule publication, the time to seek further review of the D.C. Circuit's decision in Bridgeport Hospital has not expired. CMS is evaluating the Circuit Court decision and considering options for next steps. In the interim, CMS finalized its proposal to continue the low wage index policy through FY 2027.

Public comments were similar to past comments on this issue. Some commenters supported the low-wage index policy and asked CMS to continue it while others asked that it be applied non-budget neutral. Others opposed the agency's policy on the basis that it is outside of CMS' statutory authority and ineffective in addressing the perceived problem it is intending to address. Various comments either supported or opposed the policy using a variety of arguments and data sources to support their position.

CMS reiterated its past responses to these comments. The intent of the low wage index 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 such as payment to rural hospitals, the overall financial health of hospitals in low-wage areas or broader wage index reform. In response to comments that the policy is ineffective, CMS notes that many low-wage hospitals have commented that they are indeed helped by this policy.

Cap on Wage Decreases. In the FY 2023 IPPS rule, CMS adopted a 5 percent cap on year-to-year decreases in a hospital's wage index regardless of the circumstances causing the decline. A newly opened hospital is paid the wage index for the area in which it is geographically located for its first full or partial fiscal year without any cap applied as there is no prior wage index upon which to determine the cap. CMS estimates the wage index reduction cap will require a budget neutrality adjustment of -0.05 percent for FY 2025.

H. Wage Index Tables

Final rule wage index tables 2, 3 and 4 can be found at: FY 2025 IPPS Final Rule Home Page | CMS. Select #2 under FY 2025 Final Rule Tables.

I. Labor-Related Share

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national standardized amount that is attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. The proportion of the standardized amount attributable to wages and wage-related costs is the national labor-related share. The factor that adjusts for the relative differences in labor costs among geographic areas is the wage index.

Section 1886(d)(3)(E) of the Act directs the Secretary to employ 62 percent as the labor-related share if that would result in higher payments to the hospital than using the national labor-related share. Application of the 62 percent labor-related share is not subject to wage index budget neutrality.

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

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

A. Background

Medicare makes DSH and uncompensated care payments (UCP) to IPPS hospitals that serve more than a threshold percent of low-income patients. Low-income is defined as Medicare eligible patients also receiving supplemental security income (SSI) or Medicaid patients not eligible for Medicare. To determine a hospital's eligibility for DSH and UCP, the proportion of inpatient days for each of these subsets of patients is used.

Prior to FY 2014, CMS made only DSH payments. Beginning in FY 2014, the Affordable Care Act (ACA) required that DSH equal 25 percent of the statutory formula and UCP equal the product of three factors:

- Factor 1: 75 percent of 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. Supplemental Payments: 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).[41] 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

Some commenters reiterated their support for CMS' decision in the FY 2023 IPPS/LTCH final rule to establish a supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. 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. Another commenter expressed concern that the current supplemental payment policy only protects against the reduction of uncompensated care payments below FY 2022 levels and thus would support a return to the prior method of using a proxy to determine uninsured days for hospitals in Puerto Rico given the challenges related to Worksheet S-10 data collection for hospitals in Puerto Rico.

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.

C. Uncompensated Care Payments

1. FY 2025 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 2024 Medicare DSH estimates, which were based on the March 2024 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

[41] 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.

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

OACT's June 2024 Medicare estimate of DSH payments for FY 2025 is $14.013 billion. **The Factor 1 amount is seventy-five percent of this amount, or $10.510 billion.** The final Factor 1 for 2025 is about $495 million more than the final Factor 1 for FY 2024.

The Factor 1 estimate for FY 2025 began with a baseline of $13.4 billion in Medicare DSH expenditures for FY 2021. The table below shows the factors applied to update this baseline to the current estimate for FY 2025.

Factors Applied for FY 2022 through FY 2025 to Estimate Medicare DSH Expenditures Using FY 2021 Baseline

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2022	1.025	0.946	0.997	0.9940	0.9611	12.880
2023	1.043	0.946	0.990	1.0501	1.0259	13.214
2024	1.031	0.984	1.005	1.0230	1.0434	13.787
2025	1.029	0.981	1.005	1.0022	1.0164	14.013

- 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 FY 2025 figures also assume a partial return to pre-COVID 19 trends.
- The case-mix column shows the estimated change in case-mix for IPPS hospitals and also includes the impact of the pandemic.
- The "other" column shows the changes in other factors affecting Medicare DSH estimates, including the difference between total inpatient hospital discharges and IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in other columns (such as the 20 percent add-on for COVID-19 discharges). The "other" column also includes a factor for Medicaid expansion due to the ACA.[42]

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
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
2025	3.4	-0.5	0.0	2.9

[42] The "Other" column also includes the estimated impacts on Medicaid enrollment; estimated change of +8.3 percent in FY 2022, +5.2 percent in FY 2023, -11.9 percent in FY 2024, and -5.3 percent in FY 2025.

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 addition, a few commenters emphasized their inability to accurately replicate CMS' calculations without clarity on how inputs, such as the effects of the COVID-19 PHE on Medicare discharges, case mix, Medicaid enrollment, and subsequent disenrollment through redeterminations, impact Factor 1 estimates.

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 is performed and its dependance on data sources that are not available to those trying to replicate the exact values.

CMS refers to other sources that could be helpful in how it calculates Factor 1.

- Factor 1 estimates for the proposed rule are generally consistent with the economic assumptions and actuarial analyses used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are generally consistent with those used for the Midsession Review of the President's Budget.[43]

- For a discussion on trends in MA enrollment, CMS refers readers to the 2024 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.[44]

CMS recognizes that its reliance on the economic assumptions and actuarial analyses on the President's Budget estimates for estimating Factor 1 has an impact on hospitals, health systems, and other impacted parties who wish to replicate the Factor 1 calculation by, for example, modeling the relevant Medicare Part A portion of the President's Budget. Yet, CMS believes commenters are able to meaningfully comment on its estimate of Factor 1 without replicating the budget.

2. FY 2025 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

[43] Available on the Office of Management and Budget website at: https://www.whitehouse.gov/omb/budget.
[44] See https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/trusteesreports

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.[45]

For FY 2025, CMS estimates that the uninsured rate for the historical baseline year of 2013 was 14 percent and for CYs 2024 and 2025 is 7.3 percent and 7.7 percent (estimates were 8.5 percent and 8.8 percent, respectively in the proposed rule).[46] Based on comments received, CMS updated the calculation of Factor 2 to incorporate more recent data from NHEA and notes that that the lower projected rates of uninsurance largely reflected higher expected enrollment in direct-purchase insurance in those years. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates the final Factor 2 for FY 2025 (weighting the portion of calendar years 2024 and 2025 included in FY 2025) as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2024: 7.3 percent.
- Percent of individuals without insurance for CY 2025: 7.7 percent.
- Percent of individuals without insurance for FY 2025 (0.25 times 0.073) + (0.75 times 0.077): 7.6 percent

Factor 2 = 1-|((0.076-0.14)/0.14)| = 1 - 0.0457 = 0.5429 (54.29 percent)

CMS calculated Factor 2 for the FY 2025 final rule to be 0.5429 or 54.29 percent, and the uncompensated care amount for FY 2025 to be $10.510 billion x 0.5428 = $5.706 billion which is about $232 million less than the FY 2024 UCP total of about $5.938 billion; the percentage decrease is 3.9 percent. The final rule estimates are also significantly different than the 2025 proposed rule Factor 2 estimate of 62.14 percent and an uncompensated care amount of $6.498 billion. The table below shows the Factor 1 and Factor 2 estimates for FY 2024 and the final factors for FY 2025.

FY 2025 Change in UCP
($ in billions)

	FY 2024	FY 2025	Change	% Change
Factor 1	$10.015	$10.510	$0.495	4.9%
Factor 2	0.5929	0.5428	-0.0501	-8.4%
UCP*	$5.938	$5.706	-$0.232	-3.9%

[45]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

[46] For additional information on the projection of the uninsured, see page 28 of the projection methodology documentation (See https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/projectionsmethodology.pdf)

* The UCP totals do not include supplemental payments for IHS/Tribal hospital and Puerto Rico hospitals. In FY 2025, these payments accounted for $79.9 million.

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. They urged OACT to update its estimate of Factor 2 to account for the projected increases in the number of uninsured individuals as Medicaid unwinding continues and Medicaid redeterminations continue to be processed. Several commenters referenced data sources and analyses, such as analyses by the Kaiser Family Foundation (KFF) and the Urban Institute, that project that at least 22 million individuals will lose their Medicaid coverage in FY 2024, with the number expected to grow in FY 2025.

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 2024, which reflect the most recent historical data and updated expectations for the uninsurance rate. These data account for the legislative impacts of the expiration of the Families First Coronavirus Response Act's Medicaid continuous coverage provision, the extension of the American Rescue Plan's Marketplace enhanced premium tax credits via the Inflation Reduction Act, and the effects of the COVID–19 PHE on insurance coverage. It also refers readers to the OACT memo that accompanies this final rule,[47] 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 2025.

CMS explains that the lower projected rates of uninsurance in CY 2024 and CY 2025 in the final rule relative to the proposed rule largely reflect higher expected enrollment in direct-purchase insurance in those years. Specifically, the updated figures for FY 2025 reflect 4.1 million more enrollees in direct-purchase insurance, particularly Marketplace plans. This higher expected enrollment is associated with enrollment in Marketplace plans and is related to i) the Inflation Reduction Act's extension of the American Rescue Plan Act's enhanced Marketplace premium subsidies through 2025 and ii) a Special Enrollment Period open to those who are no longer eligible for Medicaid coverage due to state-based redeterminations. Overall, CMS notes that the most recent NHEA projections anticipate that the uninsured population will increase from 22.8 million in CY 2023 and 24.4 million in CY 2024 to 26.1 million in CY 2025 and 29.6 million in CY 2026. The projected increase of the uninsured population in CY 2026 is related to the expiration of the enhanced Marketplace subsidies that year.[48]

[47] OACT Memorandum on Certification of Rates of Uninsurance (cms.gov).
[48] For more detailed projections of health insurance enrollment that underlie the estimation of final Factor 2, CMS refer readers to NHEA's Table 17 Health Insurance Enrollment and Enrollment Growth Rates. (Available at https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/projected).

3. Factor 3 for FY 2025

a. Background

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. It uses a three-year average of the most recent fiscal years for which audited data are available.

CMS provides a supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals and did not propose any changes to this methodology and will calculate these payments consistent with methodology described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051). In brief, the supplemental payment for a fiscal year is determined as the difference between the hospital's base year amount—its uncompensated care payments it 2022 which itself was calculated based on a special methodology that used low income patient days as a proxy for uncompensated care on the Worksheet S-10 of the Medicare cost report—increased by the aggregate change in uncompensated care payments for all hospitals.

b. Methodology for Calculating Factor 3 for FY 2025

CMS continues to use the same methodology applied in FY 2024 to determine Factor 3 except CMS will be using the most recent 3 years of audited cost reports from FY 2019, FY 2020, and FY 2021. This approach will be used for all eligible hospitals, including IHS/Tribal and Puerto Rico hospitals. As noted in the proposed rule, CMS used the more recent March 2024 update of HCRIS to calculate Factor 3 for the final rule.

CMS describes the steps it used to calculate Factor 3 and how it calculates 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 10 hospitals for FY 2019 reports, 8 hospitals for FY 2020 reports, and 9 hospitals for FY 2021 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.

In addition, one commenter urged CMS to include all patient care costs in the cost to- charge ratio (CCR), including teaching costs and costs for providing physician and other professional services, to ensure an accurate distribution of uncompensated care payments to hospitals with the highest levels of uncompensated care. This commenter stated that excluding GME costs when calculating the CCR disproportionately impacts teaching hospitals. CMS replies that it is not appropriate to adjust CCRs in the narrower context of calculating uncompensated care costs for teaching hospitals as the CCR in Line 1 of Worksheet S-10 is also used in other IPPS rate setting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights).

Commenters also provided feedback on the audits of the FY 2021 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 also expressed concern that the reductions in uncompensated care payments do not align with the Federal Government's focus on equity. CMS states that it may consider this issue further in future rulemaking.

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 based on a historical average of hospital 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.

For FY 2025 and subsequent fiscal years, CMS proposed to calculate the per-discharge amount for uncompensated care payments using the average of the most recent 3 years of discharge data.

Specifically, CMS proposed for FY 2025 to use an average of FY 2021, FY 2022, and FY 2023 historical discharge data.[49]

Several commenters requested that CMS use a two-year average of discharge data to estimate the per-discharge amount of interim uncompensated care payments for FY 2025 and/or for future fiscal years. These commenters argued that a two-year average would better reflect anticipated FY 2025 discharges, especially as they believe CMS has overestimated discharge volume in its rulemaking in recent years. This has the effect of lowering interim uncompensated care payments.

In light of commenters' concerns regarding a trend of decreasing discharge volume and possible overestimation of discharges in recent years, CMS believes that, on balance, omitting FY 2021 data from the calculation of interim uncompensated care payments is likely to more accurately estimate FY 2025 discharges. Therefore, CMS finalizes its proposal with modification. Specifically, CMS will calculate the per-discharge amount of uncompensated care payments for FY 2025 using an average of the most recent 2 years of available historical discharge data: FY 2022 and FY 2023. Consistent with the proposed rule, CMS finalizes that for FY 2026 and subsequent fiscal years, interim uncompensated care payments will be calculated based on an average of the most recent 3 years of available historical discharge data.

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

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

In the case of hospital mergers, CMS publishes a table on the CMS Web site, in conjunction with the issuance of each fiscal year's proposed and final IPPS rules, containing a list of the mergers known to CMS and the computed uncompensated care payment for each merged hospital. Hospitals had 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.

D. Impact of Revised Labor Market Delineations on Medicare DSH Adjustment

As discussed in section III.B. of the preamble of this final rule, CMS implements the new OMB labor market area delineations (which are based on 2020 Decennial Census data) for the FY 2025 wage index. CMS notes that this has an impact on the calculation of Medicare DSH payment adjustments to certain hospitals. Specifically, hospitals with less than 500 beds that are currently

[49] In FY 2024, CMS used two years of data (FY 2021 and FY 2022) because of concerns about using data from FY 2020 due to the effects of the COVID-19 pandemic on discharges.

in urban counties that would become rural based on the new OMB delineations, and that do not become RRCs or MDHs, would be subject to a maximum DSH payment adjustment of 12 percent.

CMS notes that its existing regulations at 42 CFR 412.102 will apply in FY 2025 with respect to the calculation of the DSH payments to hospitals that are currently located in urban counties that would become rural based on the new OMB delineations. These provisions specify that a hospital located in an area that is reclassified from urban to rural (as defined in the regulations), as a result of the most recent OMB standards for delineating statistical areas adopted by CMS, may receive an adjustment to its rural Federal payment amount for operating costs for two successive fiscal years.

In the first year after a hospital loses urban status, the hospital will receive an additional payment that equals two thirds of the difference between the disproportionate share payments as applicable to the hospital before its redesignation from urban to rural and disproportionate share payments otherwise, applicable to the hospital subsequent to its redesignation from urban to rural. In the second year after a hospital loses urban status, the hospital will receive an additional payment that equals one-third of the difference between the disproportionate share payments applicable to the hospital before its redesignation from urban to rural and disproportionate share payments otherwise applicable to the hospital subsequent to its redesignation from urban to rural.

Comment/Response

Commenters generally supported the application of 42 CFR 412.102 for urban hospitals located in an area that is redesignated as rural as a result of the most recent OMB standards for delineating statistical areas adopted by CMS. A few commenters expressed concern about the potential negative impact on DSH payments. In its reply, CMS notes that it is finalizing its proposal, as discussed in section III.B. of the final rule, to implement the new OMB labor market area delineations for FY 2025. Therefore, 42 CFR 412.102 will apply to those urban hospitals currently located in an area that will be redesignated as rural beginning October 1, 2024. It believes, however, that the special treatment for these hospitals under these regulations will help mitigate the commenters' concerns as urban hospitals in areas that will be redesignated as rural due to the new OMB labor market area delineations may receive an additional payment for two years.

E. Technical Change to Regulations on "Covered Days" in the Medicare Fraction

Prior to fiscal year (FY) 2005, when CMS calculated a hospital's DSH adjustment, its policy was to include only "covered days"—days paid by Medicare in the Medicare fraction. Days not paid by Medicare, that is, inpatient days where the patient exhausted Medicare benefits, would be included in the numerator of the Medicaid fraction if the patient was eligible for Medicaid.

CMS indicates that the approach of excluding from the Medicare fraction patient days for which Medicare did not pay was based on an interpretation of the statute's parenthetical phrase "(for such days)." Following a series of judicial decisions rejecting a parallel interpretation of the same language in the numerator of the Medicaid fraction as counting only patient days actually

paid by the Medicaid program, CMS changed its rule effective for FY 2005 to include exhausted patient days in the Medicare fraction.

This policy was challenged in *Becerra v. Empire Health Foundation (Empire,* 597 U.S. 424 (2022)). In *Empire*, the Supreme Court upheld the FY 2005 regulation and held that beneficiaries remain "entitled to benefits under part A" on days for which Medicare does not pay. CMS indicates that because the pre-FY 2005 rule as written conflicts with the plain meaning of the statute, as confirmed by the Supreme Court, the agency will not apply its pre-FY 2005 rule for hospitals with properly pending claims in DSH appeals or open cost reports. The proposed rule indicated that withdrawal of this regulation will not serve as a basis to reopen a CMS or contractor determination, a contractor hearing decision, a CMS reviewing official decision, or a decision by the Provider Reimbursement Review Board or the Administrator.

CMS indicates that its change is not pursuant to its "retroactive" rulemaking authority under section 1871(e)(1)(A) of the Act as it is applying the plain meaning of the statute (as it has existed unchanged, in relevant part, since its enactment on April 7, 1986). Moreover, CMS argues that it is applying the substantive legal standard established by the statute itself, and not filling any gap and therefore in this instance, notice-and-comment rulemaking is not required by section 1871(e)(1)(A) of the Act, as construed in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (June 3, 2019).

One commenter opposed CMS' proposal for the following reasons:

- The Supreme Court held that CMS' policy to include unpaid patient days in the Medicare fraction is merely supported by the statute, not required by the statute.
- The proposal is against the public interest, thus constituting improper retroactive rulemaking.
- The policy would be inequitable in that hospitals that are still waiting to receive DSH payments calculated in accordance with the pre-FY 2005 version of the rule would be treated differently than other hospitals that already received the benefit of that rule before the Supreme Court issued its decision in *Empire Health*.

CMS responded by reiterating many of the points it made in the proposed rule. In addition, CMS indicates that the Supreme Court in *Empire Health* did not merely support CMS' interpretation of statute but concluded that "being 'entitled' to Medicare benefits . . . means—in the [DSH] fraction descriptions, as throughout the statute— meeting the basic statutory criteria, not actually receiving payment for a given day's treatment."

It follows that the pre-FY 2005 rule that counted only covered days in the Medicare fraction conflicts with the plain meaning of the statute, and it should thus be withdrawn. CMS does not believe that withdrawing a regulation that conflicts with the governing statute constitutes an exercise of "retroactive" rulemaking authority or conflicts with the public interest. Rather, it is conforming its regulation with applicable law as determined by the Supreme Court in *Empire Health*.

CMS also disagrees with the commenter's assertion that the proposal is inequitable as it would apply the policy differently to hospitals paid on the basis of covered days relative to hospitals still awaiting payment based on the pre-2005 rule. According to CMS, it is neither unfair nor unusual for cost reports to be finalized differently from one another with respect to a legal issue depending on the outcome of litigation raising that issue and the status of a hospital's cost report at the time of a final non-appealable decision.

The regulation is being finalized as proposed. CMS reiterates that the withdrawal of this regulation will not serve as a basis to reopen a CMS or contractor determination, a contractor hearing decision, a CMS reviewing official decision, or a decision by the Provider Reimbursement Review Board or the Administrator.

F. Payment Impacts

The regulatory impact analysis presented in Appendix A of the final rule includes the estimated effects of the changes to uncompensated care payments and supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals for FY 2025 across all hospitals by geographic location, number of beds, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,399 hospitals that are projected to be eligible for DSH in FY 2025.

The total amount of uncompensated care payments ($5.706 billion) combined with supplement payments for IHS/Tribal hospitals and Puerto Rico hospitals ($79.9 million) is $5.786 billion. This is a 3.91 percent decrease from FY 2024 payments (about $236 million). Changes in FY 2025 payments are driven by a decrease in Factor 2 related to the update of NHEA data that lowered the uninsurance rate used in the calculation.

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 more negative than 3.91 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 less negative than -3.91 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 combined.

Hospital Type	Dollar Difference FY 2024-FY 2025 ($ in millions)	Percent Change (%)
All Hospitals	-$236	-3.91%
Urban	-232	-4.08
Large Urban	-90	-2.88
Other Urban	-142	-5.51
Rural	-4	-1.16
Beds: 0-99 (Urban)	8	3.43

Hospital Type	Dollar Difference FY 2024-FY 2025 ($ in millions)	Percent Change (%)
Beds: 250+ (Urban)	-178	-4.26
Beds: 0 to 99 (Rural)	-5	-2.97
New England (Urban)	-8	-5.38
Middle Atlantic (Urban)	-35	-5.33
South Atlantic (Urban)	-64	-9.95
East South Central (Urban)	-74	-4.98
West North Central (Urban)	-16	-4.52
West South Central (Urban)	10	0.84
Pacific (Urban)	-16	-3.13
East South Central (Rural)	1	1.40
West North Central (Rural)	-4	-5.44
Pacific (Rural)	0	7.53
Puerto Rico	-3	-4.20
Teaching with 100 or more residents	-82	-3.47
Teaching with fewer than 100 Residents	-104	-4.87
Non-Teaching	-50	-3.27
Voluntary	-161	-4.61
Proprietary	-31	-3.59
Government	-44	-2.63

Under this final rule, rural hospitals are projected to receive a decrease in uncompensated care payments of 1.16 percent compared to a decrease in UCP payments of 4.1 percent for urban hospitals in FY 2025 compared to FY 2024. 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 4.87 percent. Nonteaching hospitals and teaching hospitals with 100 or more residents are expected to receive smaller than average decreases of 3.27 and 3.47 percent, respectively. Voluntary ownership hospitals are expected to receive a larger than average decrease of 4.61 percent compared to Proprietary and Government hospitals, respectively.

V. Other Decisions and Changes to the IPPS

A. Post-Acute Care Transfer Policy

A post-acute care transfer is a hospital discharge occurring prior to the geometric mean length of stay to a post-acute care setting.[50] 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-

[50] 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.

DRG payment (known as the "special payment methodology" for types of cases with large costs early in the stay).

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

CMS proposed to add new MS-DRGs 426, 427, 447 and 448 to the list of MS-DRGs subject to the post-acute transfer policy. These MS-DRGs would also qualify to receive the special payment methodology. MS-DRGs 459 and 460 are currently subject to the post-acute transfer policy but CMS proposed to the remove them from the list because the proposed revisions to the MS-DRGs would make them no longer qualify. All of these MS-DRG pertain to spinal fusion.

One commenter indicated that these MS-DRGs have extremely high upfront costs and that CMS should not adopt the proposal due to the negative impact on hospitals that provide spinal fusion services. CMS responded that these MS-DRGs will be subject to the special payment methodology to recognize their high upfront costs early in the inpatient says. The policy is being finalized as proposed.

B. Inpatient Hospital Update

The inpatient hospital update for FY 2025 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 2025 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 2025 inpatient hospital update will be reduced by three-quarters of the market basket update.

The IHS Global Insight, Inc. (IGI) 2nd quarter 2024 forecast (with historical data through the 1st quarter of 2024) for the hospital market basket is 3.4 percent. IGI's 2nd quarter 2024 forecast of total factor productivity is 0.5 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 2025	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	3.4	3.4	3.4	3.4
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.85	-0.85
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.55	0.0	-2.55
Productivity Adjustment	-0.5	-0.5	-0.5	-0.5
Applicable Percentage Increase	**2.9**	**0.35**	**2.05**	**-0.5**

For updates to the hospital-specific rate for SCHs and MDHs, CMS will adopt the same four possible applicable percentage increases shown in the table above (although the MDH program is set to expire on December 31, 2024 if it is not extended by Congress).

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 equal to ¾ of the market basket (before application of total factor productivity).

Public comments were in the following categories:

Accuracy of the Hospital Market Basket: Public commenters indicated that economy-wide inflation grew by 12.4 percent from 2021 through 2023 (as measured by the Consumer Price Index (CPI)), more than two times faster than Medicare reimbursement for hospital inpatient care, which increased by 5.2 percent during the same time. The most recent CPI for March 2024 reported nationwide inflation at 3.5 percent and inpatient hospital services inflation of 6.9 percent, outpacing Medicare's reimbursement.

CMS responded that the hospital market basket update may differ from other overall inflation indexes such as the CPI which measures different mixes of products, services, or wages than the IPPS hospital market basket. The CPI for hospital inpatient services does not reflect the input price inflation facing hospitals, and in some instances can reflect hospital charges or list prices.

Several comments raised concerns that the market basket does not account for higher administrative costs due to automatic claim denials and onerous prior authorization requirements, the costs of addressing past and preventing future cyberattacks, among others.

CMS responded that the hospital market basket measures the change in prices for a mix of goods and services purchased by hospitals consistent with a base period. It does not reflect increases in costs associated with changes in the volume or intensity of input goods and services (such as the quantity of labor used) or the other factors mentioned in the comment.

Alternative Updates: Several commenters requested that CMS apply a payment increase of at least 4.1 percent. Commenters noted that MedPAC found that all-payer and overall Medicare

margins fell to record lows. According to MedPAC, Medicare hospital margins for FY 2022 were negative 12.7 percent. MedPAC recommended that Congress increase the acute hospital market basket by 1.5 percentage points over current law for FY 2025. Other commenters requested different updates above the proposed market basket or alternative data sources or methodologies to develop the hospital market basket. Many commenters requested CMS use its "exceptions and adjustments" authority to apply a higher update.

MedPAC's recommendation is for a change to the statutory update that can only be made by Congress, not CMS. CMS responds to the other comments, as it has repeatedly in the past, that the statute requires an update based on its projection of the market basket for the upcoming fiscal year less an adjustment for total factor productivity. Use of the exceptions and adjustment authority to create a separate payment update would have the effect of modifying the current law update and would not be an appropriate use of that authority according to CMS.

Accuracy of the Employment Cost Index (ECI): Many commenters expressed concerns that ECI does not reflect the shift to contract labor. CMS indicates that the ECI appropriately does not reflect a shift in the occupations that may occur due to increases in case-mix or shifts in hospital purchasing decisions as it is a fixed weight index. In most periods when there are not significant occupational shifts or significant shifts between employed and contract labor, the data has shown that the growth in the ECI for wages and salaries for hospital workers has generally been consistent with overall hospital wage trends.

Rebasing the Hospital Market Basket: A commenter encouraged CMS to adopt new or supplemental data sources in future rulemaking that more accurately reflect real time data from the hospital community. The commenter requested that CMS rebase the market basket at least every 3 years. CMS responded that the statute requires IPPS market basket to be rebased more frequently than once every 5 years. In prior rulemaking, CMS established a rebasing schedule of every 4 years, in part because the cost weights obtained from the Medicare cost reports typically do not indicate much of a change in the weights from year to year.

Forecast Error Correction: Commenters stated that since the COVID-19 PHE, IGI has shown a consistent 3-year trend of under-forecasting the market basket growth. Several commenters urged CMS to use its special exceptions and adjustments authority to implement a retrospective one-time adjustment for FY 2025 to account for the underestimation of the market basket updates over the last several years consistent with its policy for the skilled nursing facility (SNF) PPS and the capital IPPS.

CMS responded that it will continue to monitor the methods associated with the market basket forecasts to ensure there are not underlying systematic issues in the forecasting approach. It notes that the under-forecast of the IPPS market basket increase in the recent time period was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID-19 PHE. The response further notes that over a longer period of time, there have been numerous years where hospitals benefited from the forecast error.[51]

[51] HPA has reviewed the forecast market basket and the actual market basket going back to 2012—the first year in which the update was based on market basket net of productivity. The cumulative difference between the forecast market basket (37.4 percent) and the actual market basket based on later data (34.5 percent) is 2.9 percentage points.

With regard to SNF and capital IPPS, CMS responded that forecast error corrections in these systems have been a part of them since their inception. Unlike what commenters are requesting here, CMS is not selectively adjustment for forecast error only when it increases the market basket.

Productivity Adjustment: Commenters continue to believe the productivity adjustment is not applicable as the hospital sector cannot mirror productivity gains from the private nonfarm business sector. Commenters requested CMS use its exceptions and adjustments authority to eliminate the productivity adjustment for FY 2025. CMS responds that the productivity adjustment is required by statute. As with the market basket, CMS does not believe it should use the exceptions and adjustments authority to change an outcome of an explicit statutory provision.

CMS is not making any changes to its proposed update based on comments but it is using later data for the final rule IPPS market basket update. As state above, the use of later data results in a market basket of 3.4 percent in place of the 3.0 market basket used in the proposed rule. The productivity offset also is increasing from 0.4 percentage points to 0.5 percentage points.

C. 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 2025, CMS proposed to use FY 2023 data to set the CMI criteria. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2024, 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 2023, and a CMI greater than or equal to the lower of 1.7789 (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)	1.49605
2. Middle Atlantic (PA, NJ, NY)	1.5554
3. East North Central (IL, IN, MI, OH, WI	1.6382
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7271
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6315

The year 2024 remains an estimate but reflects -0.2 percentage points between the projected and actual market basket. Congress legislated an update of 1.0 percent for 2018 which was 1.3 percentage points below the actual market basket.

Census Region	CMI Value
6. East South Central (AL, KY, MS, TN	1.5962
7. West South Central (AR, LA, OK, TX	1.78235
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7742
9. Pacific (AK, CA, HI, OR, WA)	1.7888

The median regional CMIs in the final rule reflect the March 2024 update of the FY 2023 MedPAR containing data from bills received through March 31, 2024. A hospital seeking to qualify as an RRC should get its hospital-specific CMI value (not transfer-adjusted) from its MAC.

D. Low-Volume Hospitals (LVH)

Section 1886(d)(12) of the Act provides a payment in addition to a hospital's IPPS payment for each qualifying LVH beginning in FY 2005. To qualify as an LVH, the hospital must be more than a distance specified in the statute from another IPPS hospital and have fewer than a statutory specified number of discharges. The below table shows the statutory and regulatory criteria to be a low-volume hospital and how the additional payment is calculated.

Fiscal Year	Distance Criteria	Discharge Criteria	Payment Methodology
2005 - 2010	25 miles	200 Total Discharges	25%
2011 - 2018	15 miles	1,600 Medicare Discharges	Medicare Discharges<200=25%; Declining Linear Adjustment Up to 1,600
2019 - 2024 and the 1st quarter of FY 2025	15 miles	3,800 Total Discharges	Total Discharges<500=25%; Declining Linear Adjustment up to 3,800 discharges applied to each Medicare Discharge
CY 2025 and later	25 miles	200 Total Discharges	25%

Absent statutory intervention, only hospitals with less than 200 total discharges will be eligible for the LVH adjustment beginning in FY 2025. As shown in the above table, the payment adjustment for a qualifying LVH will be 25 percent for each Medicare discharge.

CMS estimates that an average of 600 hospitals qualified for the LVH adjustment for FYs 2019 through 2024. Under the criteria that were in place between FYs 2005 and 2010 that will be applicable January 1, 2025 absent a change in law, CMS indicates that fewer than 10 hospitals qualified for the LVH adjustment.

CMS proposed to continue the past process for hospitals to apply for LVH status. Hospitals must submit a written request for LVH status to its MAC by September 1, 2024 that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. Hospitals must use the latest submitted Medicare cost report for discharge information. Use of a web-based mapping tool may be used to demonstrate that the mileage criterion has been met. If a hospital's written request for LVH status for FY 2025 is received after September 1, 2024, CMS proposed that any approval will be effective prospectively within 30 days of the date of the MAC's determination.

As the criteria for receiving the LVH adjustment will change effective January 1, 2025, CMS proposed a parallel process for a hospital to be eligible for the adjustment for the remainder of FY 2025 after December 31, 2024. That is, hospitals must submit a written request for LVH status to its MAC by December 1, 2024 that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria effective January 1, 2025 to be eligible for the LVH adjustment on or after that date.

Alternatively, CMS is providing the option for hospitals to submit a single request for an LVH adjustment by the September 1, 2024 deadline for both the portion of FY 2025 beginning on October 1, 2024 and ending December 31, 2024 and the portion of FY 2025 beginning on January 1, 2025 through September 30, 2025. This option would allow the hospital to continue receiving the LVH adjustment after December 31, 2024 provided it continues to qualify for it based on the revised criteria.

Public comments requested more information on how CMS would handle a future extension of the more permissive criteria for LVHs. CMS responded that it would continue to implement any subsequent extensions as quickly and seamlessly as possible based on the requirements of the extension.

Some commenters indicated that CMS can expand eligibility for the LVH adjustment to 800 discharges under its regulatory authority and encouraged CMS to do so. While CMS acknowledged that is has the regulatory authority expand the LVH adjustment beyond 200 discharges, its empirical analysis indicated that it is only merited up to 200 discharges.

E. Medicare-Dependent Small Rural Hospitals (MDH)

Section 1886(d)(5)(G) of the Act provides special payments under the IPPS to an MDH through December 31, 2024. Beginning with discharges occurring on or after January 1, 2025, all hospitals that previously qualified for MDH status will no longer be eligible for this special status. There are currently 173 MDHs, of which CMS estimates 114 have been paid under the blended payment of the Federal rate and hospital-specific rate while the remaining 59 would have been paid based on the IPPS Federal rate. With the expiration of the MDH program, all these providers will be paid based on the IPPS Federal rate beginning with discharges occurring on or after January 1, 2025.

While the MDH program was set to expire many times previously, it has always been extended by Congress. Nevertheless, CMS advised hospitals of the MDH program expiration in the proposed rule and the potential to ameliorate the associated reduction in payment through becoming an SCH.

When the MDH program was set to expire at the end of FY 2012, CMS revised the SCH regulations to allow MDHs to apply for SCH status in advance of the expiration of the MDH program. These regulations allow SCH status to begin the day following the MDH program's expiration. In order for an MDH to receive SCH status effective January 1, 2025, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program, or by

December 2, 2024. The MDH also must request that, if approved, the SCH status be effective with the expiration of the MDH program. If the MDH does not apply by the December 2, 2024 deadline, the hospital would instead be subject to the usual effective date for SCH classification, which is the date the MAC receives the complete application.

Commenters expressed support for CMS' policy that allows MDHs to apply for SCH status in advance of the expiration of the MDH program. Other commenters also requested that CMS automatically reinstate MDH status to all previously qualifying hospitals, including hospitals that became SCHs and hospitals that cancelled rural status in anticipation of the MDH program expiration, if a retroactive extension to the MDH program is made.

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

As with past extensions, CMS will evaluate enacted legislation to determine the most appropriate approach to implement changes to the law, including instructions to the MACs to reinstate MDH status to eligible hospitals. As in the past, and as acknowledged by some of the commenters, CMS will make every effort to implement any extension of the MDH program as expeditiously as possible.

F. 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 trained. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare DGME and IME payments the hospital will receive. Since 1997, the law has limited the number of residents a hospital may count for DGME and IME (other than dental and podiatric residents) to the amount they counted in 1996.

For IME, the hospital's payment adjustment is based on a complex formula specified in statute. For DGME, the hospital's payment equals the product of a per resident amount (PRA), the number of residents and the Medicare's share of the hospital's total inpatient days. For DGME, a resident is weighted at 0.5 FTE for training beyond an "initial residency period." Generally, this means that the resident has completed an initial board certification and is engaged in subspecialty training.

2. Distribution of Additional Resident Positions Under Section 4122 of the CAA, 2023

Section 4122(a) of the CAA, 2023 ("section 4122") requires that the Secretary initiate an application process to distribute 200 residency positions effective July 1, 2026. At least 100 of

the positions must be distributed for psychiatry or psychiatry subspecialty residency training programs. Hospitals must be notified of the additional residents they are awarded by January 31, 2026. The specifications for awarding additional residents under section 4122(a) are similar to section 126 of the CAA, 2021 ("section 126") that required CMS to distribute an additional 1,000 resident positions. CMS' proposals for section 4122 followed the model it established for implementing section 126. The statute prohibits administrative and judicial review of CMS' implementation of section 4122.

CMS proposed an application deadline of March 31 of the prior fiscal year to the provision being effective—that is, March 31, 2025. The completed application must be submitted to CMS using an online application system, the Medicare Electronic Application Request Information System™ (MEARIS™). The proposed rule detailed all of the elements that will be required in the MEARIS application. In the final rule, CMS clarified for commenters that hospitals may apply under both section 126 and section 4122 for additional residents. There is no statutory prohibition on applying for additional residents under both provisions of statute at the same time.

Demonstrated Likelihood. The statute requires that for a hospital to be eligible for additional residents, it must demonstrate a likelihood that it will fill the positions that it is awarded. CMS proposed that a hospital may meet this criterion by showing it does not have sufficient room under its current FTE resident cap(s) to accommodate a planned new program or expansion of an existing program.

There were comments concerned that "demonstrated likelihood" would disadvantage rural hospitals that do not have the same resources to take on unfunded residents above their resident caps as large academic medical centers. CMS responded that a comparison between the hospitals' resident count and its cap would not be made in the first phase of distribution where a minimum of 1 resident is awarded to all qualifying hospitals that apply (prorated if there are more applicants than there are residents to award). This comparison would only be made in the second phase where there are additional residents to distribute based on the hospitals' Health Professional Shortage Areas (HPSA) scores.

Qualifying Hospitals. The law further requires that at least 10 percent of the additional residents be awarded to hospitals in each of the following four categories. CMS further proposes that a qualifying hospital must also be in at least one of these categories:

- Located or Treated as Being Located in a Rural Area. To meet this criterion, the hospital must be either geographically rural under CMS' CBSA delineations or reclassified from an urban to a rural area prior to the application deadline of March 31, 2025.

  Public comments expressed concern about this criterion as it allows geographically urban hospitals to qualify for additional residents if they have reclassified as rural. CMS responded that the statute requires hospitals that are not geographically rural but treated as rural for the IPPS be eligible to apply for additional residents.

  A few commenters were concerned that rural hospitals may not be aware of their ability to apply for additional resident positions. They requested CMS market section 4122 to

rural hospitals to increase the likelihood they apply for and are awarded additional residents. The rule details promotional efforts CMS has been undertaking to advise rural hospitals of the opportunity to receive additional resident cap slots.

- Reference Resident Level Exceeds the Hospital's Resident Limit. The "reference resident level" refers to the unweighted count—before the 0.5 weighting factor for residents in subspecialty training—from the hospital's most recent cost reporting period ending on or before the date of enactment CAA, 2023 (December 29, 2022). This criterion is met if the hospital's reference resident level exceeds its DGME cap (which is also unweighted). There were no comments on this issue.

- States with New Medical Schools, Additional Locations and Branch Campuses. This category consists of hospitals located in states that established new medical schools or additional locations and branch campuses on or after January 1, 2000. This category consists of 35 states and Puerto Rico. Based on public comments, CMS is adding three more states to this list (Minnesota, Montana and Oregon) for both section 4122 and the final rounds of implementation of section 126.

- Hospitals Serves Patients from HPSAs. To qualify under this criterion, hospitals must serve areas designated as HPSAs (not actually be located in one). If a hospital qualifies under this provision and is awarded additional residents, CMS proposed that the residents must spend at least 50 percent of their training time in a primary care or mental-health-only geographic HPSA. Specific to mental-health-only geographic HPSAs, CMS proposed that the program must be a psychiatry program or a subspecialty of psychiatry.

  One commenter requested CMS apply this criterion to hospitals that are actually in a HPSA rather than hospitals that are serving patients from HPSAs. CMS declined to make any changes to the criterion indicating that the statute is explicit that this criterion applies to hospitals that serve "areas designated as health professional shortage areas."

Psychiatry or Psychiatry Subspecialties. As indicated above, at least 100 of the additional 200 residents must be awarded to hospitals that intend to train residents in psychiatry or a psychiatry subspecialty. CMS proposed that "a psychiatry or a psychiatry subspecialty" will include psychiatry or any of its subspecialties listed at following website: Overview (acgme.org).

Several comments expressed concern about CMS receiving applications for less than 200 residents or less than 100 residents in a psychiatry or psychiatry subspecialty. If the former were to occur, comments recommended that CMS allow for a separate application cycle to allocate the unused resident slots. If the latter were to occur, commenters requested that CMS allow the unused psychiatry slots be used for distribution to non-psychiatry resident positions. CMS responded that the statute only allows for a single distribution cycle effective July 1, 2026 and does not permit the flexibility requested by commenters to allow unused psychiatry slots to be awarded for non-psychiatry positions.

By regulation, CMS has established an IME-like adjustment for inpatient psychiatric facilities (IPFs) that are paid under the IPF PPS. Under the IPF PPS, there is a regulatory, not a statutory

cap on the number of residents IPFs may count for the teaching adjustment. Given accreditation requirements for inpatient and outpatient psychiatry training in a psychiatry or psychiatric subspecialty, public commenters requested CMS make adjustments to the resident caps that apply to IPFs. CMS will consider this issue in future IPF PPS rulemaking.

A number of commenters expressed concern about shortages of physicians in other specialties or subspecialties besides psychiatry. Other commenters indicated that they have vacant slots in psychiatry residencies and CMS' priorities should be directed towards other specialties. CMS responded that the statute was explicit in requiring that 100 of the 200 available new resident slots be awarded to hospitals that will train residents in psychiatry or a psychiatry subspecialty.

Pro Rata Distribution and Limitation on Individual Hospitals. The statute requires that all qualifying hospitals receive at least 1 (or a fraction of 1) additional resident before any hospital is awarded two residents. A single hospital may not be awarded more than 10 residents. If there are more qualified applicants than there are available residents to award, CMS will prorate the 200 additional residents awarded to each qualifying hospital (rounded to two decimal places).

Many commenters were concerned that an award of 1 or a fraction of 1 resident would not allow meaningful expansion of resident training. As an example, commenters noted that to expand a psychiatry residency program by 1 resident would require adding 4 slots to the cap because psychiatry is a four year program (one resident in each program year). CMS recognizes this issue but indicates that its authority to award more residents than 200 and a minimum of 1 (or a prorated fraction of 1) is limited by statute. The rule further indicates that the DGME provisions are structured such that Medicare only pays its share of residency training.[52]

CMS also considered an alternative where every qualifying hospital would be awarded 0.01 residents and the remaining resident slots would be awarded according to HPSA priority scores. Public commenters indicated that an award of 0.01 residents would not be meaningful and would be administratively burdensome for accounting purposes. Alternatively, there were commenters who acknowledge the burden of awarding 0.01 residents but like the idea of making more residents available to hospitals in HPSAs. CMS is not adopting this alternative prioritization idea.

Prioritization of Applications by HPSA Score. If there are fewer qualified applicants than there are available slots to award, priority for awarding additional residents will be given to hospitals based on the HPSA score associated with the program for which each hospital is applying. CMS will request HPSA data from HRSA in November 2024 to be used for prioritizing applications based on HPSA score. Areas designated as a HPSA or in "proposed for withdrawal status" at the time the HPSA information is received by CMS will qualify.

There were comments both in support of and opposed to prioritizing the distribution of residency slots in the second distribution phase (if applicable) by HPSA score. Commenters opposed to using HPSA score to prioritize distribution of additional resident slots stated that it is inconsistent with the statute that states slots are to be distributed to hospitals that serve HPSAs,

[52] There is an unstated but implicit understanding that any additional financing of DGME would be from other payers paying their share of DGME costs whether it actually is happening or not.

not that are actually in HPSAs. Further, the statute is explicit that a minimum of 10 percent of the slots must be distributed to hospitals in each of the four qualifying categories for additional residents. Commenters suggested that the statute requires hospitals in each of the categories be equally prioritized.

CMS responded that HPSA prioritization does not require that the applicant hospital be located in a HPSA, although if qualified under this criterion, at least 50 percent of the training time associated with the program for which the hospital is applying must occur at training sites located within the primary care or mental-health-only population or geographic HPSA. While the statute does require that at least 10 percent of the slots awarded go to hospitals qualifying in each of the four categories, the remaining 60 percent of the residents must be allocated by CMS. There is no statutory language governing priority categorization of those additional resident slots (if they are available).

Other comments expressed concern that use of HPSA scores would not be an effective way to award residents to hospitals located in rural areas because HPSA scores often do not prioritize or accurately reflect the needs of areas with small populations. CMS acknowledges that few geographically rural hospitals have submitted applications under rounds 1 and 2 of section 126, stating that rural hospitals may be utilizing other opportunities to increase their FTE caps through participation in rural training programs and an increase in their cap each time they participate in training residents in a new program. Nevertheless, CMS believes that continuing education and outreach regarding the opportunities available under both sections 126 and 4122, rather than abandoning the HPSA prioritization method which has successfully allocated slots to programs serving underserved communities and populations, is the appropriate course of action at this point.

Other commenters indicated that while HPSA scores may adequately indicate places in the country where there is a need for more providers, they may not be the best representation of where hospitals are prepared to provide the best and most complete training environment. In response to this comment, CMS again indicated that the applicant hospital itself is not required to be physically located in the HPSA in order for the program to meet the 50 percent criterion for HPSA prioritization. Furthermore, increasing residency training in non-provider sites outside of hospitals, such as community health clinics located in HPSAs, is an important tool in addressing the shortage of primary care providers in underserved areas.

There were comments suggesting several alternative ways of prioritizing distribution of additional resident positions (if applicable) such as giving greater weight to the other three criteria for new slots or prioritizing distribution based on how many of the four statutory criteria the applicant meets. Several commenters stated that CMS should evaluate the applicant pool and award all slots on a pro-rata basis.

CMS responded that HPSA scores, while not a perfect measure, provide the best prioritization approach available at this time. They are transparent, widely used, publicly available, regularly updated, and have verifiable inputs for measuring the severity of a service area's need for additional providers. With respect to prioritizing by eligibility category such that the more eligibility categories the hospital meets the higher its prioritization, CMS' experience with

section 126 to date indicates that many applicants would meet two or three out of the four eligibility categories. CMS responded to the many other suggested alternatives as either being inconsistent with the statute, administratively infeasible or not likely to be any more effective in achieving workforce goals than using HPSA scores.

CMS is finalizing its proposal on HPSA prioritization without modification.

Requirement for Rural Hospitals to Expand Programs. Rural hospitals are permitted to establish new medical residency programs under existing provisions of statute and regulations. These programs become subject to a cap 5 years after the program begins training residents. As rural hospitals may already begin new training programs and receive DGME and IME payment, the statute explicitly limits any resident positions awarded under section 4122 to expansion of existing programs, not making new programs larger. There is no analogous requirement in section 126. Consistent with the section 4122 statutory requirement, CMS proposed that a rural hospital must use any additional residents to expand an existing residency.

DGME is paid under section 1886(h) of the Act while IME is paid under section 1886(d) of the Act. When a hospital reclassifies as rural under section 1886(d)(8)(E) of the Act, the hospital is only considered rural for the purposes of section 1886(d) or for its IME payments. As the hospital is not considered rural under section 1886(h) for DGME, such hospitals cannot receive DGME FTE cap adjustments for new medical residency programs. For this reason, public commenters suggested that the proposed limitation on resident slots awarded under section 4122 for expansion of existing programs should not apply to hospitals reclassified as rural for their DGME payments. Commenters further requested that CMS apply the same policy to additional resident slots awarded under section 126.

CMS responded that it believes that in including both geographically rural hospitals and hospitals that have reclassified as rural as qualifying hospitals, the intent of the statute was to treat these two groups of hospitals in the same manner for purposes of cap increases under section 4122. With respect to section 126, there is no statutory language that limits the use of new resident slots awarded to expansion of existing programs like there is with section 4122. Therefore, any parallel policy to CMS' proposal to limit use of new residents to expanding existing programs is inapplicable under section 126. CMS is finalizing its policy as proposed.

Distributing At Least 10 Percent of Positions to Each of the Four Categories. As noted above, CMS must distribute at least 10 percent of the resident positions awarded in each of four categories. The proposed rule indicated that some hospitals may qualify under more than 1 category.

For the 1,000 residents (200 per year) distributed under section 126 of the CAA, 2021, CMS has distributed residents for the first two years and found that it has not met the requirement to distribute at least 10 percent of the residents to hospitals in category 4. For distributing the remaining section 126 positions in years 4 and 5, CMS proposed to prioritize hospitals qualifying under category 4 regardless of HPSA score.

While there were comments in support of this proposal, many commenters stated that CMS has not addressed the structural shortcoming of the HPSA prioritization distribution methodology. Commenters urged CMS to prioritize slot distribution based solely on the four categories included in the law because they believe such an approach is consistent with the statute. Other commenters suggested CMS prioritize applications from geographically rural hospitals regardless of HPSA score or smaller hospitals over larger hospitals. There were also comments concerned that prioritizing based on HPSA score would disadvantage hospitals in the other three qualifying categories.

CMS did not explicitly address comments regarding the shortcomings of using HPSAs as a prioritization category. However, it did note that it is not amending the prioritization methodology for rounds 4 and 5 of section 126 to consider the number of eligibility categories that a hospital meets. For this reason, hospitals in other categories will not be disadvantaged by CMS' proposal but the agency does not believe that its original policy alone is sufficient to result in the minimum 10 percent of residents slots being distributed to hospitals that serve patients from HPSAs.

In response to prioritizing smaller hospitals over larger hospitals, CMS indicates that it finalized such a policy in the event of a tiebreaker in the FY 2022 IPPS final rule when implementing section 126. With respect to the comments about whether CMS' proposal is consistent with statute, CMS responded that it is necessary to take action now to ensure the statutory 10 percent distribution requirement is met upon completion of all distribution rounds for resident awards under section 126. Congress required 10 percent of the additional resident slots be awarded to hospitals within each of the prioritization categories. As those requirements were not met after the round 1 and round 2 distributions, CMS must change the prioritization in an attempt to meet the statutory goal.

CMS is finalizing its policy as proposed with respect to prioritizing hospitals that qualify under Category Four regardless of HPSA score for rounds 4 and 5 of section 126. The remaining slots awarded under rounds 4 and 5 will be distributed to hospitals qualifying under Category One, Category Two, or Category Three, or hospitals that meet the definitions of more than one of these categories, based on the HPSA score associated with the program for which each hospital is applying.

Hospital Attestation to National Culturally and Linguistically Appropriate Services (CLAS) Standards. Consistent with a requirement that CMS established for distributing additional resident positions under the section 126 of the CAA, 2021, CMS proposed that a hospital must attest to meeting the CLAS standards to be eligible to receive additional resident positions under section 4122(a) of the CAA, 2023. There were no public comments on this proposal that CMS is finalizing without change.

Medicare Payment for Additional Resident Positions. Some hospitals will have two PRAs—one for residents in primary care and obstetrics and gynecology, and one for all other residents. The two PRAs resulted from a statutory provision in the 1990s that only allowed an inflation update for two years to the PRA for residents training in primary care and obstetrics and gynecology. If a hospital's PRA was established after this point, the hospital will only have a single PRA for all

residents. If the hospital has two PRAs, the statute requires that CMS use the PRA for all other residents to pay for the additional residents awarded under section 4122. CMS proposed to use the PRA for all other residents for additional resident slots consistent with the statutory provision. There were no public comments on this proposal that CMS is finalizing without change.

Affiliation Agreements. Hospitals are permitted to aggregate their resident caps to facilitate cross training among multiple hospitals. However, the statute limits hospitals including residents awarded under section 4122 from being included in these affiliation agreements for five years. CMS' proposal was consistent with this statutory provision. There were no public comments on this proposal that CMS is finalizing without change.

3. Other GME Provisions

New Medical Residency Training Program. When the Balanced Budget Act (BBA) of 1997 capped the number of residents a hospital may count for DGME and IME, it also provided authority for CMS to establish rules that allowed the caps to be adjusted for hospitals that had not previously trained residents and established "new medical residency training programs." In order to address a concern that hospitals could move an existing program to a new teaching hospital in order to train more residents at its own hospital inconsistent with the BBA 1997, CMS defined the term "new medical residency training program."

The three primary criteria are that: (1) the residents are new, (2) the program director is new, and (3) the teaching staff are new. Over the years, CMS has received questions as to whether a program may still be considered new if the three criteria were partially but not fully met. CMS has responded that a residency program's newness would not be compromised as long as the "overwhelming majority" of the residents or staff are not coming from previously existing programs in that same specialty. CMS used the FY 2025 IPPS proposed rule to further clarify its policy on what it means for a medical residency training program to be "new."

a) Residents: CMS proposed to define "overwhelming majority" as meaning at least 90 percent of the individual resident trainees (not FTEs) must not have previous training in the same specialty as the new program. If more than 10 percent of the trainees (not FTEs) transferred from another program at a different hospital/sponsor in the same specialty, even during their first year of training, CMS proposed that this would render the program as a whole (but not the entire hospital or its other new programs, if applicable) ineligible for new cap slots.

   The proposed rule indicated that the 90 percent criterion may be more difficult for small or rural-based programs to meet. For this reason, CMS requested comment on whether to define a "small residency program" as one that is accredited for fewer than 16 positions.

b) Program Director and Faculty: CMS recognizes that a new medical residency program may want to recruit a director and faculty with prior experience so believes that a criterion of less than 90 percent should be applicable. However, CMS believes that there should be at least some threshold percentage to avoid recruiting only experienced staff

from an existing residency program that could threaten the existing program's viability. CMS did not propose a specific threshold but suggested that up to 50 percent of the faculty in a new program may come from an existing program in the same specialty but each of those staff members should come from a different previously existing program.

CMS has also been asked whether it would make a difference if a faculty member had previous teaching experience, but a certain amount of time has passed since they taught in a program in the same specialty (for example, because they accepted a non-teaching job in a different hospital, or the program where they previously taught has ceased to operate). The proposed rule indicated that in determining whether the presence of a faculty member might jeopardize the newness of a new residency program, it may make sense to consider whether a certain amount of time has passed since that faculty member last taught in another program in the same specialty. CMS requested comments on whether 10 years, or some other amount of time, would be an appropriate period during which a faculty member should not have had experience teaching in a program in the same specialty in order to be considered "new."

Similarly, CMS understands that a new teaching hospital may also want to recruit an experienced program director. The proposed rule solicited comments on whether it would make sense to define a similar period of time (for example, 5 or 10 years) during which an individual must not have been employed as the program director in a program in the same specialty in order to be considered a "new" program director.

CMS raised a similar concern in the proposed rule about whether special provisions are necessary for small or rural-based programs and solicited comment on whether these thresholds should be different for programs that are accredited fewer than 16 positions.

CMS is not finalizing any of the above proposals regarding a more specific definition of "new medical residency training program." There were many comments on these issues with significant objections to the proposals (including on the two issues that follow). As a result, CMS is presenting but not responding to the comments to allow for further public consideration of these issues in advance of potential future rulemaking.

While there were many comments supportive in principle of more specific criteria to define a new medical residency training program, commenters generally opposed the specific provisions CMS proposed. A sample of some of the comments include:

- The proposals would be administratively burdensome, ineffective at preventing the transfer of existing programs or the duplication of FTE cap slots, and detrimental to graduate medical education in general and in particular to small and rural residency programs.
- Prior training or employment history for faculty and program directors are extraneous to CMS' central concerns about whether a program has been transferred and whether FTE cap slots may have been duplicated.
- Transfer of residents and recruitment of faculty and program directors are already regulated by entities such as the Accreditation Council on Graduate Medical Education,

the American Board of Medical Specialties and the National Resident Matching Program. Commenters urged CMS to defer to the judgment and expertise of those organizations.

- CMS should use a "reasonable person standard" in assessing whether or not a program is new and/or require an attestation from the hospital that the program has not been transferred and that it does not duplicate FTE cap slots associated with an existing program.
- CMS should consider the relationship between the new program and the program that appears to have been transferred or duplicated. For example, if the original program remains open for a minimum of one full academic year, then the second program should be considered new.
- CMS should create exceptions to the newness criteria for small and rural programs and programs in urban underserved areas.
- It is common for new rural programs, including Rural Track Programs, to accept a higher proportion of non-program year 1 residents as a means of "jump starting" the program and promoting stability. If even 1 resident is not new in such a program, the program could fail to meet the 90 percent criterion (although CMS did propose exceptions for small programs to the 90 percent criterion for this precise reason).

Given the lack of consensus in the public comments, CMS is initiating a request for information seeking comment on the appropriate criterion regarding newness of residents.[53] CMS says commenters should review and consider the broad statutory authority provided to the Secretary in this area, CMS prior rulemaking on this issue, and all of the public comments on this final rule.

Comingling of Residents. This issue is very complex to understand but CMS appears to be concerned about what happens when a program is new and eligible for a cap adjustment but rotates residents to a hospital with an existing program that is eligible for a cap adjustment by virtue of being treated as rural.[54] CMS appears to believe that this "comingling" of residents in a new and existing program allows an existing program to increase residents even though it is not new. CMS requested comments on this issue. No comments were presented and no action is being taken.

One Hospital Sponsoring Two Programs in the Same Specialty. CMS has responded to questions about whether a single hospital can sponsor two programs in the same specialty by saying that if each program in fact has separate program directors, and separate staff, and separately matched residents, then it is permissible for one hospital to sponsor two programs in the same specialty. Again, CMS appears to be concerned about creating FTE caps for new medical residency training program that may not truly be new at hospitals with an urban-to-rural reclassification and requested comments on the issue. No comments were presented on this issue and no action is being taken.

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[53] While there is an explicit request for information in this section of the rule, the agency action on this rule is designated as "Final Rule" rather than "Final Rule with Comment" and the rule provides no deadline for submitting public comments.

[54] This will only affect IME as the urban-to-rural reclassification provision only applies to section 1886(d) of the Act that includes IME and not section 1886(h) of the Act that applies to DGME.

Notice of Closure of Teaching Hospital and Opportunity to Apply for Available Slots. Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency slots after closure of a hospital that trained residents in an approved medical residency program.

CMS is notifying the public of the closure of Sacred Heart Hospital located in Eau Claire, Wisconsin:

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
520013	Sacred Heart Hospital	Eau Claire, WI	20740	March 22, 2024	7.62	7.80

Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 is 90 days following notification to the public of a hospital closure. Therefore, hospitals must submit an application form to the CMS Central Office **no later than October 30, 2024** to be eligible to receive slots from this closed hospital.

CMS will only accept applications submitted via MEARIS™ (MEARIS™ (cms.gov)). Applications submitted through any other method will not be considered. CMS has not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506. However, CMS reviews all applications received by the deadline and will notify applicants of its determinations as soon as possible.

Core-Based Statistical Area (CBSA) Changes and Application to GME Policies. CMS did not propose any new policies in this area but notes that the new CBSA delineations may have implications for GME policies that are linked to whether a hospital is urban or rural. Such policies include adjustments to caps for rural hospitals and urban hospital residency programs that provide rural training, among others. CMS refers readers to the FY 2015 IPPS PPS final rule (79 FR 50111 through 50113) to learn more about CMS' policies regarding changes to the CBSAs and how IME and DGME payments are affected.

G. Nursing and Allied Health Education

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.[55]

3. Implementation for 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. In the FY 2023 IPPS final rule, CMS indicated that for 2022 and after it would propose and finalize respective nursing and allied health MA rates and direct GME percent reductions in the annual IPPS rule.

4. Proposal for 2023

CMS proposed to use the 4th quarter 2023 update of the 2021 HCRIS projected forward two years to estimate 2023 payments. CMS indicated that it would update this information using later data available for the final rule. For 2023, CMS will be distributing $60 million in nursing and allied health education MA payments with an offset of 2.74 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. The only comments CMS received were out-of-scope. The policy is being finalized without change.

H. CAR-T Cell Therapy and Immunotherapy

In some cases, the CAR-T cell or other immunotherapy patients may be part of a clinical trial where the high-cost therapy product is furnished to the hospital at no cost. Beginning with FY 2021, CMS adopted a differential payment for these cases to recognize hospitals' lower costs. CMS has also excluded CAR-T cases from the relative weight calculation where the hospital has no costs for the CAR-T product.

CMS proposed to adopt these same policies for FY 2025. Using the FY 2023 data for determining the final rule FY 2025 IPPS relative weights, the average costs of cases assigned to

[55] CMS also went more than 15 years without updating the payments made for MA nursing and allied health education and the adjustments to MA DGME payments. CMS paid more than the $60 million limitation for MA nursing and allied health education and reduced MA DGME payments more than authorized by statute. These issues were addressed in subsequent change requests that refunded money owed for MA DGME and legislation that either precluded recoupment or allowed hospitals to retain the MA nursing and allied health education overpayments.

MS-DRG 018 that are identified as clinical trial cases ($111,211) were 33 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($334,119). Accordingly, CMS is adjusting the payment for MS-DRG 018 by applying an adjustor of 0.33 to the full payment amount in those situations where the hospital does not have a cost for the CAR-T or other immunotherapy product.

I. IPPS Add-On for End-Stage Renal Disease (ESRD) Discharges

Under current regulations, Medicare provides an add-on payment to hospitals where they provide kidney dialysis to more than 10 percent of their patients where the patient is not receiving a kidney transplant or has a principal diagnosis of renal failure. The add-on equals the product of the average length of stay of ESRD beneficiaries in the hospital, expressed as a ratio to 1 week, the estimated per treatment cost of dialysis times three (as maintenance dialysis is typically furnished three times per week) and the number of patients where the add-on is applicable. The add-on payment is intended to reflect the additional costs hospitals have of providing kidney dialysis to these patients and is based on the payment rate made to ESRD facilities for maintenance kidney dialysis.

The average direct cost of dialysis was determined from data used to establish the ESRD dialysis composite rate paid to ESRD facilities that provide outpatient maintenance dialysis. This rate has not been updated since 2013 when payment to dialysis facilities reflected a blend of the ESRD PPS payment system and the composite rate. CMS proposed to change the methodology used to calculate the ESRD add-on payment under current regulations to the ESRD PPS base rate used under the ESRD PPS beginning October 1, 2024 for FY 2025. For subsequent years, CMS will use the updated ESRD PPS base rate for the ESRD add-on payment. Public comments supported CMS' proposal that it is finalizing without change.

J. Maintaining Access to Essential Medicines

1. Overview

The proposed rule indicated that over the last few years, shortages for critical medical products have persisted and continued to increase. CMS believes it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries.

In the 2024 OPPS proposed rule, CMS requested comment on separate payment under the IPPS and OPPS for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. The majority of commenters did not support making a reasonable cost payment to maintain a buffer stock of essential medicines because of concerns about exacerbating existing drug shortages or causing demand-driven shortages.

Considering these comments, CMS proposed to only establish a separate payment under the IPPS to small (100 beds or fewer), independent hospitals for the estimated additional resource costs of voluntarily establishing and maintaining access to 6-month buffer stocks of essential

medicines. CMS is focusing this policy on small, independent hospitals, many of which are rural, because these hospitals may lack the resources available to larger hospitals and hospital chains to establish and maintain buffer stocks of essential medicines for use in the event of drug shortages. By limiting separate payment to smaller, independent hospitals, CMS believes it will mitigate concerns raised by commenters regarding large demand driven shocks to the supply chain.

CMS proposed that a hospital that newly establishes a buffer stock of a medicine while it is in shortage would not be eligible for separate buffer stock payment for the duration of the shortage. However, if a hospital had already established and was maintaining a buffer stock of that medicine prior to the shortage, CMS proposed that the hospital would continue to be eligible for separate buffer stock payment for the duration of the shortage even as the hospital draws down that buffer stock and has less than 6 month supply in inventory. Once an essential medicine is no longer listed as "Currently in Shortage" in the FDA Drug Shortages Database, CMS' policy will not differentiate the essential medicine from others. Hospitals would be eligible to establish and maintain buffer stocks for the medicine as they would have before the shortage. A hospital that draws down the buffer stock to less than 6 month supply outside of a drug shortage for that medicine would be ineligible for the separate payment.

2. List of Essential Medicines

CMS proposed to use a list of 86 essential medicines included on the Advanced Regenerative Manufacturing Institute's (ARMI) Next Foundry for American Biotechnology as those that would be eligible for the additional payment. The medicines included in the ARMI List were considered, by consensus, to be most critically needed for typical acute patient care.

CMS proposed that if the ARMI list is updated to add or remove any essential medicines, all medicines on the updated list would be eligible for separate payment as of the update date. The proposed rule explicitly requested comment on the timing for incorporating updates and whether other drugs that are not typically used on an inpatient basis and are not on the ARMI list (such as oncology drugs or drugs to treat substance abuse disorder) should be eligible for this additional payment.

Because a medicine can remain on the FDA Drug Shortage Database for years, CMS requested comments on the duration that CMS should continue to pay hospitals for the maintenance of less than 6-month buffer stock of the essential medicine if it is "Currently in Shortage." CMS also requested comments on if there is a quantity or dosage minimum floor where Medicare should no longer pay to maintain a 6-month buffer stock of the essential medicine if it is "Currently in Shortage."

3. Hospital Eligibility

CMS proposed that eligible hospitals for this policy are those with 100 beds or fewer and are independent. This criterion is consistent with the MDH provisions that identify a small hospital as under 100 beds. CMS proposed that the 100 bed determination for eligibility for the policy will be from the same cost reporting period during which the hospital is seeking the separate

payment. CMS proposed that an "independent hospital" is one that is not part of a chain organization as defined for purposes of hospital cost reporting.

CAHs are paid 101 percent of reasonable costs for inpatient and outpatient services including the costs of maintaining a buffer stock on essential medicines. CMS requested comment in the proposed rule on the use of buffer stocks established or maintained by CAHs.

4. Size of the Buffer Stock

In response to the comment solicitation on the 2024 OPPS proposed rule, some commenters said drug shortages often persist for more than 3 months, making a 3-month buffer stock inadequate for providing essential medicines in shortage. CMS agrees and proposed that eligible hospitals maintain a 6-month buffer stock of essential medicines in shortage although it requested comment on whether to transition to this policy over two years: 3 months the first year and 6 months the second year.

5. Payment

Public comments on the 2024 OPPS rule indicated that hospitals typically lack the capacity to stockpile large quantities of essential medicines directly. Some of these commenters stated that any buffer stocks established under the potential policy should be maintained by upstream intermediaries or a neutral third party that is generally better positioned and equipped to maintain such an inventory. CMS proposed to allow a qualifying hospital to either receive payment for directly maintaining a buffer stock of essential medicines or contracting with an upstream entity to do so.

CMS requested comment in the proposed rule on a number of items that may be considered allowable costs for separate payment:

- Utilities like cold chain storage and heating, ventilation, and air conditioning, warehouse space, refrigeration, management of stock including stock rotation, managing expiration dates, and managing recalls, administrative costs related to contracting and record-keeping, and dedicated staff for maintaining the buffer stock(s);
- Whether staff costs would increase with the number of essential medicines in buffer stock, and if there would be efficiencies if multiple hospitals elect to establish buffer stocks of essential medicines with the same pharmaceutical manufacturer, intermediary, or distributor.

CMS proposed to base payment on the IPPS share of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock. The hospital would report these costs to CMS on a forthcoming supplemental cost reporting worksheet. These costs would not include the costs of the essential medicine itself, which would continue to be paid in the current manner. Payment could be provided as a lump sum at cost report settlement or biweekly as interim lump-sum payments to the hospital which would be reconciled at cost report settlement.

Public comments were received in the following areas:

Eligible Hospitals: The majority of commenters were generally supportive of the proposal. Those that were opposed to the proposal raised the same concerns regarding the potential to induce new drug shortages or exacerbate existing shortages. Many commenters requested that CMS expand the hospitals that are eligible for the policy.

CMS responded that it continues to believe that the pool of eligible hospitals is sufficiently small and has significantly less purchasing power than larger hospitals and hospital chains, such that the policy would not create such demand shocks or result in fragmentation that would cause or exacerbate shortages. For similar reasons, CMS disagrees with expanding the pool of eligible hospitals in the initial implementation of the policy. CMS may consider any future modifications to the scope of eligible hospitals, including potential expansions to hospitals with larger bed counts or certain provider types, as it gains experience under this policy.

Domestic Manufacturing: Some commenters requested that only domestically produced drugs be eligible for the subsidy similar to the domestic add-on payment for National Institute of Occupational Safety and Health approved surgical N95 respirators. As CMS gains experience under the policy and as the domestic manufacturing capacity of essential medicines increases, CMS may consider a domestic manufacturing requirement for future rulemaking.

Size of the Buffer Stock: There were comments in support of phasing in the buffer stock requirement from 3 to 6 months or just leaving it at 3 months given the upfront costs associated with establishing a buffer stock could be significant for a small hospital. CMS responded that the longer 6-month buffer stock would provide manufacturers with more time to increase production of an affected medicine although it may revisit this issue in future rulemaking.

Administrative Burden: Commenters were generally opposed to the use of a supplemental cost reporting form to report the costs associated with establishing and maintaining a buffer stock, stating that this would increase administrative and recordkeeping costs for participating hospitals. Some commenters requested that CMS permit contracted manufacturers, distributors, and intermediaries to directly report the costs associated with establishing and maintaining a buffer stock for a hospital to CMS.

CMS responded that it continues to believe that the Medicare cost report is the most feasible and least burdensome method of collecting and auditing cost information. To minimize burden, CMS will use the MACs to inform hospitals of drugs in shortage quarterly.

Maintenance of a Buffer Stock for a Drug In Shortage: Some commenters stated that continuing to pay for any amount of a buffer stock after a drug is listed as “Currently in Shortage” incents unnecessary retention of stock and potential for hoarding. Several commenters stated that CMS should not limit the amount of time that CMS will continue to pay for the buffer stock when it is listed as “Currently in Shortage.” Others commented that CMS should limit payments to 6 months after the drug has entered shortage. There were also comments requesting that CMS continue pay for drugs if buffer stock drops to under a 6-month reserve.

CMS responded that a small, independent hospital may be more likely to be in a position where they would need to draw down their buffer stock below a 6-month supply during a shortage because these hospitals may lack sufficient purchasing power to readily obtain these drugs, as compared to larger hospitals and hospitals that are part of chains. Taking these factors into account, CMS will continue to separately pay for the reasonable costs of maintaining an already established buffer stock after a drug enters shortage even if the number of months of supply of that medicine in the buffer stock drops to less than 6 months during the shortage. For the same reasons, CMS will continue to pay for the reasonable costs of maintaining the buffer stock after an essential medicine is listed as "Currently in Shortage."

Use of ARMI List as Source for Drugs in Shortage: Many commenters supported the use of the ARMI list of essential medicines developed in 2022. Some commenters proposed using other lists or including products that are not included in the ARMI list (for example, oncology drugs; blood and blood products). CMS responded that the medicines included in the ARMI List were considered, by consensus, to be most critically needed for typical acute patient care.

FDA as the Source of Drug Shortages: Many comments said the FDA's Drug Shortage Database is not sensitive to regional shortages. It is possible that hospitals may have to draw down their buffer stock(s) below 6 months in size for a regional shortage, despite the medicine not being listed as "Currently in Shortage" on the FDA's Drug Shortage Database. Commenters also stated that the FDA's Drug Shortage Database tends to only capture the most extreme of shortages and may not be sensitive to other supply challenges that hospitals face. Commenters recommended American Society of Health System Pharmacists' (ASHP's) Drug Shortages List as an alternative to the FDA Drug Shortage Database.

CMS considered this issue before proposing the policy. The FDA's definition considers the entire United States market supply from all manufacturers combined based on manufacturer reporting of their inventory and production for the potentially medically necessary use(s) at the patient level. By contrast, CMS understands the ASHP list defines a shortage as a supply issue that affects how a pharmacy prepares or dispenses a drug product, and would post a shortage if one manufacturer was out of stock even if the other manufacturers are able to cover the supply gap.

Miscellaneous Issues: CMS responded to comments on miscellaneous issues indicating:

- It will not delay the effective date beyond October 1, 2024 to allow manufacturers to ramp up production. The policy is entirely voluntary on the part of eligible hospitals.
- The Medicare inpatient share of costs under this policy does not include Medicare Advantage.
- Eligible hospitals that elect to maintain a shared buffer stock of essential medicines with other eligible hospitals may receive separate payment for establishing and maintaining the shared buffer stock only if all of the requirements for payment under this policy are met independently by each hospital.
- The costs of establishing and maintaining a buffer stock of an essential medicine do not include the cost of the essential medicine itself, meaning that the cost of compounding

would not be included in the cost for establishing and maintaining a buffer stock of an essential medicine.

CMS is finalizing all policies as proposed.

K. Hospital Readmissions Reduction Program (HRRP)

The HRRP is established under section 1886(q) of the Act.[56] 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 2025 are unchanged from FY 2024: 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 proposed rule for the HRRP.

The estimated percentage of hospitals that will be penalized under the HRRP for the FY 2025 HRRP is 82.81 percent (2,342 of the 2,828 hospitals), with total penalties for all such penalized hospitals estimated to be 0.42 percent of total payments for such hospitals.[57]

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

In the rule, CMS finalizes:

- Adoption of the updated Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure[58] (and scoring modifications) beginning with the FY 2030 program year after the updated survey has been publicly reported under the Hospital Inpatient Quality Reporting (IQR) program for 1 year. The updated survey is finalized as a crosscutting quality program policy under section IX.B.2 of the rule and discussed in detail under section IX.B.2 of this summary.
- Modifying the scoring of the HCAHPS Survey measure from the FY 2027 through FY 2029 program years so that hospitals are able to administer the updated survey for both the Hospital IQR and HVBP programs (rather than 2 different surveys) beginning with January 1, 2025 discharges, but for the HVBP program only be scored on the 6

[56] 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.

[57] See Table I.G.7.-01 in Appendix A of the final rule. CMS bases its analysis on the proportion of dual-eligible stays among Medicare FFS and managed care stays between July 1, 2020 and June 30, 2023.

[58] For background on how the HCAHPS Survey makes up a single "measure," see section IX.B.2.a of this summary.

dimensions of the survey that will remain unchanged for the FY 2027 through FY 2029 program years. These updated scoring modifications are finalized in section IX.B.2.f of the rule and discussed in detail in section IX.B.2.c of this summary.

CMS also provides previously and newly established performance standards for the FY 2027 through FY 2030 program years.

The impact analysis of base operating DRG payment amounts resulting from the FY 2025 HVBP Program that was included in the proposed rule is shown in Table 16 of the rule. The estimates were calculated using the FY 2024 program year's Total Performance Scores. Updated proxy value-based incentive payment adjustment factors calculated since the proposed rule are shown in Table 16A of the final rule to reflect changes based on the March 2024 update to the FY 2023 MedPAR file.[59] The analysis shows that for the 2,471 hospitals an average net percentage positive payment adjustment of 0.135 percent.

1. Background

a. Program Overview[60]

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

The HVBP Program measure set is specified by CMS through rulemaking for each program (i.e., payment) year. Each hospital's TPS is calculated by summing the greater of the hospital's achievement or improvement points for each measure then creating domain scores that 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.

b. FY 2025 Program Year Payment Details

The estimated amount of base operating MS-DRG payment reductions for the FY 2025 program year (and also the amount available for the FY 2025 VBP incentive payments) is approximately $1.67 billion, based on the March 2024 update of the FY 2023 MedPAR file.

[59] Note that the updated proxy adjustment factors will not be used to adjust hospital payments. CMS will add a new table, Table 16B, to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2025 Hospital VBP Program. That Table 16B is expected to be posted on the CMS website in the fall of 2024.

[60] Further detail on the program's requirements may be found under §§412.160 through 412.168. Additional information on the program is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/HVBP/Hospital-Value-Based-Purchasing and https://qualitynet.cms.gov/inpatient/hvbp.

2. Previously Adopted Quality Measures for the HVBP Program

No changes were proposed to the FY 2025 measure set.

Table V.L-01 in the rule shows the previously adopted measures for the FY 2025 program year and Table V.L-02 in the rule shows the previously adopted measures for the FY 2026 through FY 2030 program years. The below table consolidates the information.

Measure	CBE[61] #	2025	2026-2030
Clinical Outcomes Domain			
Acute Myocardial Infarction (AMI) 30-day mortality rate	0230	X	X
Heart Failure (HF) 30-day mortality rate	0229	X	X
Pneumonia (PN) 30-day mortality rate	0468	X	X
Complication rate for elective primary total hip arthroplasty/total knee arthroplasty (COMP-HIP-KNEE)	1550		X
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate	1893	X	X
Coronary Artery Bypass Graft (CABG) 30-day mortality rate	2558	X	X
Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)**	1550	X	X**
Safety Domain			
NHSN Central Line Associated Blood Stream Infection (CLABSI)	0139	X	X
NHSN Catheter Associated Urinary Tract Infection (CAUTI)	0138	X	X
Colon and Abdominal Hysterectomy Surgical Site Infections (SSI)	0753	X	X
NHSN Methicillin-Resistant *Staphylococcus Aureus* (MRSA) Bacteremia	1716	X	X
Clostridium Difficile Infection (CDI)	1717	X	X
Severe Sepsis and Septic Shock: Management Bundle (SEP-1)	0500		X
Person and Community Engagement Domain			
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) *** Communication with Nurses Communication with Doctors Responsiveness of Hospital Staff Communication About Medicines Cleanliness and Quietness of Hospital Environment Discharge Information Overall Rating of Hospital 3-Item Care Transition measure (CTM)	0166 (0228)	X	X
Efficiency and Cost Reduction Domain			
Medicare Spending per Beneficiary (MSPB)*	2158	X	X*

* Substantive updates to the MSPB measure will begin with FY 2028 program year.
** Substantive updates to the THA/TKA Complications measure will begin with the FY 2030 program year.
*** In sections IX.B.2.f and IX.B.2.g of the rule, several updates are finalized with regard to the HCAHPS Survey in the Hospital VBP Program, including modifying scoring while the updated version of the measure will be adopted in the Hospital IQR Program for the FY 2027 through FY 2029 program years. CMS is also adopting the updated version of the measure and modifying the scoring to account for the updates in the HVBP Program beginning in FY2030. See Table IX.B.2-03 in section IX.B.2.g(2) of the rule for the timelines for current and newly finalized HCAHPS Survey dimensions for the HVBP Program.

[61] Consensus-based entity identifier number for endorsed measures.

3. Baseline and Performance Periods for the FY 2026 Through FY 2030 Program Years

The below table shows the baseline and performance periods for FY 2026 through FY 2030 by combining information provided in Tables V.L-03 through V.L-07 in the rule.

Baseline and Performance (Perf.) Periods by Measure for the FYs 2026 Through 2030 Program Years										
Measure	Baseline Period 2026	Perf. Period 2026	Baseline Period 2027	Perf. Period 2027	Baseline Period 2028	Perf. Period 2028	Baseline Period 2029	Perf. Period 2029	Base-line Period 2030	Perf. Period 2030
Person and Community Engagement Domain										
HCAHPS	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23 *	1/1/25-12/31/25 *	1/1/24-12/31/24 *	1/1/26-12/31/26 *	1/1/25-12/31/25 *	1/1/27-12/31/27 *	1/1/26-12/31/26 *	1/1/28-12/31/28 *
Safety Domain										
CAUTI	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23	1/1/25-12/31/25	1/1/24-12/31/24	1/1/26-12/31/26	1/1/25-12/31/25	1/1/27-12/31/27	1/1/26-12/31/26	1/1/28-12/31/28
CLABSI	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23	1/1/25-12/31/25	1/1/24-12/31/24	1/1/26-12/31/26	1/1/25-12/31/25	1/1/27-12/31/27	1/1/26-12/31/26	1/1/28-12/31/28
SSI	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23	1/1/25-12/31/25	1/1/24-12/31/24	1/1/26-12/31/26	1/1/25-12/31/25	1/1/27-12/31/27	1/1/26-12/31/26	1/1/28-12/31/28
CDI	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23	1/1/25-12/31/25	1/1/24-12/31/24	1/1/26-12/31/26	1/1/25-12/31/25	1/1/27-12/31/27	1/1/26-12/31/26	1/1/28-12/31/28
MRSA	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23	1/1/25-12/31/25	1/1/24-12/31/24	1/1/26-12/31/26	1/1/25-12/31/25	1/1/27-12/31/27	1/1/26-12/31/26	1/1/28-12/31/28
SEP-1	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23	1/1/25-12/31/25	1/1/24-12/31/24	1/1/26-12/31/26	1/1/25-12/31/25	1/1/27-12/31/27	1/1/26-12/31/26	1/1/28-12/31/28
Clinical Outcomes Domain										
MORT-30-AMI	7/1/16–6/3/19	7/1/21–6/30/24	7/1/17-6/30/20 **	7/1/22-6/30/25	7/1/18-6/30/21 **	7/1/23-6/30/26	7/1/19-6/30/22 **	7/1/24-6/30/27	7/1/20-6/30/23	7/1/25-6/20/28
MORT-30-HF	7/1/16–6/3/19	7/1/21–6/30/24	7/1/17-6/30/20 **	7/1/22-6/30/25	7/1/18-6/30/21 **	7/1/23-6/30/26	7/1/19-6/30/22 **	7/1/24-6/30/27	7/1/20-6/30/23	7/1/25-6/20/28
MORT-30-COPD	7/1/16–6/3/19	7/1/21–6/30/24	7/1/17-6/30/20 **	7/1/22-6/30/25	7/1/18-6/30/21 **	7/1/23-6/30/26	7/1/19-6/30/22 **	7/1/24-6/30/27	7/1/20-6/30/23	7/1/25-6/20/28
MORT-30-CABG	7/1/16–6/3/19	7/1/21–6/30/24	7/1/17-6/30/20 **	7/1/22-6/30/25	7/1/18-6/30/21 **	7/1/23-6/30/26	7/1/19-6/30/22 **	7/1/24-6/30/27	7/1/20-6/30/23	7/1/25-6/20/28
MORT-30-PN	7/1/16–6/3/19	7/1/21–6/30/24	7/1/17-6/30/20 **	7/1/22-6/30/25	7/1/18-6/30/21 **	7/1/23-6/30/26	7/1/19-6/30/22 **	7/1/24-6/30/27	7/1/20-6/30/23	7/1/25-6/20/28
COMP-HIP-KNEE	4/1/16–3/31/19	4/1/21–3/31/24	4/1/17-3/31/20 **	4/1/22-3/31/25	4/1/18-3/31/21 **	4/1/23-3/31/26	4/1/19-3/31/22 **	4/1/24-3/31/27	4/1/20-3/31/23	4/1/25-3/31/28
Efficiency and Cost Reduction Domain										
MSPB	1/1/22–12/31/22	1/1/24–12/31/24	1/1/23-12/31/23	1/1/25-12/31/25	1/1/24-12/31/24	1/1/26-12/31/26	1/1/25-12/31/25	1/1/27-12/31/27	1/1/26-12/31/25	1/1/28-12/31/28
Source: Tables V.L.-03 through V.L.-07 in the rule, excerpted and combined by HPA										

* In section IX.B.2.f of the rule, CMS finalizes that for the FY 2027, FY 2028, and FY 2029 program years, it will only score on the 6 dimensions of the HCAHPS Survey that will be unchanged from the current version. In section IX.B.2.g of the rule, CMS finalizes adoption of the substantive updates to the HCAHP Survey beginning with the FY 2030 program year.

** These baseline periods are impacted by the Extraordinary Circumstances Exception (ECE) granted on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020-March 31, 2020 (Q1 2020) and April 1, 2020-June 30, 2020 (Q2 2020) from the claims-based complication, mortality, and CMS PSI 90 measures. See the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297-45299).

4. Performance Standards for the HVBP Program

The previously established and newly estimated performance standards for the measures, including with the HCAHPS Survey modifications newly finalized, in the FY 2027, FY 2028, FY 2029, and FY 2030 program years are set out in Tables V.L-08 through V.L-12 of the rule.

As described in section IX.B.2.g of the rule, the agency is finalizing adoption of the updated version of the HCAHPS Survey measure for use in the HVBP Program beginning in FY 2030.

Since the updated survey will be used in the Hospital IQR Program before adoption in the HVBP Program, in order to ease the burden of having to report two different surveys, CMS finalizes its proposed method to enable hospitals to report a single survey for both programs. Under section IX.B.2.f of the rule, CMS finalizes its policy to modify the scoring of the HCAHPS Survey for the FY 2027 through FY 2029 program years because the (i) Responsiveness of Hospital and (ii) Care Transition dimensions are excluded while the updated survey is publicly reported under the Hospital IQR Program for one year, as required by statute. Scoring will be modified to score hospitals only on the following 6 HVBP Program dimensions of the survey (which will remain unchanged from the current version): Communication with Nurses, Communication with Doctors, Communication about Medicines, Discharge Information, Cleanliness and Quietness, and Overall Rating. Specifically, scoring will be modified such that the achievement points (0-10) and improvement points (0-9) will be calculated for each of the 6 remaining dimensions, the larger of which will be summed up across the dimensions, resulting in a base score of 0-60 points (as compared to 0-80 points). That score will then be multiplied by 8/6 to establish the normalized HCAHPS base score, ranging from 0-80 points. HCAHPS consistency points (ranging from 0-20) will be calculated without change and added to the normalized base score (as is currently) for a total score that ranges from 0-100 points.

The finalized updated HCAHPS Survey measure scoring under the Hospital VBP Program for the FY 2027 through 2029 programs years is discussed in further detail under section IX.B.2.c of the summary and the finalized updated HCAHPS Survey measure policies under the program beginning with the FY 2030 program year are discussed in further detail under section IX.B.2.d of the summary.

M. Hospital-Acquired Conditions (HAC) Reduction Program

CMS did not in the proposed rule make any proposals or updates for the HAC Reduction Program.

CMS estimates that for the FY 2024 HAC Reduction Program, out of 2,933 hospitals, 732 hospitals will be included in the worst-performing quartile (and subject to the program's penalty).

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 2025 and Subsequent Years[62]

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 2025 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).

[62] Technical specifications for the CDC NHSN HAI measures can be found at http://www.cdc.gov/nhsn/acute-care-hospital/index.html and at https://qualitynet.cms.gov/inpatient/measures/hai/resources. Technical specifications for the CMS PSI 90 measure can be found at https://qualitynet.cms.gov/inpatient/measures/psi/resources.

N. Rural Community Hospital Demonstration Program

1. Background

The Rural Community Hospital Demonstration program allows up to 30 rural community hospitals to receive reasonable cost payment for covered inpatient hospital services furnished to Medicare beneficiaries. The program has been in place since January 1, 2005 with a statutory expiration date that has been extended three times, most recently by section 128 of the Consolidated Appropriations Act, 2021 (CAA 2021). Expiration of the program for individual hospitals will vary based on the hospital's cost reporting period and when it began participating in the program but will generally be 5 years from when the program was last extended or the hospital first began participating. The period of participation for the last hospital under the CAA, 2021 authority would extend until June 30, 2028.

The statute requires CMS to make the demonstration program budget neutral by applying an adjustment to IPPS rates that affects all hospitals rather than only demonstration program participants. CMS describes the budget neutrality calculation in detail. In summary, CMS compares reasonable cost payments to what IPPS payments would have been in the absence of the demonstration. IPPS rates are adjusted for the difference. Interim reasonable cost payments from as submitted cost reports are initially used and then later reconciled as cost reports become final.

2. FY 2025 Budget Neutrality Adjustment

CMS continues to use the general budget neutrality methodology applied in previous years, and it identifies 22 hospitals currently participating in the program.[63] Using data from "as submitted" cost reports with a cost report end date in CY 2022, CMS estimates for FY 2025 that the demonstration program will cost $49,914,526, which will be incorporated into the budget neutrality offset adjustment for FY 2025.

Using data from finalized cost reports for the 27 hospitals that completed cost reporting periods beginning in FY 2019 under the demonstration payment methodology, CMS determined the actual costs of the demonstration for FY 2019 to be $40,429,606. However, the estimated amount for the demonstration costs for FY 2019 that was incorporated into the finalized budget neutrality offset amount in the 2019 IPPS final rule was $70,929,313. CMS subtracts the amount of the difference between the actual and estimated costs for FY 2019 ($30,499,707) from the estimated amount of the costs of the demonstration for FY 2025 in determining the total budget neutrality offset amount for FY 2025.

Thus, the budget neutrality offset amount to be applied to the national IPPS payment rates for the demonstration program for FY 2025 is $19,414,819.

[63] CMS anticipates that 23 hospitals will participate in the demonstration program at the start of FY 2025.

VI. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2025. For FY 2024, CMS established a national capital Federal rate of $503.83. CMS proposed a national capital Federal rate of $516.41 for FY 2025. The final rule capital rate for FY 2025 is $510.51

Update Factor:

For FY 2025, CMS will increase the national capital Federal rate by 3.1 percent based on the capital input price index (CIPI) of 2.5 percent and other factors shown in Table 1 below.

CMS is not adopting any change to the capital update for intensity. For FY 2025, CMS projects a 0.5 percent increase in the total case-mix index. CMS estimates that the real case-mix increase will equal 0.5 percent for FY 2025. The net adjustment for change in case mix is the difference between the projected total increase in case-mix and real increase in case mix (e.g., increases in case mix due to improved coding are removed from the capital update). As projected case mix less real case mix nets to 0.0 percent, CMS is applying no adjustment for case mix change in the FY 2025 capital update framework.

The reclassification and recalibration adjustment accounts for the difference between the budget neutrality adjustment that CMS actually applied in FY 2023 compared to what it would be based on later data. CMS is not making an adjustment for FY 2023 reclassification and recalibration in the update framework for FY 2025.

CMS makes a forecast error correction if the forecast CIPI used for the update in a past year (FY 2023 for FY 2025) differs from the actual CIPI based on later information by more than 0.25 percentage points. The CIPI used in the FY 2023 update was 2.5 percent. Its later determined level was 3.0 percent or a difference of 0.5 percentage points. As the 0.5 percentage point difference exceeds the 0.25 percentage point threshold for making a forecast error correction adjustment, CMS is making an adjustment to the capital update of 0.5 percentage points.

Table 1

CMS FY 2025 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE		
FY 2018-based CIPI		2.6
Intensity		0.0
Case-Mix Adjustment Factors:		
Projected Case Mix Change	0.5	
Real Across DRG Change	0.5	
Net Case-Mix Adjustment (Projected - Real)		0.0
Effect of FY 2021 Reclassification and Recalibration		0.0
Forecast Error Correction		0.5
Total Update		3.1

Other Adjustments:

For FY 2024, CMS estimated that outlier payments would be 4.02 percent of total capital IPPS payments. For FY 2025, CMS estimates that capital outlier payments will be 4.26 percent of total capital payments in FY 2023. Taking into account outlier reconciliation, CMS is subtracting 0.03 percentage points for outlier reconciliation payments refunded to hospitals. This makes the estimate of FY 2025 capital outlier payments 4.23 percent of total capital IPPS payments. Therefore, the FY 2025 outlier adjustment factor is 0.9577 (-4.23 percent), compared to 0.9598 (-4.02 percent) in FY 2024. The net change is approximately -0.22 percent (0.9577/0.9598-1). Thus, the outlier adjustment decreases the FY 2025 capital federal rate by approximately 0.22 percentage points.

The geographic adjustment factor (GAF) is a function of the hospital wage index. As such, CMS has been reflecting changes to the wage data as well as its policy changes to the wage index (increasing the wage indexes that are below the 25th percentile and providing a 5 percent cap on reductions to certain wage indexes) in the budget neutrality adjustment.

CMS determines the net GAF budget neutrality adjustment in two steps:

- Isolate the impact of just the change to the wage data (e.g., without the increase to the lowest quartile wage indexes or the 5 percent cap on reductions to the wage index).
- Isolate the impact of the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases.

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

To remove the prior year budget neutrality adjustment for the increase in the lowest quartile wage index and the 5 percent cap on the wage index, CMS divides the capital Federal rate by 0.9964, which was the effect of these policy adjustments in FY 2024.

CMS then continues with its 2-step approach to determining GAF budget neutrality as follows:

- Isolate the impact of just the change to the wage data (e.g., without the increase to the lowest quartile wage indexes or the 5 percent cap on reductions to the wage index). CMS determined a budget neutrality adjustment of 0.9987 for this factor for FY 2025.
- Isolate the impact of the increase in the lowest quartile wage indexes and the 5 percent cap on reductions to the wage index (referred to by CMS as the Quartile/Cap adjustment factor). CMS determined a GAF budget neutrality factor of 0.9958 for FY 2025.

CMS also incorporates an adjustment for FY 2025 MS-DRG changes and recalibration inclusive of a 10 percent cap on the reduction in the relative weights and the associated budget neutrality adjustment. The adjustment for DRG reclassification and recalibration prior to applying the 10 percent cap on reductions to the DRG relative weights is 0.9970. The incremental adjustment for

the 10 percent cap on reductions to the DRG relative weights is 0.9999. The total adjustment is 0.9969 (0.9970 x 0.9999) for DRG reclassification and recalibration.

The combined adjustment due only to the wage index in step 1 above and for changes for MS-DRGs and recalibration is 0.9856 (0.9969 x 0.9987) or -1.44 percent. The quartile/cap adjustment of 0.9958 (or -0.42 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 2025 national capital Federal rate compared to the FY 2024 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2024 and FY 2025 Capital Federal Rate

	FY 2024	FY 2025	Change	Percentage Change
Update Factor*	N/A	1.0310	1.0310	3.10
GAF/DRG Adjustment Factor*	N/A	0.9856	0.9856	-1.44
Quartile/Cap Adjustment Factor**	0.9964	0.9958	0.9993	-0.07
Outlier Adjustment Factor**	0.9598	0.9577	0.9978	-0.22
Capital Federal Rate	$503.83	$510.51	1.0133	1.33

* 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 2024 to FY 2025 resulting from the application of the GAF/DRG budget neutrality adjustment factor for FY 2025 is a net change of 0.9856 (or -1.44 percent).
** The outlier adjustment factor and the lowest quartile adjustment factors are not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2025 outlier adjustment factor is 0.9577/0.9598, or 0.9978 (or -0.22 percent). The net change to the Quartile/Cap adjustment is 0.9958/0.9964 or 0.9993 (-0.07 percent).

Considering the update factor and the budget neutrality adjustments, CMS is adopting a national capital Federal rate for FY 2025 of $510.51, a 1.33 percent increase over the FY 2024 rate of $503.83.

VII. Changes for Hospitals Excluded from the IPPS

A. Rate-of-Increase

Most hospitals are paid under prospective payment systems. Some hospitals, however, continue to be paid based on reasonable costs subject to a per discharge limit updated annually under the Tax Equity and Fiscal Responsibility Act (TEFRA) of 1982. Hospitals that continue to be paid reasonable costs subject to a limit include 11 cancer hospitals, children's hospitals, and hospitals located in the U.S. Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. Religious non-medical health care institutions (RNHCIs) are also paid reasonable costs subject to a limit.

The annual update to the TEFRA limit is based on IGI's 2024 2nd quarter forecast of the hospital market basket for FY 2025 with historical data through the 1st quarter of 2024 and is 3.4 percent.

B. Report on Adjustment Payments

TEFRA hospital cost limits may be adjusted for specific factors after the hospital submits its Medicare cost report. Section 4419(b) of Pub. L. 105-33 requires the Secretary to publish a report annually in the *Federal Register* describing the total amount of adjustment payments made to excluded hospitals and hospital units. Total adjustment payments made to IPPS-excluded hospitals during FY 2023 were $98,720,259 as shown by hospital type in the below table.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	11	$285,044,869	$96,054,746
Children's Hospitals	4	$4,472,925	$2,315,097
RNHCIs	1	$371,175	$298,667
Psychiatric Hospitals	1	$51,749	$51,749
Total	17	**$289,940,718**	**$98,720,259**

C. Critical Access Hospitals (CAHs)

The Frontier Community Health Integration Project (FCHIP) Demonstration[64] 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.

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

CMS did not propose to make any budget neutrality adjustment in FY 2025 for the FCHIP demonstration project. It received no public comments on FCHIP demonstration program and is not making any budget neutrality adjustments that will affect CAHs.

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

A. Background

1. Dual Payment Structure

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 2025:

- Case cannot have a principal diagnosis relating to a psychiatric diagnosis or rehabilitation (the DRG criterion).
- Case must be immediately preceded by discharge from an acute care hospital that included at least 3 days in an intensive care unit (the ICU criterion).
- Case must be immediately preceded by discharge from an acute care hospital and the LTCH discharge must be assigned to an MS-LTC-DRG based on the beneficiary's receipt of at least 96 hours of ventilator services in the LTCH (the ventilator criterion).

To be paid the LTCH PPS standard federal payment, the case must meet the DRG criterion and either the ICU or ventilator criterion.

CMS finalizes updates for LTCHs using a process that is consistent with prior regulatory policy and that cross-links to relevant IPPS provisions. For FY 2016 and FY 2017, the site neutral payment rate was a blend of the LTCH PPS standard federal rate and the IPPS comparable amount. Section 51005 of the BBA 2018 extended the transitional blended payment rate (50 percent LTCH standard federal payment and 50 percent IPPS comparable amount) for site neutral payment cases for an additional 2 years. The FY 2019 IPPS final rule made conforming changes to the regulations to implement the extended transitional blended payment, and it removed the 25-percent threshold policy.[65] 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.

2. Criteria for Classification as an LTCH

A hospital must have an average Medicare inpatient length of stay (ALOS) of greater than 25 days to be paid under the LTCH PPS. Starting with cost reporting periods beginning on or after October 1, 2015, discharges of enrollees of Medicare Advantage (MA) plans and site neutral payment rate

[65] The 25-percent threshold policy applied a payment adjustment for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was greater than the applicable threshold for given cost reporting period.

discharges are excluded from the calculation of the ALOS for all LTCHs. Before a hospital may be classified as an LTCH, it must first be a Medicare participating hospital (typically an IPPS hospital) and during the sixth month period before its conversion to an LTCH (referred to as the qualifying period), it must demonstrate that it has the requisite ALOS for 5 consecutive months during that qualifying period.

The regulations at 42 CFR 412.23(e) do not specifically state how the qualifying period policy applies to a hospital seeking classification as an LTCH. CMS finalizes its proposal to revise paragraph (4) of §412.23(e) to codify its qualifying period policy that has been previously explicitly stated in the preamble of certain final rules. Technical changes (reordering and revising provisions in paragraphs (3) and (4) of §412.23(e)) are also finalized to clarify which provisions apply to existing LTCHs and which apply to hospitals seeking classification as LTCHs.

Some commenters objected to the use of the word "consecutive" in the proposed revisions to the regulatory text in codifying existing policy; they argued that hospitals should be allowed to demonstrate ALOS compliance for non-consecutive months. CMS responds that it had not intended a month-by-month analysis of a hospital's compliance with the ALOS requirement; rather, the ALOS for the entire qualifying period, which must be at least 5 consecutive months, must be greater than 25 days. In responding to this comment, CMS reviewed other related regulatory provisions (§§412.23(e)(4)(iii) and 412.23(e)(4)(v)) that also omit the word consecutive; CMS adds the word "consecutive" in both those sections for consistency across the related regulatory provisions. It also adds the phrase "the period of at least" to §412.23(e)(4)(iii) to be consistent with §412.23(e)(3)(iii) and §412.23(e)(4)(iv) and (v). CMS emphasizes that these changes are technical and do not represent any modification to its existing policies.

Summary of Changes to LTCH PPS Rates for FY 2025*	
Standard Federal Rate, FY 2024	$48,116.62
Rule Update Factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+3.0%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+3.0% (1.03)
Net update LTCHs not reporting quality data	+1.0% (1.01)
Final Rule Adjustments	
Area wage index budget neutrality adjustment	0.9964315
Standard Federal Rate, FY 2025	
LTCHs reporting quality data ($48,116.62 x 1.03 x 0.9964315)	$49,383.26
LTCHs not reporting quality data ($48,116.62 x 1.01 x 0.9964315)	$48,424.36
Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$77,048
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$46,152
Impact of Policy Changes on LTCH Payments in FY 2025	
Total estimated impact	2.2% (≈ $58 million)
LTCH standard federal payment rate cases (≈71% of LTCH cases)	2.0% (≈ $45 million)
Site neutral payment rate cases (≈29% of LTCH cases)**	4.2% (≈ $13 million)

Summary of Changes to LTCH PPS Rates for FY 2025*
*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 2025". Table IV does not include the impact of site neutral payment rate cases. **LTCH site neutral payment rate cases are paid a rate that is based on the lower of the IPPS comparable per diem amount or 100 percent of the estimated cost of the case.

B. MS-LTC-DRGs and Relative Weights

1. Background

Similar to FY 2024, the annual recalibration of the MS-LTC-DRG relative weights for FY 2025 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 continues to apply the same MS-DRG classification system used for the IPPS payments to the LTCH PPS in the form of MS-LTC-DRGs. Other MS-DRG system updates are also incorporated into the MS-LTC-DRG system for FY 2025 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 finalized GROUPER Version 42 are discussed in section II.E of the rule, including changes to the Medicare Code Editor (MCE) software and the ICD-10-CM/PCS coding system, which apply to the LTCH PPS.

3. Development of the FY 2025 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 2025, CMS will use its historical 11-step methodology for calculating the relative weights, as described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58898 through 58907), subject to a 10-percent cap on the reduction to an 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).

CMS uses three different categories of MS-LTC-DRGs based on volume of cases within specific MS-LTC-DRGs to determine relative weights:

- MS-LTC-DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight;
- MS-LTC-DRGs that contain between 1 and 24 applicable LTCH cases (i.e., low-volume MS-LTC-DRGs) that are grouped into quintiles and assigned the relative weight of the quintile; and

- No-volume MS-LTC-DRGs that are cross-walked to other MS-LTC-DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS-LTC-DRG.

CMS finalizes its proposal to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2025 MS-LTC-DRG relative weights without modification.

a. Relative Weights Source Data

FY 2025 relative weights are derived from the March 2024 update of the FY 2023 MedPAR file. These data were 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 2023 with admission dates on or before May 11, 2023 (the COVID-19 PHE expiration date) 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 2025 (including MS-LTC-DRG relative weights), it used FY 2023 cases that met the statutory patient criteria without consideration as to how those cases were paid in FY 2023. The filtered data were trimmed to exclude all-inclusive rate providers, Medicare Advantage claims, and demonstration project participants, yielding "applicable LTCH data."

Because one LTCH (CCN 312024) received an excessive amount of high-cost outlier payments in FY 2021 and FY 2022, CMS removed claims from that provider when determining the FY 2024 MS-LTC-DRG relative weights and in all other FY 2024 rate-setting 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. Citing Department of Justice actions against this same provider for alleged false claims related to excessive cost outlier payments,[66] CMS removed the provider's claims from the FY 2025 MS-LTC-DRG relative weights and in all other FY 2025 rate-setting calculations.

As it has done previously, CMS removed cases with a length of stay of 7 days or less.

b. Volume-related Adjustments

To account for low-volume MS-LTC-DRG cases, CMS continues 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 them in ascending order by average charge. Based on data from the March 2024 update, the agency finds that there are 235 such MS-LTC-DRGs in the claims, and the quintiles each contained 47 MS-LTC-DRGs (235/5 = 47). CMS determines the relative weight and (geometric) average length of stay for each quintile on an iterative basis using the hospital-specific relative value methodology (described below). Each quintile's weight and length of stay are then assigned to each MS-LTC-DRG within that quintile.[67]

[66] https://www.justice.gov/opa/pr/new-jersey-hospital-and-investors-pay-united-states-306-million-alleged-false-claims-related

[67] See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these low-volume MS-LTC-DRGs.

c. Remove Statistical Outliers

Consistent with its current methodology, CMS removed statistical outlier cases from the LTCH cases with a length of stay of at least 8 days, and 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

CMS adjusts for 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) 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 finalizes its proposal to continue using its HSRV methodology in FY 2025 to mitigate relative weight distortions due to nonrandom case distribution across MS-LTC-DRGs and charge variation across providers. The HSRV methodology scales each LTCH's average relative charge value by its case mix.

f. Adjustment for Nonmonotonically Increasing Relative Weights

Each MS-LTC-DRG contains one, two or three severity levels; resource utilization and relative weights typically increase with higher severity. CMS believes that using nonmonotonic relative weights to adjust payments would result in inappropriate payments; this is because payment for cases in the higher severity level in a base MS-LTC-DRG (generally expected to have higher resource use and costs) would be lower than payment for cases in a lower severity level within the same base MS-LTC-DRG (which are generally expected to have lower resource use and costs). When relative weights decrease as severity increases in a DRG ("nonmonotonic"), CMS combines severity levels within the nonmonotonic MS-LTC-DRG to compute a relative weight to assure that monotonicity is maintained. Table 11 (listed in section VI. of the Addendum to the 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 (426 of these MS-LTC-DRGs were identified for the final rule), CMS will cross-walk that MS-LTC-DRG 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 398 no-volume MS-LTC-DRGs for which CMS assigns relative weights based on clinical similarity and relative costliness to 1 of the remaining 347 (773 – 426 = 347) MS-LTC-DRGs for which it calculated relative weights based on the trimmed applicable LTCH cases in the March 2024 update of the FY 2023 MedPAR file data. When necessary, adjustments were made to account for nonmonotonicity. (See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these zero-volume MS-LTC-DRGs.) The preamble includes an example of this methodology for determining the relative weights for the FY 2025 MS-LTC-DRGs with no applicable LTCH cases.

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. Normalizing the Relative Weights

CMS finalizes its proposal to normalize relative weights using its established methodology for FY 2025. 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 2025, 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." CMS calculated a normalization factor of 1.27408.

i. Budget Neutrality

Annual updates to the MS-LTC-DRG classifications and relative weights are done in a budget neutral manner. As proposed, CMS continues to use its existing methodology to achieve budget neutrality for the FY 2025 MS-LTC-DRG relative weights update, including for the application of a 10-percent cap on relative weight decreases. It applies two budget neutrality factors to determine the MS-LTC-DRG relative weights for FY 2025; one before the application of the 10-percent cap (referred to as the "uncapped relative weights") and the other after application of that cap.

(1) *Budget neutrality for uncapped relative weights*.

To determine budget neutrality adjustments for the update of the MS-LTC-DRG classifications and relative weights before applying the 10-percent cap (or the uncapped relative weights), CMS uses its established two-step budget neutrality methodology.

First, it applies its normalization factor to the recalibrated relative weights. To calculate the normalization factor for FY 2025, CMS uses the applicable LTCH cases from LTCH discharges from the FY 2023 MedPAR file, and groups them using Version 42 of the GROUPER and the recalibrated FY 2025 MS-LTC-DRG uncapped relative weights to calculate the average case-mix index. Next, it groups the same applicable LTCH cases using the FY 2024 GROUPER (Version 41) and FY 2024 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 2024 by the average case-mix index for FY 2025. As a result, in determining the MS-LTC-DRG relative weights for FY 2025, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by the normalization factor of 1.27408 in the first step of the budget neutrality methodology, which produces "normalized relative weights."

Next, CMS determines the first budget neutrality adjustment factor (for uncapped relative weights) by calculating the ratio of estimated aggregate FY 2025 LTCH PPS standard federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2025 LTCH PPS standard federal payment rate payments for applicable LTCH cases after reclassification and recalibration. It calculated a budget neutrality factor of 0.9885836, which is applied to each uncapped normalized relative weight.

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

Under its policy to limit reductions in relative weights to 10 percent in a given year, the 10-percent cap is only applied to the relative weights for MS-LTC-DRGs with at least 25 applicable LTCH cases. For any MS-LTC-DRG where the FY 2025 relative weight would otherwise have been reduced by more than 10 percent, CMS applies a capped FY 2025 MS-LTC-DRG relative weight equal to 90 percent of that MS-LTC-DRG's FY 2024 relative weight. However, the 10-percent cap does not apply to the relative weight for any new or renumbered MS-LTC-DRGs.

3. Budget Neutralize Application of the 10-percent Cap Policy

As proposed, CMS continues to use its 3-step methodology to determine the budget neutrality adjustment factor for its 10-percent cap on relative weight reductions for FY 2025. The agency:

- Simulates estimated total FY 2025 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the capped relative weights for FY 2025 (determined in Step 10) and GROUPER Version 42;
- Simulates estimated total FY 2025 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the uncapped relative weights for FY 2025 (determined in Step 9) and GROUPER Version 42; and
- Calculates the ratio of the estimated total payments.

The budget neutrality adjustment factor for the 10-percent cap is 0.9945741. To determine the FY 2025 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 is provided in the rule (pages 1163 through 1184 of the display copy).

C. Payment Rates and Other Changes

1. Overview of Development of the 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. FY 2025 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

CMS finalizes its proposal to rebase and revise the 2017-based LTCH market basket to reflect a 2022 base year, which is primarily based on the Medicare cost report data submitted by LTCHs and uses data from cost reporting periods beginning on and after April 1, 2021, and before April 1, 2022. Further details on the agency's policy to use a 2022 base year are described in section VIII.D. of the summary below.

Based on IGI's second quarter 2024 forecast with historical data through the first quarter of 2024, the update to the 2022-based LTCH market basket is 3.5 percent less 0.5 percentage points (PP) for multifactor productivity (renamed by BLS to be the total factor productivity (TFP)), which results in an update factor of 1.03 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 will be further reduced by 2.0 percentage points for an update factor of 1.01. CMS notes that the "other adjustment" under section 1886(m)(4)(F) of the Act does not apply for FY 2025. The updates for FY 2025 are as follows:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	3.5%	3.5%
Multifactor Productivity	-0.5 PP	-0.5 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	3.0%	1.0%

CMS notes that the update based on the 2022-based LTCH market basket is currently projected to be 0.1 percentage point higher for FY 2025 compared to the current 2017-based LTCH market basket. The increase is primarily due to the higher Compensation cost weight in the 2022-based market basket (61.8 percent) compared to the 2017-based LTCH market basket (53.2 percent).

3. Area Wage Levels and Wage-Index

a. Labor Market Areas

CMS adopts the revised labor market area delineations announced in OMB Bulletin No. 23-01[68] (issued on July 21, 2023) effective for FY 2025 under the LTCH PPS. See section III.B. of the summary above for a detailed discussion of the changes and their impacts. Highlights of the impacts by reason of the revised OMB delineations for the LTCH PPS are as follows:

- 53 counties (and county equivalents) that were located in an urban CBSA will be located in a rural area.
- 54 counties (and county equivalents) that were located in a rural area will be located in an urban CBSA.
- Some urban counties shift from one urban CBSA to another urban CBSA.
    - Some of these shifts result only in a name change.
    - Some CBSAs are split into multiple new CBSAs.
    - An urban CBSA will lose one or more counties to other urban CBSAs.
- The Census Bureau implemented Connecticut's request to replace the 8 counties in the state with 9 new "Planning Regions," which will serve as county equivalents. CMS provides the following crosswalk for each LTCH in Connecticut with the current and new FIPS county and county-equivalent codes and CBSA assignments:

CCN	Current FIPS	Current County	Current CBSA	New FIPS	New Planning Area (County Equivalent)	New CBSA
072003	09009	New Haven	35300	09170	South Central Connecticut	35300
072004	09003	Hartford	25540	09110	Capitol	25540

The FY 2025 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum reflect the revisions to the CBSA-based labor market area delineations previously described. CMS provides a supplemental data file that includes an updated county-to-CBSA crosswalk reflecting the revisions to the CBSA-based labor market area delineations, which will be posted at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

b. Labor-related Share

CMS finalizes an FY 2025 labor-related share of 72.8 percent based on IGI's second quarter 2024 forecast of the 2022-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (68.9 percent) and capital costs (3.9 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.

[68] https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.

c. Wage Index for FY 2025 for the Standard Federal Payment Rate

To determine the applicable area wage index values for the FY 2025 LTCH PPS standard federal payment rate, CMS uses the same data used to compute the FY 2025 acute care hospital inpatient wage index, which uses wage data for cost reporting periods beginning during FY 2021. The FY 2025 standard federal payment rate area wage index values are calculated consistent with the "urban" and "rural" geographic classifications, not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act. As proposed, CMS 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, consistent with the IPPS policy.

To determine area wage index values for areas where there are no IPPS wage data, CMS determines the LTCH PPS wage index value for urban CBSAs with no IPPS wage data by using an average of all the urban areas within the state. For LTCH PPS wage index values for rural areas with no IPPS wage data, CMS uses the unweighted average of the wage indices from all the CBSAs that are contiguous to the rural counties of the state. CMS notes there are no IPPS wage data for rural North Dakota (CBSA 35). The agency calculated the FY 2025 wage index value for CBSA 35 as the average of the wage index values for all CBSAs that are contiguous to the rural counties of the state.

d. Permanent Cap on Wage Index Decreases

The FY 2023 IPPS/LTCH PPS final rule established a permanent policy to apply a 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 it mitigates significant payment reductions due to changes in wage index policy, such as the adoption of the revised CBSAs. To ensure budget neutrality, it includes this policy in the determination of the area wage level budget neutrality factor.

Under this policy, an LTCH's wage index will not be less than 95 percent of its wage index for the prior fiscal year. New LTCHs that became operational during the prior federal fiscal year would be subject to the LTCH PPS wage index cap whereas LTCHs that become operational on or after the first day of the fiscal year to which this 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 calculates an "IPPS comparable amount" to determine payments for short-stay outliers and the site neutral payment rate. Additionally, an "IPPS equivalent amount" is calculated for LTCHs that do not meet the applicable discharge payment percentage. Calculation of these amounts includes adjustments to the IPPS operating and capital standardized amounts by the applicable IPPS wage index for non-reclassified hospitals in the same geographic area as the LTCH. CMS adopted, beginning with FY 2023, the application of a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Historically, CMS has not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for non-reclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner.

e. Budget Neutrality Adjustments or Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

CMS computes the wage index in a manner that is consistent with prior years, including 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 calculated an FY 2025 LTCH PPS standard federal payment rate area wage level adjustment budget neutrality factor of 0.9964315.

4. Cost-of-Living (COLA) Adjustment

CMS continues to update 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 2025, which are unchanged from the COLAs in effect for FY 2024.

Area	**FY 2025**
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) of the Act requires CMS to set an outlier threshold such that estimated outlier payments equal 99.6875 percent of the 8 percent estimated aggregate payments for standard federal payment rate cases (that is, 7.975 percent). Under the HCO policy, an LTCH

receives 80 percent of the difference between the estimated cost of the case and the HCO threshold, which is the sum of the LTCH PPS payment for the case and the fixed-loss amount for that case.

a. Determining LTCH CCRs

CMS calculates the estimated cost of an LTCH case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. Generally, an LTCH's overall CCR is computed based on the sum of LTCH operating and capital costs as compared to total Medicare charges, with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in some cases, an alternative CCR is used, such as the statewide average CCR, a CCR that is specified by CMS, or one that the hospital requests. The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling (which is 3 standard deviations from the national geometric average CCR). If the LTCH's CCR exceeds the LTCH total CCR ceiling, it is assigned the applicable statewide CCR.

CMS uses its established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2024 update of the Provider Specific File (PSF). Thus, it establishes a LTCH total CCR ceiling of 1.368 under the LTCH PPS for FY 2025 for HCO cases under either payment rate and for the site neutral payment rate.

CMS also uses its established methodology for determining the LTCH statewide average CCRs for urban and rural hospitals, based on the most recent complete IPPS total CCR data from the March 2024 update of the PSF. They are effective for discharges occurring on or after October 1, 2024 through September 30, 2025.

Payments for HCO cases are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. Commenters expressed concern that CMS added new criteria in Change Request (CR) 13566 for determining which LTCHs will have their outlier payments reconciled. Noting that all LTCH outlier payments are subject to reconciliation, the agency responds that the instructions in CR 13566 establish an enforcement policy that determines when MACs will identify additional LTCHs for reconciliation referral—they do not change the legal standards that govern the LTCHs.

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 7.975 percent of total estimated payments under the LTCH PPS for federal standard payment cases. 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 2025.

(1) Charge Inflation Factor

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

- Identify standard federal payment rate cases for the two most recently available fiscal years, removing any Medicare Advantage or all-inclusive rate provider claims as well as claims from providers that only had claims in one of the fiscal years.
- 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 fiscal year; and trimming claims for providers whose calculated charge growth factor is outside 3 standard deviations from the mean provider charge growth factor.
- Using remaining claims, calculate a national charge inflation factor by dividing the national average charge for the more recent fiscal year by the average charge for the prior year.

CMS computed a charge inflation factor using the March 2024 update of the FY 2023 MedPAR file and the March 2023 update of the FY 2022 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 1.073005, and a 2-year charge inflation factor of 1.15134 (calculated by squaring the 1-year factor). It inflates the billed charges obtained from the FY 2023 MedPAR file by the 2-year charge inflation factor of 1.15134 when determining the fixed-loss amount for LTCH PPS standard federal payment rate cases for FY 2025.

(2) CCRs

Historically, CMS uses 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 uses the following four-step methodology, which was finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562-45566):

- Identify providers with standard federal payment rate cases from the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims) and identify for each of these providers the CCR from the most recently available PSF and from the prior year PSF.
- Trim providers with insufficient CCR data in the most recent PSF or the prior year PSF (i.e., providers whose CCR was missing; providers assigned the statewide average CCR for their state; and providers whose CCR was not updated between the most recent PSF and the prior year PSF).
- Remove statistical outliers. Calculate a provider's CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year PSF, and remove

providers whose CCR growth factor is outside 3 standard deviations from the mean provider CCR factor.
- Using remaining providers, calculate a national CCR adjustment factor by determining the average case-weighted CCR from both the most recent PSF and the prior year PSF and dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

Under this methodology for FY 2025, CMS used the March 2024 PSF as the most recently available PSF and the March 2023 PSF as the PSF that was made available one year prior to the most recently available PSF. It also used claims from the March 2024 update of the FY 2023 MedPAR file in calculating the average case-weighted CCRs in the last step of the methodology. CMS calculated a March 2023 national average case-weighted CCR of 0.234910 and a March 2024 national average case-weighted CCR of 0.234910, which results in a 1-year national CCR adjustment factor of 0.991315. CMS notes that incorporating more recent cost-to-charge ratio data into the payment model was principally responsible for the reduction in the fixed-loss amount calculated in the final rule as compared to the proposed rule.

(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.

CMS acknowledges that the proposed fixed-loss amount determined for FY 2025 was significantly higher than the fixed-loss amount finalized for FY 2024 ($59,873), which in turn was significantly higher than the fixed-loss amount finalized for FY 2023 ($38,518). Using LTCH claims data from the March 2024 update of the FY 2023 MedPAR file adjusted for charge inflation and adjusted CCRs from the March 2024 update of the PSF, CMS calculated a fixed-loss amount for standard federal rate cases of $77,048 for FY 2025.

Alternative Considered. CMS considered in the proposed rule, but did not adopt in this final rule, establishing the FY 2025 fixed-loss amount as an average of the FY 2024 fixed-amount ($59,873) and the proposed FY 2025 fixed-loss amount ($90,921), which would have resulted in an FY 2025 fixed-loss amount of $75,397. This alternative would have provided a one-year transition to the full increase to the fixed-loss amount for LTCH PPS standard federal payment rate cases that it projects would result in estimated outlier payments projected to be equal to 7.975 percent of estimated payments for such cases. CMS estimated the alternative fixed-loss amount would have resulted in estimated outlier payments projected to be equal to 9.5 percent of estimated FY 2025 payments for these cases, and the estimated difference between the 7.975 percent target and the estimated percentage of outlier payments under the alternative fixed-loss amount would be non-budget neutral. CMS had said in the proposed rule that it believes that the mandate in section 123(a)(1) of the BBRA for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). However, due to the use of updated data in the final rule, CMS did not adopt this alternative methodology nor did it further explain

the statement in the preamble to the proposed rule on its interpretation about the BBRA budget neutrality requirement.

Comments/Responses. Commenters objected to the proposed fixed-loss amount determined for FY 2025, warning that most LTCHs would not be able to absorb the level of financial loss. This in turn would lead to reduced access to LTCH services, which would increase length of stays and costs in the intensive care units of IPPS hospitals. Another commenter believes the alternative approach of averaging fixed loss amounts for FY 2025 and FY 2024 would only delay the steep cliff in the fixed-loss amount. Other suggestions included a multi-year phase-in of the fixed-loss amount calculated for FY 2025, using the FY 2024 fixed-loss amount for another year, and adopting a non-budget neutral cap on annual increases to the fixed-loss amount. As noted above, CMS declines to adopt any of these suggestions at this time because, using more recent data for the final rule, it calculated an FY 2025 fixed-loss amount of $77,048, which it describes as significantly lower than the proposed fixed-loss amount of $90,921 notwithstanding the fact that it is substantially in excess of the FY 2024 fixed-loss amount ($59,873) and more than twice the FY 2023 fixed-loss amount ($38,518).

Commenters also objected to the proposed fixed-loss amount determined for FY 2025 and specifically to the charge inflation factor, which they believe should equal the market basket update per the methodology used before FY 2022 to provide stability and predictability to the outlier fixed-loss amount. CMS acknowledges that the calculated fixed-loss amount would have been lower in recent years if it estimated charge inflation based on the market basket update, but it does not believe the fixed-loss amounts calculated under the previous market basket methodology would have resulted in outlier payments closer to the statutory target in either FY 2022 or FY 2023. The agency continues to believe using a charge inflation factor based on actual growth rates in charges from historical claims data (rather than one based on quarterly market basket update values) leads to better accuracy in calculating the fixed-loss amount that would result in actual outlier payments meeting the statutory target. In response to concerns about the impact of COVID-19 claims on the fixed-loss amount for 2025, CMS notes that roughly 4 percent of LTCH standard payment rate claims from FY 2023 had a COVID-19 diagnosis code, and it does not assume there will be any meaningful difference from that rate in FY 2025. CMS also rejects a suggestion to exclude dialysis claims when calculating the fixed-loss threshold because commenters did not provide sufficient evidence to support why costs for these patients would differ significantly from FY 2023 to FY 2025.

Some commenters observed that under the dual rate payment structure the majority of LTCH standard federal payment rate cases are concentrated to only a few MS-LTC-DRGs, but there is great variation in patient severity and costs among the cases grouped to these MS-LTC-DRGs. Many of these cases qualify for outlier payments, which contributes to the significant increases in the fixed-loss amount. Some of these base MS-LTC-DRGs are not subdivided based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC), and CMS was asked to refine certain MS-LTC-DRGs, such as by creating subgroups within these base MS-DRGs based on the presence or absence of CCs and MCCs. Commenters believe this refinement would increase LTCH PPS payment accuracy and reduce outlier payments made to cases grouped to such MS-LTC-DRGs. The agency may take these suggestions into consideration in future rulemaking.

(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 2025, CMS establishes a fixed-loss amount for site neutral payment rate cases of $46,152. CMS also applies a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2025. 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. Update to the IPPS Comparable Amount to Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

CMS includes in the calculations of the "IPPS comparable amount" (under the SSO policy at §412.529) and the "IPPS equivalent amount" (under the site neutral payment rate at §412.522) an applicable operating Medicare DSH and uncompensated care payment amount. For FY 2025, the DSH/uncompensated care amount equals 65.72 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. Rebasing of the LTCH Market Basket

CMS finalizes its proposal to rebase and revise the market basket applicable to the LTCH PPS and moves the base year from 2017 to 2022. It cannot use data from the FY 2022 HCRIS file because the dataset is not yet complete, so, as it proposed, CMS combines data from multiple HCRIS files to obtain a 2022 base year and to use data from cost reporting periods beginning on and after April 1, 2021, and before April 1, 2022. This results in a weighted average of costs occurring in FY 2022 (accounting for the distribution of providers by Medicare cost report begin date) of 82 percent. CMS believes that these data represent the most recent, complete set of Medicare cost report data available to develop a 2022-based LTCH market basket for the final rule. The agency notes that these cost report data showed an increase in the compensation cost weight from 2017 to 2022, which is consistent with comments it received with respect to the 2017-based LTCH PPS market basket.

The below table shows the impact from changing to a 2022-based LTCH PPS market basket.

FY	2022-Based LTCH Market Basket Index Percent Change	2017-Based LTCH Market Basket Index Percent Change
Historical Data		
FY 2020	2.2	2.0
FY 2021	2.6	2.8
FY 2022	5.1	5.5
FY 2023	5.1	4.8
Average: FY 2020 – FY 2023	**3.8**	**3.8**
Forecast		

FY	2022-Based LTCH Market Basket Index Percent Change	2017-Based LTCH Market Basket Index Percent Change
FY 2024	4.0	3.7
FY 2025	3.5	3.4
FY 2026	3.1	3.1
FY 2027	2.9	2.9
Average FY 2024 – FY 2027	**3.4**	**3.3**

The below table shows the FY 2025 labor-related share using the 2022-based LTCH market basket relative importance and the FY 2024 labor-related share using the 2017-based LTCH market basket. The total labor-related share increases from 68.5 percent to 72.8 percent.

FY	FY 2025 Labor-Related Share based on 2022-based LTCH Market Basket[1]	FY 2024 Final Labor-Related Share based on 2017-based LTCH Market Basket[2]
Wages and Salaries	54.6	47.6
Employee Benefits	8.1	6.7
Professional Fees: Labor-Related[3]	3.0	4.4
Administrative and Facilities Support Services	0.5	1.0
Installation, Maintenance and Repair Services	1.0	2.1
All Other: Labor-Related Services	1.7	2.5
Subtotal	**68.9**	**64.3**
Labor-Related portion of capital (46%)	3.9	4.2
Total Labor-Related Share	**72.8**	**68.5**

[1] IHS Global Inc. 2nd quarter 2024 forecast.
[2] Based on IHS Global Inc. 2nd quarter 2023 forecast as published in the August 28, 2023 *Federal Register* (84 FR 59367).
[3] Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office/related organization contract labor costs.

E. Impacts

CMS projects that the overall impact of the payment rates and factors for all LTCHs will result in an increase of 2.2 percent or approximately $58 million in aggregate payments. Based on the FY 2023 LTCH cases that were used for the analysis in this final rule, approximately 29 percent of those cases were classified as site neutral payment rate cases, and the Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be classified as site neutral payment rate cases in FY 2025 will not change significantly from the most recent historical data. Thus, CMS estimates that aggregate LTCH PPS payments for these site neutral payment rate cases would increase by approximately 4.2 percent (or approximately $13 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, as well as an estimated increase in costs for these cases determined using the charge and CCR adjustment factors.

CMS found approximately 71 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2025, 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 2025 will increase by approximately

2 percent (or approximately $45 million), which is primarily due to the projected 3 percent annual update to the LTCH PPS standard federal payment rate being partially offset by a projected 0.8 percent decrease in high-cost outlier payments as a percentage of total LTCH PPS standard federal payment rate payments.

CMS estimates that aggregate FY 2025 LTCH PPS payments will be approximately $2.638 billion, as compared to estimated aggregate FY 2024 LTCH PPS payments of approximately $2.581 billion.

Table IV "Impact of Payment Rate and Policy Changes to LTCH PPS Payments For LTCH PPS Standard Federal Payment Rate Cases for FY 2025" 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 only; it does not include a detailed impact on payments for site neutral payment rate cases.

Summary of Impact of Changes to LTCH PPS Standard Federal Payment Rate Cases for FY 2025		
	Number of LTCHs	**Percent Change Due to All Standard Payment Rate Changes**
All LTCH providers	331	2.0%
By Location:		
Rural	19	2.8%
Urban	311	1.9%
By Ownership Type:		
Voluntary	53	1.3%
Proprietary	267	2.1%
Government	10	1.2%
By Region		
New England	10	0.4%
Middle Atlantic	19	1.8%
South Atlantic	59	2.4%
East North Central	47	2.0%
East South Central	32	2.7%
West North Central	21	1.5%
West South Central	92	2.2%
Mountain	27	2.7%
Pacific	23	1.1%
*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 2025" on pages 2947 and 2948 of the display copy.		

IX. Quality Data Reporting Requirements for Specific Providers

A. Overview

CMS finalizes under this section changes to the Hospital Inpatient Quality Reporting (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. Crosscutting Quality Programs

1. Adoption of Patient Safety Structural Measure

a. Overview

CMS is finalizing its proposal to adopt the attestation-based Patient Safety Structural measure in the Hospital IQR Program beginning with the 2025 reporting period/FY 2027 payment determination and the PCHQR Program beginning with the 2025 reporting period/FY 2027 program year, with a modification to the attestation statement in Domain 4 Statement B (discussed in further detail under section f. below). Table IX.B.1-01 of the rule shows the 5 attestation domains and corresponding attestation statements that were proposed. Table IX.b.1-02 of the rule shows the finalized 5 attestation domains and corresponding attestation statements.

The measure will be included in the Hospital IQR Program beginning with the CY 2025 reporting period/FY 2027 payment determination and in the PCHQR Program beginning with the CY 2025 reporting period/FY 2027 program year.

b. Background

CMS describes that, since the COVID-19 PHE, there have been declines in patient safety metrics, including considerable increases in preventable harms such as healthcare-associated infections (HAIs), pressure injuries, and patient falls among hospitalized patients. In addition, the agency brings attention to the prevalence of postoperative respiratory failure and acute kidney injuries (AKI). CMS further reviews national strategies taken to advance patient and workforce safety, including by promoting safety measures throughout the CMS quality programs, and notes the current gap in systems-level measurement for safety within the Hospital IQR and PCHQR Programs.

c. Measure Overview and Calculation

The measure is a structural measure that assesses how well hospitals have implemented strategies and practices that demonstrate a structure, culture, and leadership commitment that prioritizes safety. The measure includes 5 domains ((i) Leadership commitment to eliminating preventable harms, (ii) Strategic planning and organization policy, (iii) Culture of safety and learning health systems, (iv) Accountability and transparency, and (v) Patient and family engagement), each containing a set of corresponding statements (or attestations).

A hospital will be able to earn up to one point for each of the 5 domains, for a total of up to 5 points. To receive a point for a domain, a hospital will need to attest affirmatively to each of the statements that correspond to that domain. A hospital will not be able to receive partial points for a domain, and therefore will receive zero points for any domain for which it cannot attest affirmatively to each of the corresponding statements. If a hospital includes more than one acute care hospital facility reporting under the same CCN, all the facilities will need to satisfy these criteria for the hospital to affirmatively attest and receive points.

Hospitals participating in the Hospital IQR or PCHQR Program will satisfy their reporting requirement for the measure in the respective program as long as they attest "yes" or "no" to each attestation statement in all five domains.

d. Pre-Rulemaking

The Patient Safety Structural measure (MUC2023-188) was reviewed by the Pre-Rulemaking Measure Review (PRMR) Hospital Recommendation Group during January 2024 and it was included for consideration in the Hospital IQR and PCHQR Programs on the 2023 Measures Under Consideration (MUC) list. The committee recommended the measure for both programs with conditions, including (i) the publication of an implementation guide that documents how safety is to be measured and (ii) for CMS to use data to narrow the scope of the attestations. CMS addresses the first condition by stating that an attestation guide is to be available at the time of the publication of this proposal. The agency also states that it could use data obtained from the measure's national use to evaluate the effectiveness of the proposed attestations as well as the potential for narrowing the scope of the attestations.

The measure is not endorsed by the consensus-based entity (CBE), but CMS finalizes adoption of the measure consistent with the exception for non-CBE-endorsed measures,[69] having found no currently available, alternative measure that is comparable, CBE-endorsed, feasible, and practical.

e. Data Submission and Reporting

Hospitals will be required to submit information for the measure once annually using the CDC's data submission and reporting standard procedures for the National Healthcare Safety Network (NHSN).

Beginning in fall 2026, CMS will publicly report the hospital's measure performance score (0 to 5 points) on an annual basis on, as applicable, Care Compare or on the Provider Catalog available at data.cms.gov.

f. Selected Comments/Responses

Many commenters expressed support for adoption of the Patient Safety Structural measure for multiple reasons, including that it addresses patient safety and is an attestation-based structural measure with relatively low reporting burden. Some commenters suggested additional domains for the measure, with some specifically recommending a domain related to workforce well-being and engagement and others a domain for diagnostic excellence. CMS agrees that such domain topics would be linked with a learning culture that prioritizes safety, but explains the measure was developed by identifying the highest priority domains in order to balance the consideration of burden on hospitals. Therefore, the agency is adopting the measure without additional domains or attestations, but will consider updating it if appropriate in the future. Other commenters suggested streamlining the measure because of the duplication of domains 1 and 2

[69] See section 1886(b)(3)(B)(viii)(IX)(bb) of the Act for the Hospital IQR Program and section 1866(k)(3)(B) of the Act for the PCHQR Program.

with hospital conditions of participation related to quality assessment and performance improvement (QAPI) programs. CMS clarifies that the measure is not redundant with, but instead complements, existing requirements, and that public display requirements of the Hospital IQR and PCHQR programs would make the information available to patients, family caregivers, and other interested parties, which can further quality improvement.

Some commenters raised concerns that terms within the attestation statements were not defined. CMS responds that it intentionally leaves these terms undefined in order to provide flexibility to hospitals to adopt the practices that are most effective for their specific circumstances. But the agency also refers to common definitions used by safety experts that may guide hospitals attesting to the measure.[70] Others expressed concern regarding reporting the measure through NHSN instead of the Hospital Quality Reporting (HQR) system including because of operational challenges that NHSN has which could impact reporting. The agency believes, however, that because the Patient Safety Structural measure is related to health care safety and the NHSN collects information related to patient safety that using the NHSN for reporting is most appropriate. To address concerns that only certain staff has access to the NHSN and that hospitals may want more staff to obtain such access to report the measure, CMS notes that the CDC plans to open the measure for test access in NHSN several weeks before the submission period begins on April 1, 2026.

Many commenters did not support adoption of the measure on the basis that the number of attestations is excessive, it does not assess patient outcomes, and attestation measures generally are subjective. CMS points to other adopted structural measures which require hospitals to attest to specific statements and to provide meaningful information to consumers on individual hospital characteristics. It points to research showing a link between hospital characteristics identified by the attestations and improved care and outcomes and reiterates that the measure provides hospitals flexibility in meeting each of the attestations.

Many other commenters did not support the measure because of the scoring approach which does not provide partial credit, but requires hospitals to positively attest to all statements within a domain to receive a point for that domain. CMS believes that each action within a domain is an important best practice and hospitals must therefore attest to all the actions within a domain to receive credit for the domain. The agency, however, does not expect all hospitals to achieve a score of 5 on the measure, especially initially. The measure identifies opportunities for hospital improvement in structural safety practices. CMS reiterates that the Hospital IQR program is a pay-for-reporting program under which hospitals that report the required measure data (regardless of the 0-5 point score received) in accordance with the form, manner, and timing policies specified by the Secretary are not subject to a financial penalty and the PCHQR program is a quality reporting program that does not have a financial penalty associated with it.

Several commenters recommended specific updates to and raised specific concerns regarding the language of certain attestation statements within specific domains. CMS generally responds that

[70] Common definitions are described in the Attestation Guide, available on the Web-Based Data Collection tab under the IQR Measures page and PCHQR Measures page at https://qualitynet.cms.gov/inpatient/iqr/measures#tab2 and https://qualitynet.cms.gov/pch/measures, respectively.

the measure was developed and informed with extensive input from national experts, including from a TEP, to allow hospital flexibility in how they meet each statement.

Many commenters raised various concerns about the Domain 4 Statement B. In response, CMS modifies the attestation in that statement to remove the portion related to voluntary reporting to the Network of Patient Safety Databases (NPSD) and to remove references to whether the hospital reports patient safety work product to a Patient Safety Organization (PSO). That is, hospitals will not need to attest whether they report patient safety event information to PSOs so long as they perform other patient safety activities with a PSO, nor will they need to report to the NPSD to affirmatively attest to the statement.

- Domain 4 Statement B, as proposed, stated: "Our hospital reports serious safety events, near misses and precursor events to a Patient Safety Organization (PSO) listed by the Agency for Healthcare Research and Quality (AHRQ) that participates in voluntary reporting to AHRQ's Network of Patient Safety Databases."
- As revised (and finalized) the statement is the following: "Our hospital voluntarily works with a Patient Safety Organization listed by the Agency for Healthcare Research and Quality (AHRQ) to carry out patient safety activities as described in 42 CFR 3.20, such as, but not limited to, the collection and analysis of patient safety work product, dissemination of information such as best practices, encouraging a culture of safety, or activities related to the operation of a patient safety evaluation system."

As finalized, a hospital will be able to positively attest to the revised Domain 4 Statement B even if the hospital chooses to work with a large-scale learning network that is not a PSO to analyze and understand patient safety events and with a PSO for other patient safety activities. In response to concerns about privacy of information, CMS also clarifies that before any patient safety work product (PSWP) is shared with the NPSD, a PSO submits the data to the PSO Privacy Protection Center to ensure all identifying information has been removed and the data are aggregated before transferring it to the NPSD.

2. Adoption of Modified HCAHPS Survey Measure

a. Background

The HCAHPS Survey makes up a single "measure" for purposes of the Hospital IQR, PCHQR, and Hospital VBP Programs. In the Hospital IQR and PCHQR Programs, each element of the survey that is publicly reported is a "sub-measure" and within each of those sub-measures are corresponding survey questions. In the HVBP Program, the sub-measures are instead referred to as "dimensions" and within each dimension are corresponding questions. In the Hospital IQR and PCHQR Programs, the current HCAHPS Survey measure consists of 29 survey questions organized into 10 sub-measures, of which 19 questions ask how often or whether patients experience an aspect of hospital care (and not whether they were satisfied with that care), 3 questions are screener questions directing patients to relevant questions, 5 questions are to adjust for the mix of patients across hospitals, and 2 questions regarding race and ethnicity are in support of statutorily required reports. In contrast, under the HVBP Program, the survey

questions are organized into 8 dimensions (rather than the 10 sub-measures) under the Person and Community Engagement Domain.[71]

CMS discusses its literature review and extensive testing through its 2021 mode experiment, technical expert panel (TEP), and focus group studies that contributed to the development of the updates to the HCAHPS Survey questions.

b. Modifications to HCAHPS Survey Measure

Overview. CMS finalizes, as proposed, its updates to the HCAHPS Survey measure for the Hospital IQR, PHCQR, and Hospital VBP Programs.

The finalized updates result in the following:

- For the Hospital IQR and PHCQR Programs, beginning with the 2025 Reporting Period/FY 2027 Payment Determination or Program Year (as applicable), a survey with 32 questions that make up 11 sub-measures.
- For the Hospital VBP, the survey with 32 questions making up 9 dimensions, beginning with the 2030 Program Year (and scoring on only 6 dimensions during the 2027 through 2029 Program Years).

Hospital IQR and PHCQR Programs. Table IX.B.2-01 in the rule includes the updated sub-measures and survey questions. The information from that table is presented below (with modifications to the formatting and organization).

Updated HCAHPS Survey Sub-Measures and Corresponding Survey Questions
(Based on Table IX.B.2-01 in the Final Rule)

Sub-Measure: Communication with Nurses
During this hospital stay, how often did nurses treat you with courtesy and respect?
During this hospital stay, how often did nurses listen carefully to you?
During this hospital stay, how often did nurses explain things in a way you could understand?
Sub-Measure: Communication with Doctors
During this hospital stay, how often did doctors treat you with courtesy and respect?
During this hospital stay, how often did doctors listen carefully to you?
During this hospital stay, how often did doctors explain things in a way you could understand?
Sub-Measure: Cleanliness
During this hospital stay, how often were your room and bathroom kept clean?
Sub-Measure: Restfulness of Hospital Environment
During this hospital stay, how often were you able to get the rest you needed?
During this hospital stay, how often was the area around your room quiet at night?
During this hospital stay, did doctors, nurses and other hospital staff help you to rest and recover?
Sub-Measure: Care Coordination
During this hospital stay, how often were doctors, nurses and other hospital staff informed and up-to-date about your care?
During this hospital stay, how often did doctors, nurses and other hospital staff work well together to care for you?

[71] The HCAHPS Survey can be found at https://hcahpsonline.org/en/survey-instruments/.

Did doctors, nurses or other hospital staff work with you and your family or caregiver in making plans for your care after you left the hospital?
Sub-Measure: Responsiveness of Hospital Staff
How often did you get help in getting to the bathroom or in using a bedpan as soon as you wanted?
During this hospital stay, when you asked for help right away, how often did you get help as soon as you needed?
Sub-Measure: Communication about Medicines
Before giving you any new medicine, how often did hospital staff tell you what the medicine was for?
Before giving you any new medicine, how often did hospital staff describe possible side effects in a way you could understand?
Sub-Measure: Information about Symptoms
Did doctors, nurses or other hospital staff give your family or caregiver enough information about what symptoms or health problems to watch for after you left the hospital?
Sub-Measure: Discharge Information
During this hospital stay, did doctors, nurses or other hospital staff talk with you about whether you would have the help you needed after you left the hospital?
During this hospital stay, did you get information in writing about what symptoms or health problems to look out for after you left the hospital?
Sub-Measure: Rating
Using any number from 0 to 10, where 0 is the worst hospital possible and 10 is the best hospital possible, what number would you use to rate this hospital during your stay?
Sub-Measure: Recommend
Would you recommend this hospital to your friends and family?

Specifically, the modifications in the Hospital IQR and PCHQR Programs will include the following:

Addition of Care Coordination Sub-Measure. The new sub-measure is composed of 3 new questions (shown above) that fill a gap of furthering coordination efforts within the hospital setting. Multiple focus groups had provided feedback that how well hospital staff worked together in caring for a patient was the most important information for them to have for comparing care hospitals provide.

Addition of the Restfulness of Hospital Environment Sub-Measure. This new sub-measure consists of 2 new questions and one current question and is intended to fill a gap related to providing a restful and healing environment and would address person-centered care. The current question, which is not being changed, is currently a stand-alone question that comprises the existing "Quietness" sub-measure.

Addition of Information About Symptoms Sub-Measure. This new sub-measure is intended to fill a gap of providing information for family and caregivers to take care of patients after discharge.

Modification of the Responsiveness of Hospital Staff Sub-Measure. One new survey question is being added to this existing sub-measure to address a gap related to nursing and other staff within the hospital setting, and one current question (the "Call Button" question) is being removed based on feedback that call buttons have been replaced by a direct phone line or other such mechanisms.

Removal of the Care Transition Sub-Measure.[72] CMS is replacing this sub-measure with the new Care Coordination sub-measure, believing the new sub-measure will be more encompassing and more congruent with other questions in the survey than the current care transition sub-measure.

Modification to the "About You" Section. The "About You" questions are used in the Hospital IQR, PCHQR, and HVBP Programs for patient-mix adjustments or congressionally mandated reports. The updated survey will include the following changes:

- Replacing the existing Emergency Room Admission question with a new Hospital Stay Planned in Advance question because the new question is believed to be better understood;
- Reducing the number of response options for the existing Language Spoken at Home question to include only English, Spanish, Chinese, or Some Other Language as options;
- Alphabetizing the response options for the existing ethnicity question; and
- Alphabetizing the response options for the existing race question.

HCAHPS Survey results are adjusted for patient-mix and mode of survey to account for factors not under the hospital's control that affect how patients answer questions. This is to ensure that the measure results reflect differences in hospital quality only. Neither patient race nor ethnicity is used to adjust HCAHPS Survey results, but are instead questions included in the survey for congressionally mandated reports. The modifications to the language options, ethnicity question and race question will not be included in public reporting of the survey nor will they affect scoring under the HVBP Program. The "Hospital Stay Planned in Advance" question will be used in the patient-mix adjustment of responses.

Implementation Timing for Hospital IQR and PCHQR Programs. The updated measure will be implemented in the Hospital IQR and PCHQR Programs beginning with patients discharged on January 1, 2025, and the reporting from responses from the measure for discharges between January 1, 2025 and December 31, 2025 will be used for the 2025 reporting period/FY 2027 payment determination for the Hospital IQR Program and 2025 reporting period/FY 2027 program year for the PCHQR Program.

Public Reporting for Hospital IQR and PCHQR Programs. HCAHPS Survey sub-measures are publicly reported on a quarterly rolling basis, with the oldest quarter of data removed and the most recent quarter included with each refresh. Therefore, there will be a period during which some quarters of reported data are coming from the current survey measure and others are coming from the updated survey measure. The agency finalizes that during that period the publicly reported survey data for the Hospital IQR and PCHQR Programs will consist only of data from the 8 unchanged sub-measures (those that are in the current version and that remain in the updated version). Once 4 quarters of the updated HCAHPS survey data have been submitted, then public reporting will reflect all of the modifications in the updated measure. Table IX.B.2-02 in the final rule includes the timeline for public reporting of the updated HCAHPS Survey measure in the Hospital IQR and PCHQR Programs.

[72] This sub-measure had been added to the survey in the IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53513-53516).

Burden Estimate. CMS determined that adopting the updated version of the HCAHPS Survey measure will amount to a minimal change in burden because the combination of removals and additions of survey questions would result in only an additional 45 seconds to complete the survey. The updates will not affect the survey administration, data submission and reporting requirements, or data collection protocols.

Pre-Rulemaking. The PRMR Hospital Recommendation Group reviewed the proposed updated HCAHPS Survey measure during its January 2024 meeting. For each of the PCHQR, Hospital IQR, and HVBP Programs, the group recommended the updates with the following conditions: CBE endorsement, consideration should be given to removal of overlapping items and not extending the survey length, use of adaptive questions in computerized administration to minimize items, and use of a mechanism to monitor trends in performance data.

In response to the conditions raised, CMS states that (i) the current HCAHPS Survey measure was most recently endorsed by a CBE on October 25, 2019, that it remains an endorsed measure, and that the agency intends to submit the updated measure (which only modifies some of the questions within the current survey) to the CBE for endorsement in fall 2025; (ii) its estimate for the total time required to complete the updated 32-question survey is, on average, 8 minutes, which is 45 seconds longer than the current survey after considering the balance of questions being added and removed; and (iii) adaptive survey questions in computerized administration would not be feasible in the mail mode of the survey and that since all modes available for the survey must be parallel, it could not include changes to address that condition raised. CMS will monitor trends in performance with the updated survey.

Selected Comments/Responses. Many commenters broadly supported the updates to the measure for reasons including that the updates promote person-centered care, better align with CMS' quality strategies, make the survey questions more relevant to patients and families while being useful to hospitals, reflect best practices for patient care, and include family caregivers in the updated questions.

Some commenters did not support the updates because of concern that the survey would be longer with more questions when the current survey already is burdensome to patients. CMS reviews feedback from patient focus groups, which informed the topics of the questions to be addressed, and further replies that it did not receive negative feedback about the length of the survey tested in the 2021 HCAHPS mode experiment which was 43 items compared to the 32 items in the updated survey measure. Also, the agency points to the 12-item limit on supplemental items that had been finalized in the 2024 IPPS/LTCH final rule, which limits the number of additional items hospitals may add. Other commenters suggested additional survey questions, including a medication reconciliation question, a patient consent question that would eliminate the need for organizations to add supplemental questions, and a question similar to one in the Medicare Advantage CAHPS Survey that addresses patients' perceptions of unfair or insensitive treatment during their hospital stay. CMS responds that it will consider these recommendations for future program years.

A few commenters requested clarifications regarding the impact of the updated HCAHPS Survey measure on the Star Ratings. CMS clarifies that the HCAHPS Summary Star Rating would

continue to be the average of the publicly reported HCAHPS Survey measure, as described in the Technical Notes for HCAHPS Star Ratings.[73] During the transition period when only 8 sub-measures will be used, the HCAHPS Summary Star Rating would be determined by averaging the Star Ratings from "Communication with Nurses," "Communication with Doctors," "Communication about Medicines," "Discharge Information," the average of the Star Ratings assigned to "Cleanliness of Hospital Environment" and "Quietness of Hospital Environment," and the average of the Star Ratings assigned to "Hospital Rating" and "Recommend the Hospital." The agency will update the technical notes on the HCAHPS website before the January 2026 public reporting on the Compare tool to describe how the 8 sub-measures will be used to calculate the Star Ratings, and will then again update the technical notes before the October 2026 public reporting on the Compare tool to describe the calculation of the HCAHPS Star Ratings when the number of publicly reported HCAHPS Survey sub-measures increases from 8 to 11. The weight of the Patient Experience measure group (which includes the HCAHPS Survey measure) in the Overall Hospital Quality Star Rating will not change without notice-and-comment rulemaking.

In response to comments regarding caregivers, CMS clarifies that the agency does not collect standardized patient assessment data or protected health information from patients or hospitals and the HCAHPS Survey measure does not include patient assessment data, and therefore the agency cannot add Caregiver Status to the list of standardized patient assessment data elements. CMS does say that it may consider developing and testing, though, items on caregiver status for future use. The agency further points out that it has added questions on communicating with family and caregivers in the new Care Coordination and Information about Symptoms sub-measures and that the agency finalized in the FY 2024 IPPS/LTCH PPS final rule the ability for a patient's proxy to respond to the HCAHPS Survey beginning with January 2025 discharges.

Several commenters suggested changes to the language of specific items included in the sub-measures. Generally, while the agency recognized the points raised for making changes, CMS did not agree with the suggested changes and responded that the specific language and items included in the measure underwent extensive review by patient focus groups and were tested for reliability and validity.

c. Modifications to Scoring of the HCAHPS Survey for the HVBP Program for the FY 2027 through FY 2029 Program Years

Section 1886(o)(2)(C)(i) of the Act prevents CMS from selecting a measure for inclusion into the HVBP Program for a performance period unless the measure has first been specified under the Hospital IQR Program and included on the Hospital Compare Internet website (Care Compare) for at least one year. This applies for the updated HCAHPS Survey measure, meaning that CMS must first collect and publicly report four quarters of data on the updated measure before the beginning of the performance period for which the updated measure could be included in the HVBP Program.

Therefore, CMS finalizes its policy, as proposed, to adopt the updated version of the measure into the HVBP Program beginning with the FY 2030 program year, and in order for hospitals to

[73] https://hcahpsonline.org/en/hcahps-star-ratings/#TechNotes.

not have to use two different surveys in the Hospital IQR and HVBP Programs during the period between FY 2027 through 2029, to score for that period only the 6 dimensions of the HCAHPS Survey that would remain unchanged from the current version. Specifically, during that three-year period HVBP Program hospitals will be able to administer the updated version of the survey beginning with January 1, 2025 discharges and CMS will score only the 6 dimensions of the HCAHPS Survey that will remain unchanged from the current version. Those 6 dimensions are: (i) Communication with Nurses, (ii) Communication with Doctors, (iii) Communication about Medicines, (iv) Discharge Information, (v) Cleanliness and Quietness, and (vi) Overall rating. The Care Transition and Responsiveness of Hospital Staff dimensions in the Person and Community Engagement domain will not be scored for the FY 2027 through FY 2029 program years.

For scoring purposes for that FY 2027 through FY 2029 program year period, CMS will calculate achievement points (0-10) and improvement points (0-9) for each of the 6 dimensions, the larger of which would be summed across the dimensions. This will create the pre-normalized HCAHPS Base Score of 0-60 (rather than the current 0-80 for the current 8 dimensions). The agency will then create a normalized HCAHPS Base Score by multiplying the pre-normalized score by 8/6 and applying standard rounding rules. Because each of the 6 dimensions would be given equal weight, the normalized score will range from 0 to 80 points. HCAHPS consistency points will be calculated consistent with current rules and would continue to range from 0 to 20 points, but will only include scores across the 6 unchanged dimensions. Finally, as with the current methodology, the normalized score will be added with the consistency points score for a total score, ranging from 0-100 points.

Selected Comments/Responses. Many commenters supported the modification to scoring for the FY 2027 through FY 2029 program years for reasons including that it minimizes burden and inconvenience by allowing for the administration of a single survey under the Hospital IQR and Hospital VBP Programs. A commenter raised concerns about there being greater pressure placed on the scores in the existing six dimensions rather than dispersed over more dimensions and therefore suggested delaying implementation. However, CMS believes that the process it will use to normalize the scores accounts for some of the differences in the number of dimensions.

d. Adoption of Updated HCAHPS Survey Measure and Scoring Modifications in the Hospital VBP Program Beginning with the FY 2030 Program Year

CMS is finalizing, as proposed, adoption of the updated HCAHPS Survey measure into the HVBP Program (aligning with the updated measure proposed for the Hospital IQR Program) beginning with the FY 2030 program year, which consists of the 2028 performance period and 2026 baseline period. The newly finalized modifications include the following:

- The current Care Transition dimension is removed.
- The new Care Coordination, Restfulness of the Hospital Environment, and Cleanliness and Information about Symptoms dimensions are added.
- The current Cleanliness and Quietness dimension is modified. The dimension is renamed as the Cleanliness and Information About Symptoms dimension, and the Quietness

question is moved to the new Restfulness of Hospital Environment dimension, but the question remains the same.

- The resulting 9 dimensions are (i) Communication with Nurses, (ii) Communication with Doctors, (iii) Responsiveness of Hospital Staff, (iv) Communication about Medicines, (v) Cleanliness and Information About Symptoms, (vi) Discharge Information, (vii) Overall Rating of Hospital, (viii) Care Coordination, and (ix) Restfulness of Hospital Environment.
- The number and content of the dimensions will differ slightly from the newly adopted number and content of sub-measures in the updated survey for the Hospital IQR and PCHQR Programs. Namely, the "Cleanliness" and "Information about Symptoms" sub-measures will be combined into one dimension in the HVBP Program.
- Table IX.B.2-03 of the rule provides the timelines for the current and newly adopted HCAHPS Survey dimensions.

CMS also finalizes, as proposed, the following new scoring methodology beginning with the FY 2030 program year. The agency will calculate the achievement points (0-10) and improvement points (0-9) for each of the 9 dimensions. The larger of the achievement and improvement scores for each will then be summed across the dimensions to create a pre-normalized HCAHPS Base Score of 0-90 points (instead of the current 0-80 points for the current 8 dimensions). The result will be multiplied by 8/9 and rounded to arrive at the normalized HCAHPS Base Score (ranging between 0-80 points). HCAHPS consistency points will be determined as they are now and will range from 0-20 points and will consider scores across all 9 dimensions. Finally, the normalized HCAHPS Score will be added to the HCAHPS consistency points score to determine the total score (ranging from 0-100 points).

Selected Comments/Responses. In response to a commenter's question regarding domain weights, CMS clarifies that the domain weights would remain unchanged, with each of the four domains in the Hospital VBP Program ((i) clinical outcomes, (ii) person and community engagement, (iii) safety, and (iv) efficiency and cost reduction) continuing to be weighted at 25 percent.

3. Advancing Patient Safety and Outcomes Across the Hospital Quality Programs: Request for Comment Feedback

In the FY 2025 IPPS LTCH PPS proposed rule, CMS sought feedback on ways to build upon current measures in CMS quality reporting programs that account for unplanned patient hospital visits to incentivize hospitals to improve discharge processes, such as by introducing existing quality reporting measures into the VBP programs or by adopting new measures that better represent the range of patient outcomes post discharge. There are currently 3 Excess Days in Acute Care measures in the Hospital IQR Program that estimate days spent in acute care within 30 days post discharge from an inpatient hospitalization ((i) Excess Days in Acute Care (EDAC) after Hospitalization for Acute Myocardial Infarction, (ii) EDAC after Hospitalization for Heart Failure, and (iii) EDAC after Hospitalization for Pneumonia). The Hospital Visits After Hospital Outpatient Surgery measure has been adopted in the Hospital Outpatient Quality Reporting and Rural Emergency Hospital Quality Reporting Programs. The agency does not believe that these measures comprehensively capture unplanned patient returns to inpatient or outpatient care after

discharge, and notes that since the existing measures are in quality reporting, and not VBP programs, performance on measures is not enforced through payment incentives.

Selected Comments/Responses. Many commenters supported measuring a wider range of post-discharge patient outcomes, including ED visits and observations services, which some commenters believe would allow for better analysis of post-discharge care. Several commenters preferred the EDAC measures to CMS' readmission measures for assessing preventable hospital returns, but requested refinements to the EDAC measures. Many commenters raised concerns about unintended consequences of readmission measures for hospitals and patients, including that the measures do not account for factors outside of hospitals' control and may result in physicians choosing healthier patients or deferring timely evaluation of post-operative concerns. Other commenters questioned if adding the EDAC measures into the Hospital VBP Program would be allowed under statute, and instead suggested adding readmission measures into quality reporting programs that do not have performance-based penalties. CMS acknowledges that the agency does not have statutory authority to adopt readmission measures into the Hospital VBP Program. The agency also acknowledges that there are factors outside of the hospital's control that influence health outcomes of patients, but believes that hospitals are usually one of the most resourced health care entities in communities and have an important influence over the health of their patients. CMS notes that any future proposal to implement a new measure or program change would be announced through notice and comment rulemaking.

Other feedback was provided on ways to reduce unplanned readmissions and improve patient post-discharge outcomes. Some commenters suggested promoting access to at home care, such as through the Acute Hospital Care at Home program, as a means to reduce readmissions. Other suggestions included counting observation stays towards the skilled nursing facility 3-day rule, under Medicare Part A payment, or eliminating observation stays to create a single hospitalization status.

C. Hospital Inpatient Quality Reporting (IQR) Program

CMS finalizes changes to the Hospital IQR program that add 7 new measures (including the Patient Safety Structural measure described above), modify 2 existing measures (including the updated HCAHPS Survey measure described above), and remove 5 measures. The agency also finalizes changes to the reporting and submission requirements for electronic clinical quality measures (eCQMs) and the validation process.

CMS estimates a total information collection burden increase for 3,050 IPPS hospitals of 40,160 hours at a cost of $1,282,329 annually associated with the finalized policies across a 3-year period from the 2025 reporting period/FY 2027 payment determination through the 2028 reporting period/FY 2030 payment determination, compared to the currently approved information collection burden estimates.

CMS further estimates that for FY 2025, 90 hospitals will not receive the full market basket rate update factor increase for failure to meet the IQR Program requirements or choosing not to participate in the program (but that are meaningful users under the Medicare Promoting Interoperability Program) and will receive a 2.05 percent update; 82 hospitals will not receive the

full update for not being meaningful EHR users (but do meet the IQR Program requirements) and will receive a 0.35 percent update; and 27 hospitals will not receive the full update for failure to satisfy both requirements and will receive a -0.5 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.

CMS did not propose any changes to the previously finalized retention of adopted measures policy,[74] the measure removal factors policy codified at 42 CFR 412.140(g)(2) and (3), or the considerations used to expand and update quality measures under the Hospital IQR Program.[75] However, the agency describes the statutory and regulatory background for these policies.

2. New Measures for the Hospital IQR Program Measure Set

CMS finalizes, as proposed, adoption of 7 new measures (all discussed in further detail below):

- Beginning with the 2025 reporting period/FY 2027 payment determination:
  - The Patient Safety Structural measure (the cross-program measure proposed under section IX.B.1. of the rule); and
  - The Age Friendly Hospital measure.
- Beginning with the 2026 reporting period/FY 2028 payment determination:
  - The Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations measure;
  - The Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure;
  - The Hospital Harm - Falls with Injury eCQM; and
  - The Hospital Harm - Postoperative Respiratory Failure eCQM.
- Beginning with the July 1, 2023 – June 30, 2025 reporting period/FY 2027 payment determination, the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) measure.

[74] The policy 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. The finalized measure retention policy can be found in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 and 53513), codified at 42 CFR 412.140(g)(1).

[75] See FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for considerations used to expand and update quality measures. Also, see section IX.B.1.c. of the proposed rule for details on the updated pre-rulemaking measure review (PRMR) process, including for measure endorsement and maintenance.

a. Age Friendly Hospital Measure

Background. CMS describes the aging population in the United States and the increasing complexity of treating this population, which often has multiple chronic conditions. Multiple organizations, including the American College of Surgeons, the Institute for Health Improvement (IHI), and the American College of Emergency Physicians collaborated to establish age-friendly initiatives based on evidence-based best practices to address the challenges of delivering care to this population. The organizations developed a framework of 4 evidence-based elements called the "4 Ms" (What Matters, Medication, Mentation, and Mobility) to help organize care for older adults' wellness regardless of a person's culture, race, ethnicity, religious background, or chronic conditions.

CMS is finalizing, as proposed, the adoption of an attestation-based structural measure, the Age Friendly Hospital measure, to ensure that hospitals are reliably implementing the "4 Ms". The elements of the measure align with the IHI's and Hartford Foundation's national initiative for Age Friendly Systems in which many hospitals already participate. This is a streamlined and combined version of the former two potential geriatric care measures on which the agency solicited comment for inclusion in the Hospital IQR Program in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27103 through 27109).

Overview of Measure. The Age Friendly Hospital measure assesses hospital commitment to improving care for patients age 65 or older receiving services in the hospital, operating room (OR), or emergency department (ED). It consists of 5 attestation domains ((i) Eliciting Patient Healthcare Goals, (ii) Responsible Medication Management, (iii) Frailty Screening and Intervention, (iv) Social Vulnerability, and (v) Age-Friendly Care Leadership) and corresponding attestation statements (shown in Table IX.C-1 of the rule).

Measure Calculation. The measure consists of 5 domains and corresponding attestation statements. For each domain, to receive a point for the domain, hospitals need to affirmatively attest to all of the statements within the domain for each hospital reported under their CCN, with a total of 5 possible points (one per domain). Partial points will not be available. However, because the Hospital IQR Program is a pay-for-reporting program, hospitals will receive credit for reporting results regardless of their responses or points.

Data Submission and Reporting. Structural measures are required to be reported once annually using a CMS-approved web-based data collection tool available within the HQR System. CMS is requiring reporting of the measure beginning with the 2025 reporting period/FY 2027 payment determination.

Pre-Rulemaking. The measure was included on the 2023 MUC List and considered by the PRMR Hospital Committee in January 2024. The committee did not reach consensus and did not recommend including this measure in the Hospital IQR Program. Several members of the committee supported the measure because it prioritizes improving care for older patients, but other members were concerned that the domains were not structured tightly enough in scope to drive action. CMS disagrees, believing the measure supports practices that promote transparent

reporting and prioritization of resources to implement best practices. CMS is adopting the measure, consistent with the exception for non-CBE-endorsed measures.[76]

Selected Comments/Responses. Many commenters supported adoption of the measure, including because it would create a safer environment for older adults in hospitals, is evidence-based, builds on guidelines established by several medical specialty societies, and uses the "4 Ms." Some commenters did not support the measure for reasons including that some of the practices captured by the measure are duplicative of other reporting requirements. CMS responds that the Medicare conditions of participation (CoP) for hospitals related to quality assessment and improvement programs is different from the Age Friendly Hospital measure. The CoPs set forth minimum activities regarding developing and implementing an effective quality assessment and improvement program while the measure requires hospitals to attest to whether they have built upon the minimum requirements to exemplify optimizing care for older patients in certain ways – and thus the measure complements the CoP rather than duplicates it.

Some commenters raised concerns about the accuracy of provider self-reported data and about the utility of measures that use such data, as compared to outcome measures. CMS acknowledges there is no existing validation process confirming the accuracy of hospitals' responses to these types of measures, but structural measures in certain instances have advantages over other types of measures, such as they provide a way to address a new topic for which no outcome measure exists. In addition, the agency clarifies that it requires all hospitals participating in the Hospital IQR Program to complete the Data Accuracy and Completeness Acknowledgement, which is an annual attestation that all information reported to CMS for the program is accurate and complete.

A few commenters did not support the measure because of concerns about increased administrative burden, but the agency believes that adopting the measure promotes the implementation of evidence-based practices for quality care for older adults with multiple medical conditions and that implementation of such practices is integral to improving patient care and outcomes.

b. Adoption of Two Healthcare-Associated Infection (HAI) Measures Beginning with 2026 Reporting Period/2028 Payment Determination

Background. CMS describes how the agency previously adopted the NHSN Catheter-Associated Urinary Tract Infection (CAUTI)[77] and NHSN Central Line-Associated Bloodstream Infection (CLABSI)[78] measures into quality reporting programs to measure the risk-adjusted standardized infection ratio among adult inpatients. Though the measures include most major inpatient care wards at inpatient hospitals reporting under the Hospital IQR Program, oncology wards at these hospitals have not been included despite the vulnerability of patients with cancer developing HAIs.

CMS finalizes, as proposed, adoption of the CAUTI Standardized Infection Ratio Stratified for Oncology Locations and the CLABSI Standardized Infection Ratio Stratified for Oncology

[76] See section 1886(b)(3)(B)(viii)(IX)(bb) of the Act for the exception to the rule for CBE endorsement.
[77] The CAUTI measure is used in the HAC Reduction and Hospital VBP Programs.
[78] The CLABSI measure is used in the HAC Reduction and Hospital VBP Programs.

Locations (referred to as the CAUTI-Onc measure and CLABSI-Onc measure, respectively), beginning with the 2026 reporting period/FY 2028 payment determination. The original CAUTI and CLABSI measures look at hospital inpatients except for those in oncology wards, whereas these newly finalized measures look only at patients in oncology wards.

CAUTI-Onc Measure.

Overview. The measure is to encourage best practices (set by the CDC) for the use of urinary catheters to reduce the incidence of CAUTIs for patients with cancer. Hospitals will need to verify that all locations, including those with oncology patients, are mapped in NHSN in order to report the measure.

Measure Calculation. The NHSN calculates the quarterly risk-adjusted standardized infection ratio (SIR) of CAUTIs among inpatients at acute care hospitals who are in oncology wards. The CDC calculates the SIR using all four quarters of data from the reporting period year, which CMS then uses for performance calculation and public reporting. The SIR compares the actual number of CAUTIs to the expected number. An oncology ward is defined by the CDC as an area for the evaluation and treatment of patients with cancer. The SIR of one facility is not meant to be compared to another facility's, but to compare the facility's CAUTI rate to the national rate after adjusting for facility and patient risk factors.

- Numerator. Number of annually observed CAUTIs among acute care hospital inpatients in oncology wards.
- Denominator. Number of annually predicted CAUTIs among acute care hospital inpatients in oncology wards.

Pre-Rulemaking. The measure was included on the 2023 MUC List and considered by the PRMR Hospital Committee during January 2024. The committee recommended including the measure in the Hospital IQR Program with the following conditions: (i) consideration of expanding the reporting period, and (ii) for the measure to evaluate data by oncology unit type. CMS believes that expanding the reporting period would cause critical loss in the ability to observe changes in the SIR over time, which would degrade the ability to assess prevention efforts and drive improvement. CMS may consider the second condition for future rulemaking. The current CAUTI measure (CBE # 0138) was endorsed on October 23, 2019, and CMS states that additional endorsement of the CAUTI-onc measure is not necessary since it has the same specifications as the CAUTI measure but is stratified for oncology specific locations. The CDC will incorporate information on the stratification by oncology patients during the regularly scheduled measure maintenance re-endorsement process.

Data Submission and Reporting. The measure will be collected through the CDC's NHSN. For purposes of the Hospital IQR Program requirements, hospitals will report data for the CAUTI-onc measure quarterly. Hospitals will collect the numerator and denominator for the measure each month and submit data to the NHSN, and the data from all 12 months will be calculated into quarterly reporting periods. Currently, CAUTI data is reported to the NHSN monthly and the SIR is calculated on a quarterly basis.

CLABSI-Onc Measure.

Overview. This measure is to encourage use of best practices for central line use, to promote CLABSI prevention activities, and to reduce incidence of CLABSIs for patients with cancer. Hospitals will need to verify that all locations, including those with oncology patients, are mapped in NHSN in order to report the measure.

Measure Calculation. The NHSN calculates the quarterly risk-adjusted SIR of CLABSIs among inpatients at acute care hospitals who are in oncology wards. The CDC calculates the SIR using all four quarters of data from the reporting period year, which CMS then uses for performance calculation and public reporting. The SIR compares the actual number of CLABSIs to the expected number. The SIR of one facility is not meant to be compared to another facility's, but to compare the facility's CLABSI rate to the national rate after adjusting for facility and patient risk factors.

- Numerator. Number of annually observed CLABSIs among acute care hospital inpatients in oncology wards.
- Denominator. Number of annually predicted CLABSIs among acute care hospital inpatients in oncology wards.

Pre-Rulemaking. The measure was included on the 2023 MUC List and considered by the PRMR Hospital Committee during January 2024. The committee recommended including the measure in the Hospital IQR Program with the following conditions: (i) consideration of expanding the reporting period, and (ii) for the measure to evaluate data by oncology unit type. CMS believes that expanding the reporting report would cause critical loss in the ability to observe changes in the SIR over time, which would degrade the ability to assess prevention efforts and drive improvement. CMS may consider the second condition for future rulemaking. The current CLABSI measure (CBE # 0139) was endorsed on October 23, 2019, and CMS states that additional endorsement of the CLABSI-onc measure is not necessary since it has the same specifications as the CLABSI measure but is stratified for oncology specific locations. The CDC will incorporate information on the stratification by oncology patients during the regularly scheduled measure maintenance re-endorsement process.

Data Submission and Reporting. The measure will be collected through the CDC's NHSN. For purposes of the Hospital IQR Program requirements, hospitals will report data for the CLABSI-onc measure quarterly. Hospitals will collect the numerator and denominator for the measure each month and submit data to the NHSN, and the data from all 12 months will be calculated into quarterly reporting periods. Currently, CLABSI data is reported to the NHSN monthly and the SIR is calculated on a quarterly basis.

Selected Comments/Responses. In response to a request for further information on how SIRs would be calculated, CMS clarifies that the SIR is a scalable, risk-adjusted metric. In CAUTI and CLABSI SIRs, risk adjustment is applied at the individual location level, resulting in a count of infection events (SIR numerator) and predicted number of infections (SIR denominator). The NHSN then aggregates location-specific results for all of a facility's locations prior to calculating the SIR. Further, the calculated SIR for both of the newly adopted measures is adjusted for

volume. The SIR compares the actual number of cases to the predicted number of cases and is calculated where there is at least one predicted infection event.

In response to another request for clarification on the impact of a "not applicable" response for hospitals, CMS responds that NHSN does not have such a response option when reporting these measures. Therefore, hospitals that do not have oncology wards would leave these location types blank in the system, NHSN would not be able to calculate a SIR, and the hospital's data would not be publicly reported. A hospital without an oncology ward would need to complete the Measure Exception form to indicate this on that form in order to avoid a penalty through a reduction in a hospital's annual payment update (APU) for failing to report the measure.[79]

c. Adoption of Hospital Harm – Falls with Injury eCQM Beginning with 2026 Reporting Period/FY 2028 Payment Determination

Background. CMS describes how patient falls are among the most commonly reported hospital harms and can increase length of stay and costs, and that since there is great variation in fall rates between hospitals, this is an area where quality measurement and improvement is needed. Further, the agency describes that there are no electronic clinical quality measures (eCQMs) that focus on acute care inpatient falls with major or moderate injury in any of the hospital quality reporting or VBP Programs.

Overview and Calculation of Adopted Measure. CMS finalizes, as proposed, to adopt the Hospital Harm – Falls with Injury measure, a risk-adjusted outcome eCQM, beginning with the 2026 reporting period/FY 2028 payment determination. Adoption of this measure in the Medicare Promoting Interoperability Program is discussed in section IX.F.6.a(2) of the rule and a discussion of use of this measure in the Transforming Episode Accountability Model (TEAM) is discussed in section X.A.3.c of the rule.

The measure is reported as the number of inpatient hospitalizations with falls with moderate or major injury per 1,000 patient days, and is calculated as the ratio of the numerator to the denominator multiplied by 1,000.

- Numerator. Total number of encounters with falls with moderate or major injury; determined as inpatient hospitalizations for patients identified in the initial population (and not subject to exclusion) and who during the hospitalization had a fall that results in moderate injury or major injury.
- Denominator. Total number of eligible hospital days; determined as inpatient hospitalizations for patients aged 18 and older with a length of stay less than or equal to 120 days that ends during the measurement period.
- Exclusions. Diagnosis of a fall and of a moderate or major injury that was present on admission.

Pre-Rulemaking. The measure was included on the 2023 MUC List and considered by the PRMR Hospital Committee during January 2024. The committee recommended including the

[79] For more information about the submission process, see the CDC's operational guidance for reporting CAUTI and CLABSI data, available at: https://www.cdc.gov/nhsn/cms/ach.html.

measure in the Hospital IQR Program with the condition of monitoring unintended consequences, such as use of patient restraints. CMS notes that it consistently monitors all of the adopted measures for unintended consequences. The measure (CBE #4120e) was endorsed on January 29, 2024.

Data Sources. The measure uses data collected through hospitals' EHRs and is designed to be calculated using certified electronic health record technology (CEHRT) and then submitted to CMS. The measure will be part of the eCQM measure set, from which hospitals may self-select measures to report to meet the eCQM reporting requirement.

Selected Comments/Responses. Several commenters raised concerns that the eCQM overlaps with the PSI 08 component of the PSI 90 measure in the HAC Reduction Program and pointed out the burden of these overlapping measures. CMS responds that the Hospital Harm – Falls with Injury eCQM assesses the rate of falls with a wider range of injuries in a larger population and uses more timely information from patients' electronic medical records, as compared to PSI 08 (which uses administrative claims data).

d. Adoption of the Hospital Harm – Postoperative Respiratory Failure eCQM Beginning with 2026 Reporting Period/FY 2028 Payment Determination

Background. CMS describes how postoperative respiratory failure, which is considered the most serious postoperative respiratory complication, is potentially preventable, and that there are currently no eCQMs that focus on postoperative respiratory failure in the inpatient setting in any of the quality reporting or VBP programs. CMS acknowledges the postoperative respiratory failure related component (PSI 11) of the PSI 90 composite measure, but in comparison the agency believes the Hospital Harm – Postoperative Respiratory Failure eCQM will enable assessment of the rate of postoperative respiratory failure in a larger population and use more timely information from patients' electronic medical records (EMRs) instead of administrative claims data.

Overview and Calculation of Measure. CMS finalizes, as proposed, adoption of the Hospital Harm – Postoperative Respiratory Failure measure, a risk-adjusted outcome eCQM, beginning with the 2026 reporting period/FY 2028 payment determination. Adoption of the measure in the Medicare Promoting Interoperability Program is discussed in section IX.F.6.a(2) of the rule and use of the measure in TEAM is discussed in section X.A.3.c of the rule.

The measure will be calculated as 1,000 multiplied by the ratio of the number of encounters in the numerator to the number of encounters in the denominator (accounting for the denominator exclusions).

- Numerator. Elective inpatient hospitalizations for patients with postoperative respiratory failure.
- Denominator. Elective inpatient hospitalizations that end during the measurement period for patients at least 18 years of age without an obstetrical condition and for whom at least one surgical procedure was performed within the first 3 days of the encounter.

- Risk-adjustment. Accounts for 10 comorbidities present at admission (weight loss, deficiency anemias, heart failure, diabetes with chronic complications, moderate to severe liver disease, peripheral vascular disease, pulmonary circulation disease, valvular disease, and American Society of Anesthesiologists categories 3-5) and lab values for oxygen, leukocytes, albumin, blood urea nitrogen, bilirubin, and pH of arterial blood.

Pre-Rulemaking. The measure was included on the 2023 MUC List and considered by the PRMR Hospital Committee during January 2024. The committee recommended including the measure in the Hospital IQR Program with the condition of monitoring unintended consequences, such as avoidance of life-saving procedures with higher risk for respiratory failure. CMS notes that it consistently monitors all of the adopted measures for unintended consequences. The measure (CBE #4130e) was endorsed on January 29, 2024.

Data Submission and Reporting. The measure uses data collected through hospitals' EHRs and is designed to be calculated using CEHRT and then submitted to CMS. The measure will be part of the eCQM measure set, from which hospitals may self-select measures to report to meet the eCQM reporting requirement.

Selected Comments/Responses. Many commenters supported inclusion of the eCQM. Some commenters recommended expanding the denominator exclusion criteria. CMS indicates it will consider expansion of the exclusion criteria for future updates to the eCQM. A few hospitals raised concerns about how hospitals capture the data used in the measure and how that data would be mapped to an eCQM, including concerns on data not being captured in a standardized manner. The agency responded that feasibility test results confirmed that the data elements used in the measure are captured within the EHR in a structured manner using nationally accepted terminology standards or local system codes that could be easily mapped. To account for certain underlying conditions that place some patients at a higher risk of respiratory failure post-surgical procedure, the measure excludes inpatient hospitalizations for patients with select underlying conditions and diagnoses. In addition, CMS clarifies that to meet the measure's numerator criteria, patients must have experienced (i) the initiation of mechanical ventilation within 30 days after the first operating room procedure, or (ii) mechanical ventilation with a duration of more than 48 hours after the first operating room procedure.

In response to a comment regarding the burden of new eCQMs given the future shift to digital quality measures (dQMs), the agency notes that eCQMs would be considered a subset of dQMs, specifically pointing to its definition of dQMs as: "quality measures that use standardized, digital data from one or more sources of health information that are captured and exchanged via interoperable systems; apply quality measure specifications that are standards-based and use code packages; and are computable in an integrated environment without additional effort."

e. Adoption of the Thirty-Day Risk-Standardized Death Rate Among Surgical Inpatients with Complications (Failure-to-Rescue) Measure Beginning With 2027 Payment Determination

Overview. CMS finalizes as proposed adoption of the Failure-to-Rescue measure, which is a risk-standardized measure of death after hospital-acquired complication, beginning with the July 1, 2023 through June 30, 2025 performance period affecting the FY 2027 payment determination. Use of the measure in TEAM is discussed in section X.A.3.c of the rule.

Background. CMS describes how hospitals benefit from knowing their ability to rescue patients after an adverse occurrence, and that using a failure-to-rescue measure could be informative especially if hospital resources for preventing complications are different from those needed for rescue. The Failure-to-Rescue measure is designed to improve upon the CMS Patient Safety Indicator 04 Death Rate Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) measure in the Hospital IQR Program, and will replace that measure, which CMS finalizes for removal under section IX.C.6 of the rule. CMS describes the common aspects of the 2 measures, including that both focus on hospitals' ability to rescue patients who experience clinically significant complications after inpatient operations, and both are affected by nurse staffing and nurse skill-mix. The agency also lists the major differences between the newly finalized measure and the CMS PSI 04, including that the Failure-to-Rescue measure:

- Captures all deaths of denominator-eligible patients within 30 days of the first qualifying OR procedure, regardless of site.
- Limits the denominator to patients in general surgical, vascular, and orthopedic MS-DRGs.
- Excludes patients whose relevant complications preceded their first inpatient OR procedure and broadens the definition of denominator-triggering complications to include other complications that may predispose to death.
- Has a cohort that includes MA patients.

Calculation of Measure. The measure uses Medicare FFS Part A inpatient claims data, Medicare inpatient encounter data for MA enrollees, and validated death data from the Medicare Beneficiary Summary File or resources equivalent to such file.

- Numerator. Patients who died within 30 days from the date of their first OR procedure, regardless of site of death.
- Denominator. Patients at least 18 years of age admitted for certain procedures in the general surgery, orthopedic, or cardiovascular MS-DRGs who upon admission were Medicare beneficiaries with no documented complication present.[80]

Lower scores (i.e., hospitals performing in the lower percentiles) represent better performance.

Pre-Rulemaking. The measure was included on the 2023 MUC List and considered by the PRMR Hospital Committee during January 2024. The committee recommended including the measure in the Hospital IQR Program with the condition of monitoring unintended consequences, such as encouraging patients to sign a DNR order or enter hospice. CMS notes that it consistently monitors all of the adopted measures for unintended consequences. The measure was submitted for CBE endorsement and on January 29, 2024 the Endorsement & Maintenance (E&M) Committee of the Partnership for Quality Measurement (PQM) voted to endorse the measure (CBE #4125) with the condition for performing additional reliability testing for endorsement review, primarily conducting additional simulation analyses of minimum case

[80] For details on, and a complete list of, the denominator exclusions, see the Failure-to-Rescue Measure Specifications on the QualityNet website at: https://qualitynet.cms.gov/inpatient/iqr/measures.

volume adjustments. CMS notes that it will monitor data as part of standard measure maintenance.

Data Submission and Reporting. The measure uses administrative claims data routinely generated and submitted to CMS; therefore, hospitals will not be required to report additional data. The measure will be calculated and publicly reported on an annual basis using a rolling 24 months of prior data, consistent with what is currently used for CMS PSI 04 and the Patient Safety and Adverse Events Composite measure, PSI 90.

Selected Comments/Responses. Many commenters supported the measure. Other commenters expressed concerns generally about using patient safety measures derived from claims data because the data would eliminate the clinical components of care from quality calculations and not accurately reflect hospital performance. CMS disagrees and points to (i) studies that show using claims data captures variation in mortality outcomes across hospital systems and (ii) support by TEP members for the measure's relevance in assessing quality of care.

Several commenters expressed concerns about the performance period for the measure beginning on July 1, 2023, which is more than a year before the measure's adoption in the Hospital IQR Program, and requested that the timeline be reconsidered to avoid the use of claims data for years for which the measure had not been adopted. CMS clarifies that the measure is calculated and publicly reported on an annual basis using a rolling 24 months of prior data for the measurement period and that such a performance period (which occurs in the past) is consistent with the CMS PSI 04 measure and the CMS PSI 90 composite measure. The 24 months of prior data, CMS explains, is necessary to ensure the measure is calculated with sufficient reliability and validity using a large enough set of claims data. The agency also notes that before public reporting, information on a hospital's performance on the measure will be provided to the hospital as part of the program's preview period process. Quality data displayed for each quarter on Care Compare are made available to providers for a 30-day preview period about two months ahead of display.

A few commenters did not support the measure because of concerns raised regarding its reliability. CMS agrees with potential for unintended consequences and notes that it will consistently monitor all measures in the Hospital IQR. The agency also notes that the measure is an improvement compared to the CMS PSI 04 measure because of its increased reliability and validity largely because of the application of the measure to both FFS and MA enrollees.[81]

3. Measure Removals

a. Removal of the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) Measure Beginning with FY 2027 Payment Determination

[81] Additional details related to the Failure-to-Rescue measure's reliability results can be found on the Partnership for Quality Measurement website: Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) | Partnership for Quality Measurement (p4qm.org).

CMS finalizes, as proposed, the removal of the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) claims-based measure beginning for the FY 2027 payment determination (and corresponding July 1, 2023 through June 30, 2025 reporting period).

Measure Description. The CMS PSI 04 measure is a claims-based measure that records in-hospital deaths per 1,000 elective surgical discharges among patients ages 18 through 89 years old or obstetric patients with serious treatable complications. The measure's CBE endorsement has not been maintained and it has not been updated since 2017. The agency describes recent studies that indicate the measure does not consistently recognize failure-to-rescue cases.

Basis for Removal. Removal factor 3, the availability of a more broadly applicable measure or a measure that is more proximal in time to desired patient outcomes for the particular topic. CMS is removing the measure and at the same time adopting the Failure-to-Rescue measure, discussed in section IX.C.5.e of the rule, which it believes will be a more broadly applicable measure and more appropriate for inclusion in the measure set. Some differences described between the measures are outlined above in section IX.C.2.e of this summary.

Selected Comments/Responses. Many commenters broadly supported the removal of the CMS PSI 04 measure. A few commenters were concerned that the change from in-hospital deaths (measured by CMS PSI 04) to 30-day mortality (measured by Failure-to-Rescue) will increase the possibility of data being skewed by mortalities that are unrelated to hospital complications. CMS responds that unlike the CMS PSI 04 measure, the Failure-to-Rescue measure excludes patients whose relevant complications preceded their first inpatient operating room procedure and limits the scope of patients assessed to the general surgical, vascular, and orthopedic MS-DRGs. Further, the agency responds that the measure's risk-standardization process controls for factors that are beyond the hospital's control.

b. Removal of Four Clinical Episode-Based Payment Measures Beginning with FY 2026 Payment Determination

CMS finalizes, as proposed, removal of the following 4 clinical episode-based payment measures beginning for the FY 2026 payment determination (i.e., FY 2025 will be the final payment determination for each):

- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI Payment) measure; the final performance period will be July 1, 2020 – June 30, 2023.
- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF Payment) measure; the final performance period will be July 1, 2020 – June 30, 2023.
- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN Payment) measure; the final performance period will be July 1, 2020 – June 30, 2023.
- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (THA/TKA Payment) measure; the final performance period will be April 1, 2020 – March 31, 2023.

All 4 measures are being removed under removal factor 3, the availability of a more broadly applicable measure or a measure that is more proximal in time to desired patient outcomes for the particular topic, specifically the Medicare Spending Per Beneficiary (MSPB) Hospital measure in the HVBP Program. The MSPB Hospital measure evaluates hospitals' efficiency and resource use relative to the efficiency of the national median hospital and captures the same data as the 4 measures being removed but incorporates a larger set of conditions and procedures. It does not, however, provide the same level of granularity of data.

Selected Comments/Responses. Generally, there was broad support for removal of the 4 measures. A few commenters did not support removal and expressed concern about the adequacy of the MSPB Hospital measure as a replacement, including because it does not include non-Medicare costs and lacks granular details that would be provided by the measures being removed. CMS disagrees and believes the MSPB Hospital measure in an adequate replacement, stating that it captures the same data as the 4 measures being removed and incorporates a larger set of conditions and procedures.

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

In addition to the newly finalized refinements to the HCAHPS Survey measure (discussed in section IX.B.2 of the rule and described in section IX.B.2 of this summary), CMS is also finalizing, as proposed, a modification to the Global Malnutrition Composite Score (GMCS) eCQM beginning with the 2026 reporting period/FY 2028 payment determination. The agency's newly finalized modification to the measure expands the applicable population (currently hospitalized patients 65 and older) to hospitalized adults 18 or older. This is the only change to the current measure specifications.[82] Adoption of this measure in the Medicare Promoting Interoperability Program is discussed in section IX.F.6.a(2) of the rule.

Background on Current Measure. CMS adopted, in the FY 2023 IPPS/LTCH PPS final rule,[83] the current GMCS eCQM measure into the Hospital IQR Program beginning with the 2024 reporting period/FY 2026 payment determination. It assesses the percentage of hospitalizations for *patients 65 and older* with a length of stay of at least 24 hours who received optimal malnutrition care during the current inpatient hospitalization. CMS discusses that screening *all patients over 18* years of age, rather than only those over age 65, for malnutrition could improve clinical outcomes and reduce health system costs.

Modified GMCS eCQM Calculation. The modified measure continues to use data collected through hospitals' EHRs and is calculated by the hospitals' CEHRT using patient-level data and then submitted by hospitals to CMS. The modified measure also continues to consist of 4 component measures ((i) completion of malnutrition screening, (ii) completion of nutrition assessment for patients at-risk for malnutrition, (iii) appropriate documentation of malnutrition diagnosis, and (iv) nutrition care plan for malnourished patients after completed assessment), which are first scored separately. Each measure component is a proportion with a possible performance score of 0-100 percent (higher reflects better performance). A final composite score for the individual is calculated as the unweighted average of all 4 scores.

[82] Measure specifications can be found at https://ecqi.healthit.gov/ecqm/eh/2024/cms0986v2.
[83] 87 FR 49239-49246.

- Numerator. Comprised of 4 component measures, which are individually scored for patients 18 and older admitted to an acute inpatient hospital.
- Denominator. Total of the 4 component measures for patients 18 and older admitted to an acute inpatient hospital.
- Exclusion. Patients whose length of stay is less than 24 hours.

Pre-Rulemaking. The modified measure was on the 2023 MUC List and considered by the PRMR Hospital Committee in its January 2024 meeting. The committee recommended adopting the measure with the condition that screening and assessment include hospital-acquired malnutrition and high-risk nutritional practices in hospitals and that CMS obtain more feedback from patient groups. CMS states that it consistently monitors all measures for unintended consequences. The current measure received CBE endorsement in the Fall 2020 cycle (CBE #3592e) and the modified measure, as finalized, is scheduled for endorsement review in 2024.

Data Submission and Reporting. The modified GMCS eCQM will be included in the measure set from which hospitals can self-select beginning with the 2026 reporting period/FY 2028 payment determination. Same data sources and collection methods will be used as with the current measure.

5. Summary of Previously and Newly Finalized Hospital IQR Program Measures

CMS provides tables (Table IX.C.5 through Table IX.C.8) showing the Hospital IQR Program measure set for each of the FY 2026 through FY 2029 payment determinations and subsequent years, including with the newly finalized policies. Selected information from those tables is consolidated into the table below.

Summary Table IQR Program Measures by Payment Determination Year				
	2026	**2027**	**2028**	**2029**
Chart-Abstracted Process of Care Measures				
Severe sepsis and septic shock: management bundle (NQF #500)	X	X	X	X
Electronic Clinical Quality Measures				
STK-2 Antithrombotic therapy for ischemic stroke (CBE #0435e) STK-3 Anticoagulation therapy for Afib/flutter (CBE #0436e)*** STK-5 Antithrombotic therapy by end of hospital day 2 (CBE #0438e) VTE-1 VTE prophylaxis (CBE #0371) VTE-2 ICU VTE prophylaxis (CBE #0372) Safe Use of Opioids (CBE#3316e) HH-HYPO Hospital Harm-Severe Hypoglycemia (CBE #3503e) HH-HYPER Hospital Harm-Severe Hyperglycemia (CBE #3533e) Hospital Harm Opioid Related Adverse Events HH-ORAE (CBE# 3501e)	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications AND 3 of the following eCQMs: STK-02 STK-03 STK-05 VTE-1	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications AND 3 of the following eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications *AND, AS FINALIZED#, HH-HYPO and HH-HYPER* AND 3 of the following eCQMs:	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications *AND, AS FINALIZED, HH-HYPO#, HH-HYPER#, and HH-ORAE##* AND 3 of the following eCQMs: STK-02 STK-03

Summary Table IQR Program Measures by Payment Determination Year				
	2026	**2027**	**2028**	**2029**
PC-02 Cesarean Birth (CBE# 0471e) PC-07/SMM Sever Obstetric Complications (CBE# 3687e) Global Malnutrition Composite Score GMCS (CBE #3592e) HH-PI Hospital Harm-Pressure Injury (CBE 3498e) HH-AKI Hospital Harm-Acute Kidney Injury (CBE 3713e) IP-ExRad Excessive Radiation Does or Inadequate Image Quality for Diagnostic CT in Adults (CBE# 3663e) *HH-FI Hospital Harm-Falls with Injury* (CBE#4120e)* *HH-RF Hospital Harm-Postoperative Respiratory Failure* (CBE#4130e)*	VTE-2 HH-HYPO HH-HYPER HH-ORAE GMCS	HH-HYPO HH-HYPER HH-ORAE GMCS HH-PI HH-AKI IP-ExRad	STK-02 STK-03 STK-05 VTE-1 VTE-2 *HH-ORAE* *GMCS** HH-PI HH-AKI IP-ExRad *HH-FI** *HH-RF** *# as finalized, these eCQMs will be mandatory rather than among the list for self-selection beginning for the 2028 payment determination year*	STK-05 VTE-1 VTE-2 *GMCS** HH-PI### HH-AKI### IP-ExRad *HH-FI** *HH-RF** *## as finalized, this eCQM will be mandatory rather than among the list for self-selection beginning for the 2029 payment determination year* *### as finalized, these eCQMs will be mandatory rather than among the list for self-selection beginning for the 2030 payment determination year*
National Healthcare Safety Network Measures				
Healthcare Personnel Influenza Vaccination (CBE #0431)	X	X	X	X
Healthcare Personnel COVID-19 Vaccination (CBE# 3636)	X	X	X	X
CAUTI-onc (CBE #0138)*			X	X
CLABSI -onc (CBE #0139)*			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				
Excess days in acute care after hospitalization for AMI (CBE #2881) Refined	X	X	X	X
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 #2879e)**	X	X	X	X

Summary Table IQR Program Measures by Payment Determination Year				
	2026	**2027**	**2028**	**2029**
Hybrid HWM (all-cause mortality) (CBE #3502)***	X	X	X	X
Patient Safety				
CMS PSI-04 Death among surgical inpatients with serious, treatable complications (CBE #0351)	X	Finalized Removal		
FTR 30-day Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (CBE #4125) ^		X	X	X
Claims-Based Payment				
AMI payment per 30-day episode of care (CBE #2431)	Finalized Removal			
Heart Failure payment per 30-day episode of care (CBE # 2436)	Finalized Removal			
Pneumonia payment per 30-day episode of care (CBE #2579)	Finalized Removal			
THA/TKA payment per 30-day episode of care (CBE#3474) Refined	Finalized Removal			
MSPB-Hospital (CBE#2158)	X	X		
Patient Experience of Care				
HCAHPS survey (CBE #0166) (0228)	X	X Finalized Refinements	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
Age Friendly Hospital^		X	X	X
Patient Safety^		X	X	X
Process Measures				
SDOH-1 Screening for social Drivers of Health****	X	X	X	X
SDOH-2 Screen Positive Rate for Social Drivers of Health****	X	X	X	X

* Finalized in this rule for inclusion beginning with FY 2028 payment determination. Plus, in this rule GMCS finalized refinements beginning with FY 2028 payment determination.
^ Finalized in this rule for inclusion beginning with FY 2027 payment determination. Plus, in this rule HCAHPS finalized refinements beginning with FY 2027 payment determination.
** In the FY 2020 IPPS/LTCH PPS final rule, CMS finalized removal of the HWR claims-only measure (CBE #1789) and will replace it with the Hybrid HWR measure (CBE #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59161-59168), CMS finalized revisions to the measures beginning with the FY 2027 payment determination.
*** 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).
**** 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

Summary Table IQR Program Measures by Payment Determination Year				
	2026	2027	2028	2029
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).				

6. Form, Manner, and Timing of Quality Data Submission

Currently, hospitals must report 4 calendar quarters of data for each of the 3 required eCQMs (Safe Use of Opioids, Cesarean Birth, and Severe Obstetric Complications) and 3 self-selected eCQMs (for a total of 6 eCQMs).

CMS is finalizing changes to reporting and submission requirements for eCQMs, but with a modification to its proposal in response to feedback the agency received regarding administrative burden concerns. Specifically, the agency finalizes its proposal for a progressive increase in the number of mandatory eCQMs a hospital must report beginning with the 2026 reporting period/FY 2028 payment determination from the current mandatory eCQMs to a total of 11 mandatory eCQMs, but instead of phasing in the increase over a two-year period as proposed, the increase will be phased-in over a three-year period.

Specifically, the agency had proposed to include 5 previously adopted Hospital Harm eCQMs to the list of mandatory eCQMs according to the following timeline:

- Beginning with the 2026 reporting period/FY 2028 payment determination, hospitals would need to report on 6 mandatory eCQMs and 3 self-selected (for a total of 9 eCQMs). In addition to the current 3 mandatory eCQMs, the following would be included as mandatory eCQMS:
    - Hospital Harm - Severe Hypoglycemia eCQM;
    - Hospital Harm - Severe Hyperglycemia eCQM; and
    - Hospital Harm - Opioid-Related Adverse Events eCQM.
- Beginning with the 2027 reporting period/FY 2029 payment determination, hospitals would need to report on 8 mandatory eCQMs and 3 self-selected (for a total of 11 eCQMs). In addition to the current 3 mandatory eCQMs and the 3 eCQMs proposed to be mandatory beginning with the 2028 payment determination, the following would be included as mandatory eCQMS:
    - Hospital Harm – Pressure Injury eCQM; and
    - Hospital Harm – Acute Kidney Injury eCQM.

As finalized, the 5 previously adopted Hospital Harm eCQMs will instead be added to the list of mandatory eCQMs (which currently includes 3) according to the following timeline:

- Beginning with the 2026 reporting period/FY 2028 payment determination, hospitals will need to report on 5 mandatory eCQMs and 3 self-selected (for a total of 8 eCQMs). That is, *in addition to the current 3 mandatory eCQMs*, the following 2 eCQMs will be included as mandatory eCQMS:
    - Hospital Harm - Severe Hypoglycemia eCQM; and
    - Hospital Harm - Severe Hyperglycemia eCQM.
- Beginning with the 2027 reporting period/FY 2029 payment determination, hospitals will need to report on 6 mandatory eCQMs and 3 self-selected (for a total of 9 eCQMs). In addition to the 5 mandatory eCQMs required for reporting for the previous year,

beginning with the 2028 payment determination, the following would also be included as a mandatory eCQM:
    - Hospital Harm - Opioid-Related Adverse Events eCQM.
- Beginning with the 2028 reporting period/FY 2030 payment determination, hospitals will need to report on 8 mandatory eCQMs and 3 self-selected (for a total of 11 eCQMs). In addition to the 6 mandatory eCQMs required for reporting for the previous year, beginning with the 2028 payment determination, the following 2 eCQMs will be included as mandatory eCQMs:
    - Hospital Harm – Pressure Injury eCQM; and
    - Hospital Harm – Acute Kidney Injury eCQM.

If a hospital does not have patients that meet the denominator criteria for a mandatory eCQM, the hospital will submit a zero denominator declaration for the measure, which allows the hospital to meet the reporting requirements for that eCQM.

Selected Comments/Responses. Many commenters supported the modifications, particularly regarding patient safety outcome eCQMs (such as Hospital Harm – Severe Hyperglycemia, Hospital Harm – Severe Hypoglycemia, Hospital Harm – Pressure Injury, and Hospital Harm – Opioid-Related Adverse Events) that address adverse events that are preventable.

Many other commenters did not support the proposal and instead recommended focusing on efforts towards the future development of dQMs. CMS acknowledges its goal of transitioning to digital quality measurement for all CMS quality reporting and VBP programs, including by transitioning to dQMs. The agency further points to its definition of dQMs,[84] under which eCQMs are a subset. Therefore, the agency describes that increasing eCQM reporting requirements is part of its National Quality Strategy to accelerate and support the transition to a digital health care system.

Several commenters did not support the modifications, including because of the burden associated with the timeline for the additional mandatory measures and limited health IT resources, and recommended delaying mandatory reporting requirements and changes to the phased-in approach. In response to these concerns raised, CMS modifies the timeline for its proposed incremental increase in mandatory eCQMs as described above.

7. Validation of Hospital IQR Program Data

a. Background

Beginning with validation affecting the FY 2024 payment determination, eCQMs are incorporated into the existing validation process for chart-abstracted measures such that there is one pool of up to 200 hospitals randomly selected 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).

[84] The definition of dQMs can be found on the eCQI Resource Center at: dQMs - Digital Quality Measures | eCQI Resource Center (healthit.gov).

b. Modification of eCQM Validation Scoring Beginning with CY 2025 eCQM data affecting FY 2028 Payment Determination

Under the existing validation policy, hospitals are scored on the completeness of eCQM medical record data submitted for the validation process; the accuracy of the data does not affect the validation score.

CMS finalizes its policy, as proposed, that beginning with 2025 eCQM data affecting the FY 2028 payment determination, eCQM validation scoring be based on the accuracy of the data. In addition, the agency finalizes removal of the requirement that hospitals submit 100 percent of the requested eCQM medical records to pass the validation requirement and finalizes that missing eCQM medical records be treated as mismatches (consistent with the practice for chart-abstracted measure validation). Also, eCQM validation scores will be determined using the same methodology that is currently used to score chart-abstracted measure validation.

In addition, beginning with 2025 eCQM data affecting the FY 2028 payment determination, CMS finalizes, as proposed, its policy to have 2 separate validation scores—one for chart-abstracted measures and one for eCQMs—rather than the existing combined validation score. Hospitals will need to receive passing scores for both to pass validation. A hospital that fails to meet validation requirements may not receive the full annual payment update. Under the finalized policy, to be eligible for the full update (if all other Hospital IQR Program requirements are met) a hospital will have to attain at least a 75 percent validation score for each of the separate scores. Table IX.C.10 in the rule shows a summary of current and the new validation scoring policies.

Selected Comments/Responses. Some concerns were raised regarding the timeline for validation of eCQM data (including requests for delaying implementation of additional validation requirements), concerns about additional administrative burden, and opposing eCQM validation scoring changes for measures that have been adopted for their first or second year of reporting. CMS believes the measures are ready for validation and that hospitals can successfully report eCQM data accurately. The agency will continue to observe hospitals' experience with eCQM validation and consider whether any changes are needed in future years.

8. Reconsideration and Appeals Procedures

As part of the reconsideration process, hospitals can request reconsideration of a CMS determination that the hospital did not meet validation requirements.[85] As part of that process, hospitals must resubmit copies of all medical records originally submitted to the Clinical Data Abstraction Center, but this is no longer necessary given the transition to electronic submission of copies of medical records for the validation.[86]

CMS, therefore, finalizes as proposed, beginning with 2023 discharges affecting the FY 2026 payment determination, to no longer require the resubmission of previously submitted medical records as part of a hospital's request for reconsideration of validation.

[85] Reconsideration and appeals procedures can be found at 42 CFR 412.140(e).
[86] Electronic submission was established in the FY 2021 IPPS/LTCH final rule (85 FR 58949-58950).

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

1. Background: Overview of Finalized Proposals

The PCHQR Program applies to hospitals meeting the description of *PPS-exempt cancer hospital* (PCH) as defined at section 1886(d)(1)(B)(v) of the Act. The program has 11 participants that focus on the care of oncology patients and are paid on a cost basis, subject to a per discharge limit (target amount), rather than through a prospective payment system (PPS). The program requires quality reporting by PCHs and measure data are publicly available, but the results have no associated payment consequences.

In addition to the newly finalized cross-program (the new Patient Safety structural measure described in the cross-program proposal under section IX.B.1 of the summary and the modified HCAHPS Survey measure described in section IX.B.2 of the summary) adopted beginning with the 2025 reporting period/FY 2027 program, CMS also finalizes its proposal to move up the start date for publicly displaying hospital performance on the Hospital Commitment to Health Equity measure.

CMS estimates a total information collection burden increase for the 11 PCHs of 166 hours at a cost of $4,047 annually with the finalized policies beginning with the FY 2027 program year compared to the currently approved information collection burden estimates.

2. Summary of Previously Adopted and Newly Finalized PCHQR Program Measures for FY 2027 Program Year and Subsequent Years

CMS summarizes the PCHQR program's measure set in table IX.D-01. The below table shows the previously and newly adopted measures, with corresponding public display start date (as shown in Table IX.D-02 of the rule).

PCHQR Program Measures for FY 2027 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
*Patient Safety Structural Measure***	
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	

PCHQR Program Measures for FY 2027 and Subsequent Years	
Measure	**Public Display Start Date**
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
Surgical Treatment Complications for Localized Prostate Cancer	July 2024 or as soon as feasible thereafter
Health Equity Measures	
Hospital Commitment to Health Equity*	January 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.-01 and IX.D.-02 of the rule, consolidated and modified by HPA ** Indicates newly adopted measures in the final rule. * Newly finalized start date of January 2026 for publicly displaying.	

3. New Start Date for Public Display of Hospital Commitment in Health Equity Measure

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. When the Hospital Commitment to Health Equity measure was finalized beginning for the FY 2026 program year, CMS finalized publicly reporting performance on the measure (using the 2024 data) beginning July 2026 or as soon as feasible.[87]

CMS finalizes its proposal to move up the public reporting timeframe for the measure and to start publicly reporting performance on the measure (using 2024 data) beginning January 2026 or as soon as feasible thereafter.

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

CMS finalizes its proposals for four new items as standardized patient assessment data elements (SPADEs) to be required to be reported to the LTCH Continuity Assessment Record and Evaluation Data Set (LTCH CARE Data Set or LCDS), modification of one item collected as a SPADE, and extension of the admission assessment window for the LCDS. The agency also

[87] FY 2024 IPPS/LTCH PPS final rule (88 FR 59204-59210; 59228).

reviews comments received in response to its request for information on future measure concepts and on a future LTCH Star Rating system.

CMS estimates a total information collection burden increase for the 330 eligible LTCHs of around 2,117 hours for a total cost increase of around $138,232 annually (attributable to the finalized policies) compared to the currently approved information collection burden estimates.

1. Background

The LTCH QRP is a pay-for-reporting quality program implemented in FY 2014. LTCHs submit data to CMS on the LCDS patient assessment instrument using the Internet Quality Improvement Evaluation System Assessment Submission and Processing (iQIES ASAP) system. The LCDS requires reporting of multiple SPADEs that are interoperable and are common to post-acute care (PAC) providers.[88] An LTCH that fails to meet the program's quality data reporting requirements is subject to a 2.0 percentage point reduction in the annual update factor. Information about many aspects of the program is available through the LTCH QRP website at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/LTCH-Quality-Reporting.[89]

The 18 quality measures currently adopted for the FY 2024 LTCH QRP are shown in Table IX.E.-01 of the rule. No new measures were proposed. A summary table of program measures for FY 2025-2027 is provided below.

Measure Title	FY 2025	FY 2026	FY 2027
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (CBE #0138)	X	X	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (CBE #0139)	X	X	X
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	X	X	X
Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay	X	X	X
Ventilator Liberation Rate	X	X	X
Influenza Vaccination Coverage among Healthcare Personnel (CBE #0431)	X	X	X
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717)	X	X	X
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674)	X	X	X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (CBE #2632)	X	X	X
Medicare Spending Per Beneficiary (MSPB-PAC LTCH)	X	X	X

[88] Post-acute care providers required to report SPADEs are long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.
[89] For a detailed discussion of considerations 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).

Measure Title	FY 2025	FY 2026	FY 2027
Discharge to Community PAC LTCH	X	X	X
Potentially Preventable Readmissions 30 Days Post LTCH Discharge	X	X	X
Drug Regimen Review Conducted with Follow-up	X	X	X
Transfer of Health Information to the Provider – PAC Measure (TOH-Provider)	X	X	X
Transfer of Health Information to the Patient – PAC Measure (TOH-Patient)	X	X	X
COVID-19 Vaccination Coverage among Healthcare Personnel	X	X	X
Discharge Function (DC Function) Measure	X	X	X
COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date		X	X

2. Collection of Four New Items as SPADES and Modify one SPADE Beginning with the FY 2028 LTCH QRP

a. Definition of Standardized Patient Assessment Data

LTCHs are statutorily required, as a post-acute care (PAC) provider,[90] to submit standardized patient assessment data under the LTCH QRP with respect to the admission and discharge of an individual (or more frequently as specified by the Secretary) using a standardized patient assessment instrument, which for LTCHs is the LCDS. Standardized patient assessment data is data required with respect to the following categories: (1) functional status, such as mobility and self-care at admission to and before discharge from a PAC provider; (2) cognitive function, such as ability to express ideas and understand, and mental status, such as depression and dementia; (3) special services, treatments, and interventions, such as need for ventilator use, dialysis, chemotherapy, central line placement, and total parenteral nutrition; (4) medical conditions and comorbidities, such as diabetes, congestive heart failure, and pressure ulcers; (5) impairments, such as incontinence and an impaired ability to hear, see, or swallow; and (6) other categories deemed necessary and appropriate by the Secretary.[91]

b. Social Determinants of Health (SDOH) Collected as SPADEs

CMS currently collects seven items in the SDOH category of SPADEs: ethnicity, race, preferred language, interpreter services, health literacy, transportation, and social isolation.[92] The agency states that standardized data relating to SDOH on national levels allows it to assess the data's appropriateness as risk adjustors or in future quality measures. The adopted SDOH items use common standards and definitions across the PAC provider settings to facilitate care coordination, continuity in care planning, and discharge planning from PAC settings. CMS further explains that health-related social needs (HRSNs) are adverse social conditions that negatively affect a person's health or health care, such as lack of access to food, housing, or transportation, and are associated with poorer health outcomes and higher health care costs.

[90] Section 1886(m)(5)(F)(ii) of the Act requires LTCHs to submit standardized patient assessment data required under section 1899B(b)(1) of the Act, which requires PAC providers to submit such data under applicable reporting provisions.
[91] These six categories are specified under section 1899B(b)(1)(B) of the Act.
[92] See 84 FR 42578-42581.

c. Collection of Four New Items as SPADEs

CMS is finalizing its proposal to require LTCHs to submit, beginning with the FY 2028 LTCH QRP, the following four new items as SPADEs under the SDOH category using the LCDS, all selected from the Accountable Health Communities (AHC) HRSN Screening Tool developed for the AHC Model.

One Living Situation Item. CMS describes the potential negative impacts that housing instability may have on health and believes that LTCHs can use information from the Living Situation item during a patient's discharge planning, including to better coordinate with other providers, facilities, and agencies during transitions of care.

CMS finalizes its proposal to adopt the Living Situation item, which will ask "What is your living situation today?" The response options will be: I have a steady place to live; I have a place to live today, but I am worried about losing it in the future; I do not have a steady place to live; Patient declines to respond; and Patient unable to respond.

Two Food Items Proposed. CMS describes food insecurity, which is not having enough food or having a diet that is not nutritious, as a factor for negative health outcomes and health disparities. The agency believes LTCHs could use data on food insecurity to help them with patient transitions of care and referrals, including to federal assistance initiatives. Therefore, CMS finalizes two new food items:

- The first states: "Within the past 12 months, you worried that your food would run out before you got money to buy more."
- The second states: "Within the past 12 months, the food you bought just didn't last and you didn't have money to get more."
- The response options for each are: Often true; Sometimes true; Never true; Patient declines to respond; and Patient unable to respond.

One Utilities Item Proposed. CMS describes a lack of utility security as an inability to adequately meet basic household energy needs. The effects of a lack of utility security include vulnerability to environmental exposures which impact a person's health. The agency believes LTCHs could use information on utility security to help refer patients to (and help them apply for) utility assistance programs for paying for their home energy costs.

CMS finalizes for adoption the Utilities item, which asks "In the past 12 months has the electric gas, oil, or water company threatened to shut off services in your home?" The response options are: Yes; No; Already shut off; Patient declines to respond; and Patient unable to respond.

Selected Comments/Responses. Some commenters supported the addition of the SDOH assessment items as valuable sources of information. Other commenters did not support the proposal, including because of concerns with increased burden. CMS responds that the new items will provide key information to LTCHs to support effective discharge planning. The

agency plans to provide training resources before the initial collection of the items to provide LTCHs with tools to administer the new items.

A few commenters raised concerns that the assessment items were not applicable to LTCH patients who are generally unable to respond to questioning because of mechanical ventilation or sedation and are more severely ill than the average Medicare beneficiary. In addition, the concern was raised that patients may feel stigmatized if they are asked the questions included in the assessment items. CMS acknowledges these points raised, but believe that LTCHs are accustomed to working with patients with very complex medical conditions and can collect this data in a consistent manner; in addition, the assessment item responses include the options or patients that decline to respond or are unable to respond.

Some commenters raised concerns about the 12-month lookback period for the Utilities Item and Food Items, but the agency believes that this longer period is more appropriate than a shorter period because a person's utilities or food situation may fluctuate.

d. Modification of the Transportation Item Beginning with the FY 2028 LTCH QRP

The Transportation item (A1250) is one of seven items LTCHs began collecting as of October 1, 2022 on the LCDS as SPADEs under the SDOH category.[93] It currently asks "Has lack of transportation kept you from medical appointments, meetings, work, or from getting things needed for daily living?" The response options are: Yes, it has kept me from medical appointments or from getting my medications; Yes, it has kept me from non-medical meetings, appointments, work, or from getting things I need; No; Patient unable to respond; and Patient declines to respond.

As part of routine monitoring, CMS has determined that the Transportation item could be improved by revising the look-back period to a defined 12-month period (as opposed to the current look-back period of 6 to 12 months) and by simplifying the response options to reduce burden. The modifications will align the item with a Transportation item collected on the AHC HRSN Screening Tool, which is a tool available to the Inpatient Psychiatric Facility Quality Reporting and Hospital IQR Programs.

Beginning with the FY 2028 LTCH QRP, therefore, CMS finalizes its proposal to modify the Transportation item. The modified item asks: "In the past 12 months, has lack of reliable transportation kept you from medical appointments, meetings, work or from getting things needed for daily living?" The response options are: Yes; No; Patient declines to respond; and Patient unable to respond.

[93] Adopted in the FY 2020 LTCH PPS final rule (84 FR 42587).

3. LTCH QRP Quality Measure Concepts Under Consideration for Future Years: RFI Feedback

In the proposed rule, CMS solicited input on the following three concepts for the LTCH QRP:

- A composite measure of vaccinations, which could represent overall immunization status of LTCH patients.[94]
- The concept of depression, which may be similar to the Clinical Screening for Depression and Follow-up measure in the Universal Foundation.[95]
- The concept of pain management.

Selected Comments. Several commenters supported the concept of a vaccination composition measure. Many other commenters did not support a vaccination composition measure because they do not believe the LTCH is an appropriate setting for collecting vaccination rates and because of the increase in administrative burden.

Several commenters supported the pain management measure concept. Several others opposed the concept of such a measure in the LTCH QRP because pain is often an unavoidable part of recovery and not necessarily an indicator of a patient's improvement.

More than half of the comments received regarding the concept of depression for a future measure, supported such a measure. Those that opposed this measure concept did so for reasons such as potential redundancy in data collection, concern about the lack of resources to treat depression, and administrative burden.

4. Future LTCH Star Rating System: RFI Feedback

CMS describes how it currently reports data submitted on measures within the LTCH QRP on its Care Compare website. Care Compare displays star ratings (which summarize performance) for doctors and clinicians, hospitals, nursing homes, home health, hospice, and dialysis facilities. Star ratings are a tool for patients, caregivers, and families to quickly understand and compare information on the quality of care furnished among providers.

In the proposed rule, the agency sought feedback on the development of a 5-star methodology for LTCHs and on measures to use in a star rating system. Specifically, the agency asked about specific criteria it should use to select measures and how the agency should present star ratings information.

Selected Comments. In response to the agency's question regarding specific criteria for measure selection, several commenters suggested selected measures that focus on patient and diagnostic safety outcomes, such as alignment with measures from the Universal Foundation measure set. Some commenters suggested including patient experience measures, while others were concerned with the reliability of such measures.

[94] The Adult Immunization Status Measure in the Universal Foundation is provided as an example. Centers for Medicare and Medicaid Services Measures Inventory Tool (cms.gov).
[95] See Centers for Medicare and Medicaid Services Measures Inventory Tool (cms.gov).

Regarding display of star ratings information, several commenters recommended that CMS engage with patients, caregivers, providers, and specialty societies to inform the development of such presentation.

CMS states that it will take recommendations into consideration in future star rating development efforts.

5. Form, Manner, and Timing of Data Submission under the LTCH QRP[96]

a. Reporting Schedule for the New SPADEs and Modified Transportation Data Element

- For the FY 2028 LTCH QRP, LTCHs will submit data on the 4 new items and the modified Transportation item using the LCDS beginning with patients admitted on October 1, 2026.
- Beginning with the FY 2029 LTCH QRP, LTCHs will (starting in CY 2027) submit data for the entire calendar year.
- LTCHs will be required to submit the new items (Living Situation, Food, and Utilities) and the modified Transportation item with respect to admission only (and not also at discharge).[97]

b. Modification of the LCDS Admission Assessment Window to Four Days

Currently, the LCDS Admission assessment has a maximum 3-day assessment period (beginning on date of admission) during which the patient's assessment must be conducted to collect data for the assessment items. CMS has received feedback about the difficulty of collecting data during this period when medically complex patients are admitted prior to and on weekends.

CMS finalizes its proposal to extend the admission assessment period to 4 days, beginning with LTCH admissions on October 1, 2026 (corresponding to the FY 2028 LTCH QRP).

F. Medicare Promoting Interoperability Program

1. Background

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.[98] A critical access hospital that is not identified as a meaningful user of CEHRT is subject to a payment reduction to 100 percent of reasonable costs, from the 101 percent of reasonable costs it might have otherwise earned.[99] In the following provisions of this section, the term hospital includes a critical access hospital unless otherwise noted.

[96] The current policies for reporting LTCH QRP data can be found at 42 CFR §412.560(b).
[97] Note that currently, the Transportation item is required at admission and discharge.
[98] Sections 1886(b)(3)(B)(ix) of the Act.
[99] Section 1814(l)(4) of the Act.

2. Change to Antimicrobial Use and Resistance (AUR) Surveillance Measure Beginning with EHR Reporting Period in 2025

One of the ways that hospitals have been required to demonstrate compliance with the Medicare PIP is through the submission of data on Antimicrobial Use and Resistance (AUR) derived from electronic health records (EHR). The AUR Surveillance measure requires hospitals to report antimicrobial use (AU) data and antimicrobial resistance (AR) data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN).[100] To receive credit for reporting the measure, hospitals must report a "yes" response that they have submitted data for AU and AR, unless they claim an exclusion for which they are eligible, and they must use technology certified in accordance with 45 CFR 170.315(f)(6) for submitting the data.

CMS finalizes its proposal (without modification) to separate the AUR Surveillance measure into two measures, an AU surveillance measure and an AR surveillance measure, beginning with the EHR reporting period in 2025. Hospitals must report a "yes" response or claim an exclusion separately for each measure to receive credit. The separation into two measures is intended to clarify reporting requirements, incentivize data reporting, and to more appropriately target potential exclusions since the AU and AR data rely on different data sources. Hospitals must report AU data or AR data, respectively, to CDC's NHSN for the selected EHR reporting period and will receive a separate report for each measure from NHSN indicating successful submission.

Currently, if a hospital meets the exclusion criteria for reporting either AU data or AR data then it is excluded from the entire measure. There are three exclusions for which a hospital could be eligible:

- Exclusion 1: During the reporting period the hospital does not have any patients in any patient care location for which data are collected by NHSN.
- Exclusion 2: During the reporting period the hospital does not have an electronic medication administration record/bar-coded medication administration (eMAR/BCMA) records or electronic admission discharge transfer (ADT) system.
- Exclusion 3: During the reporting period the hospital does not have an electronic LIS or electronic ADT system.

CMS adds an exclusion for hospitals when they do not have a data source containing the minimal discrete data elements that are required for reporting. The exclusion applies to both measures, as does exclusion #1 described above. Exclusion #2 described above applies to the AU measure and exclusion #3 described above applies to the AR measure to align the appropriate exclusion to the data on which each separate measure would rely.

CMS finalizes its proposal to treat those measures as independent of any prior level of active engagement for the AUR surveillance measure in the EHR reporting period in 2024. This means that for each measure hospitals could spend only one reporting period at the Option 1: Pre-

[100] The FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) finalized required reporting of the AUR Surveillance measure with a modification to begin reporting with the EHR reporting period in 2024.

production and Validation level of active engagement, and then must continue to the Option 2: Validated Data Production level for the next reporting period.

The agency notes that hospitals report AU and AR data under the current AUR Surveillance measure and that requiring the same scope of data to be reported as two measures instead of one is not an expansion on reporting requirements. Therefore, CMS maintains the scoring value of 25 points for reporting all required measures in the Public Health and Clinical Data Exchange objective and the current exclusion redistribution policy, even though the objective increases from five measures to six measures.

Comments/Responses. Widespread support was expressed for the proposals; some commenters suggested implementing them beginning with 2024 instead of 2025. CMS believes adopting the change in 2025 gives hospitals another year of experience with the Pre-production and Validation stage (Option 1). CMS does not agree with a recommendation to establish a bonus for the AU Surveillance and AR Surveillance measures because the AUR Surveillance measure is currently required for reporting for the EHR reporting period in 2024.

Support was also expressed for adopting the exclusions for the AU and AR Surveillance measures because they provided needed clarity for the associated measures and they help hospitals avoid penalties when they cannot report AU and AR data. Commenters agreed with CMS that treating the AU and AR Surveillance measures as new measures with respect to level of active engagement will be helpful and will allow hospitals additional time to gain familiarity with reporting to the NHSN. One commenter was concerned that the proposal to maintain the 25-point scoring value for the objective did not account for challenges in reporting among resource-constrained hospitals; CMS may consider a weighted scoring approach in future rulemaking.

3. Overview of Objectives and Measures for the EHR Reporting Period in 2025

Table IX.F.-01 lists the objectives and measures for the Medicare PIP for the EHR reporting period in 2025 as revised to reflect the previously finalized and newly finalized measures and objectives in the final rule, including the above changes to the AUR surveillance measure.

4. Updates to the Definition of CEHRT Beginning with the EHR Reporting Period in 2024

CMS reviews the updates to the definition of CEHRT for the Medicare PIP under 42 CFR 495.4 that were finalized in the 2024 Medicare Physician Fee Schedule final rule.[101] Among the described revisions, CMS notes the updates to the definition of Base EHR in 45 CFR 170.102 and the update that technology meeting the CEHRT definition must meet health IT certification criteria established by the Office of the National Coordinator for Health Information Technology (ONC).[102]

CMS describes how the updates to the definition of Base EHR and to applicable ONC health IT certification criteria in 45 CFR 170.315 are automatically incorporated into the CEHRT

[101] See 88 FR 79307-79312.
[102] See the ONC rule finalized on January 9, 2024, the Health Data, Technology, and Information Sharing (HTI-1) final rule (89 FR 1192).

definition without additional regulatory action by CMS. Table IX.F._02 lists the ONC health IT certification criteria required to meet the Medicare PIP objectives and measures. CMS also highlights some of the updates to the criteria finalized in the ONC HTI-1 final rule[103] that impact certification criteria under the CEHRT definition, including:

- Beginning January 1, 2025, decision support interventions (DSI) criterion replaces the clinical decision support (CDS) criterion. The DSI criterion requires that certified Health IT Modules must enable a limited set of identified users to select evidence-based and predictive DSIs and support source attributes for evidence-based and predictive DSIs. A Health IT Module may meet the Base HER definition by being certified to the existing CDS version of criterion or the revised DSI criterion through December 31, 2024.
- Beginning January 1, 2026, under the transmission to public health agencies-electronic case reporting criterion, consensus-based, industry-developed electronic standards and implementation guides replace functional, descriptive requirements.
- The United States Core Data for Interoperability (USCDI) version 3 is adopted. The current USCDI version 1 will expire January 1, 2026.

5. Changes to Scoring Methodology Beginning with the EHR Reporting Period in 2025

There is currently a 60-point minimum scoring threshold that hospitals must meet to satisfy the requirement to report on the objectives and measures of meaningful use.

CMS proposed, beginning for the EHR reporting period in 2025, to increase the minimum scoring threshold to 80 points. Based on 2022 Medicare PIP performance results, 98.5 percent of hospitals (97 percent of CAHs and 99 percent of eligible hospitals) that reported to the program successfully met the current minimum threshold of 60 points, and 81.5 percent of hospitals (78 percent of CAHs and 83 percent of eligible hospitals) would have exceeded the proposed threshold of 80 points. Therefore, the agency believes the higher threshold would encourage higher levels of performance, increase data exchange and interoperability, and incentivize more hospitals to align their health information systems with changing industry standards.

Comments/Responses. While some support was expressed for the proposal, many commenters opposed increasing the minimum threshold to 80 points in 2025. Various rationale for delaying the increase for several years were provided, including the need for more time for hospitals to adjust to reporting requirements, to independently analyze the Medicare PIP performance data, and to avoid higher failure rates and decreased compliance. Others suggested a smaller increase such as 70. One commenter believed the most likely path to increased points would be HIE or TEFCA participation, which requires more time and money. CMS is not sympathetic to these concerns. It notes that average scores for hospitals have steadily increased since 2020: 72.5 in 2020 (72.4 for eligible hospitals and 73.8 for CAHs), 74.9 in 2021 (74.5 for eligible hospitals and 76.6 for CAHs), and 94.6 in 2022 (95.5 for eligible hospitals and 91.7 for CAHs). The agency also disagrees that choosing participation in TEFCA or HIE bidirectional exchange is the most likely path to increasing overall points.

[103] See the ONC rule finalized on January 9, 2024, the Health Data, Technology, and Information Sharing (HTI-1) final rule (89 FR 1192).

However, the agency agrees with those commenters who recommended an incremental increase over time to an 80-point threshold. CMS finalizes an increase to the minimum performance-based scoring threshold from 60 points to 70 points for the EHR reporting period in 2025, and from 70 points to 80 points beginning with the EHR reporting period in 2026 and subsequent years.

Table IX.F.-03 of the rule (shown below with slight stylistic modifications) includes the scoring methodology beginning in 2025, reflecting previously adopted policies and the proposals for the separate AU and AR Surveillance measures in the rule.

TABLE IX.F.-03: PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIOD IN 2025

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 6* measures: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Electronic Reportable Laboratory Result Reporting AU Surveillance* AR Surveillance*	25 points	Required
	Report one of the following 2 measures: Public Health Registry Reporting Clinical Data Registry Reporting	5 points (bonus)	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of MACRA are required, but will not be scored. eCQM measures are required, but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at the Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the next EHR reporting period. See FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement.
* Signifies a measure finalized in this rule. For details on finalized modifications to the AUR Surveillance measure, which is separated into an AU Surveillance measure and an AR Surveillance measure, see section IX.F.2 of the final rule.

Table IX.F.-04 shows how points will be redistributed for the EHR reporting period in 2025 and subsequent years if an exclusion were claimed. No changes were proposed to the point redistribution policy. 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 six Public Health and Clinical Data Exchange measures is claimed (which reflects the split of the AUR Surveillance measure into 2 measures), the 25 points are redistributed to the Provide Patients Electronic Access to Their Health Information.

6. Update to Clinical Quality Measures

a. Updates to Clinical Quality Measures and Reporting Requirements in Alignment with Hospital IQR Program

Background. Hospitals must report on clinical quality measures selected by CMS using CEHRT (referred to as eCQMs) as part of satisfying the definition of being a meaningful EHR user under the Medicare PIP.[104] Tables IX.F.-05 and IX.F.-06 of the final rule summarize the previously finalized eCQMs available for hospitals to report under the Medicare PIP for the 2024 and 2025 reporting periods.

Adoption of Additional eCQMs. CMS intends to continue to align the Medicare PIP eCQM reporting requirements with similar requirements under the Hospital IQR Program. To that end, the agency finalizes the following changes for the Medicare PIP eCQM measure set (consistent with the changes made in the rule for the Hospital IQR Program) beginning with the 2026 reporting period:

- Adopt the following two new eCQMs, which hospitals may self-select to report:
  - Hospital Harm – Falls with Injury eCQM (CBE #4120e).
  - Hospital Harm – Postoperative Respiratory Failure eCQM (CBE #4130e).
- Modify the Global Malnutrition Composite Score eCQM (CBE #3592e) to add patients ages 18 to 64 to the current cohort of patients 65 years or older.

Tables IX.F.-07 shows the new and previously finalized eCQMs for the 2026 reporting period and subsequent years.

Some commenters raised concerns about the additional costs associated with the proposals. Others objected to the mandate of using CEHRT when hospitals could instead perform their own data extracts and submit the data directly to CMS; benefits of this approach include decreased vendor reliance, increased agility to adapt to changes, and use of fewer resources. CMS believes requiring the use of CEHRT for the transmission of this data helps to ensure standardization, interoperability, data accuracy, and integrity.

[104] See sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act for these requirements applied to CAHs and hospitals, respectively.

b. Revisions to eCQM Reporting and Submission Requirements for the 2026 Reporting Period and Subsequent Years

As part of being a meaningful user under the Medicare PIP, hospitals must currently report four calendar quarters of data for three self-selected eCQMs and for each of the following required eCQMs selected by CMS (i) the Safe Use of Opioids-Concurrent Prescribing eCQM; (ii) the Severe Obstetric Complications eCQM; and (iii) the Cesarean Birth eCQM (resulting in required reporting on a total of six eCQMs).

CMS made the following proposals:

- If the proposals to adopt the Hospital Harm – Falls with Injury eCQM and the Hospital Harm – Postoperative Respiratory Failure eCQM are finalized, those measures would be available for hospitals to select as one of their three self-selected eCQMs for the 2026 reporting period and subsequent years.
- Beginning with the 2026 reporting period, CMS would transfer from the self-select measures to the mandatory eCQM measure set 3 eCQMs (the Hospital Harm –Severe Hypoglycemia eCQM, Hospital Harm – Severe Hyperglycemia eCQM, and the Hospital Harm – Opioid-Related Adverse Events eCQM). This would result in 3 self-selected eCQMs and 6 required eCQMs selected by CMS that would need to be reported, for a total of 9 eCQMs that would be reported.
- Beginning with the 2027 reporting period, CMS would transfer from the self-selected measures to the mandatory eCQM measure set an additional two eCQMs (the Hospital Harm – Pressure Injury eCQM and the Hospital Harm – Acute Kidney Injury eCQM). This would result in three self-selected eCQMs and eight required eCQMs selected by CMS needing to be reported, for a total of 11 eCQMs that would be reported.

Comments/Responses. While some support was expressed for the proposals, many commenters objected to the increased burden associated with implementing, monitoring and maintaining increased numbers of eCQMs. Recommendations from stakeholders included a less aggressive approach to increases or a delay in any increase in reporting requirements. Other commenters suggested that the agency wait at least three years after the introduction of a new measure before requiring it so hospitals can self-select measures to gain experience with the new measure before they become mandatory; CMS disagrees with this approach.

However, in response to concerns from stakeholders, CMS adopts a modified approach in the final rule. It removes one mandatory eCQM for the 2026 reporting period, which results in a total of 8 eCQMs hospitals must report for that reporting period, and it phases in the proposed increase to 11 eCQMs for the 2027 reporting period over two years as follows:

- For the 2026 reporting period, hospitals must report three self-selected, and the Safe Use of Opioids, Severe Obstetric Complications, Cesarean Birth, Hospital Harm – Severe Hypoglycemia, and Hospital Harm – Severe Hyperglycemia eCQMs, for a total of eight eCQMs.

- For the 2027 reporting period, hospitals must submit data for the eight eCQMs finalized for the 2026 reporting period as well as the Hospital Harm – Opioid-Related Adverse Events eCQM, for a total of nine eCQMs.
- For the 2028 reporting period and subsequent years, hospitals must submit data for the nine eCQMs required for the 2027 reporting period as well as the Hospital Harm – Pressure Injury and Hospital Harm – Acute Kidney Injury eCQMs, for a total of eleven eCQMs.

7. Potential Future Update to the SAFER Guides Measure

CMS adopted the SAFER Guides measure under the Protect Patient Health Information Objective beginning with the EHR reporting period in 2022. Hospitals must attest to whether they have conducted an annual self-assessment using all nine SAFER Guides at any point during the year in which the EHR reporting period occurs. Beginning in 2022, the attestation of this measure was required, but hospitals were not scored, and an attestation of "yes" or "no" were both acceptable answers without penalty. Beginning with the 2024, hospitals must attest "yes" to satisfy this measure; attesting "no" means that the hospital did not meet the measure and thus was not a meaningful EHR user for the reporting period, subjecting the hospital to a downward payment adjustment.

CMS notes that efforts to update the SAFER Guides are underway, the agency anticipates that updated versions may become available as soon as 2025, and that it would consider proposing a change to the measure for the EHR reporting period beginning in 2026 to permit use of an updated version of the SAFER Guides at that time. CMS did not propose and does not make any changes to these policies.

8. Update the Definition of Meaningful EHR User for Healthcare Providers That Have Committed Information Blocking

CMS describes some of the policies finalized in the Disincentives rule[105] issued on July 1, 2024, to implement the requirement under the 21st Century Cures Act that a health care provider determined by the HHS Office of Inspector General (OIG) to have committed information blocking[106] must be referred to the appropriate agency to be subject to disincentives established through rulemaking. Under that final rule, if the OIG determines a hospital committed information blocking and refers the hospital to CMS during a calendar year of an EHR reporting period, then the hospital is not considered a meaningful EHR user in that reporting period or payment adjustment year. This means the hospital will be subject to the downward payment adjustment two years after the year of the referral (except that CAHs would have the downward payment adjustment apply to the payment adjustment year in which the OIG referral was made).[107] An eligible hospital subject to this disincentive will be subject to a three-quarters reduction of the annual market basket increase, and a CAH subject to this disincentive will have its payment reduced to 100 percent of reasonable costs, from the 101 percent of reasonable

[105] 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (hereafter referred to as the Disincentives final rule) (89 FR 54662).
[106] Information blocking is defined in 45 CFR 171.103.
[107] 89 FR 54691.

costs it might have otherwise earned, for failing to qualify as a meaningful EHR user in an applicable year.

CMS notes the revised definition of Meaningful EHR User in 42 CFR 495.4 became effective on July 31, 2024, when the Disincentives final rule took effect.

9. Future Goals of Medicare PIP

Fast Healthcare Interoperability Resources (FHIR) Application Programming Interfaces (APIs) for Patient Access. As it did in the proposed rule, CMS describes how the agency is working in partnership with ONC on a number of initiatives, including to require the use of APIs that use the Health Level Seven International (HL7) FHIR. The agency further describes provisions finalized by ONC in the HTI-1 final rule, including revisions to the standardized API for patient and populations services certification criterion,[108] the adoption of the HL7 FHIR US Core Implementation Guide (IG) Standard for Trial Use version 6.1.0,[109] and the creation of the Insights Condition and Maintenance of Certification requirements (Insights Condition) within the ONC HIT Certification Program.[110] CMS believes these updated standards, implementation specifications, certification criteria, and conditions of certification will improve interoperability, transparency, and the exchange of health information.

Improving Cybersecurity Practices. CMS also reviews resources regarding appropriate cybersecurity practices, including the National Institute of Standards and Technology (NIST) updated guidance[111] and HHS resources, and indicates the agency's intent to consider how the Medicare PIP can promote cybersecurity best practices for hospitals in the future.

Improving Prior Authorization Processes. CMS references the CMS Interoperability and Prior Authorization final rule (CMS-0057-F), in which the agency finalized the Electronic Prior Authorization measure under the HIE objective for the Merit-based Incentive Payment System (MIPS) promoting interoperability performance category and for the Medicare PIP. For the Medicare PIP the measure is included beginning in the EHR reporting period in 2027.[112]

10. RFI Regarding Public Health Reporting and Data Exchange

CMS sought feedback on efforts across HHS to advance the public health information infrastructure, aimed to offer opportunities to further evolve the Medicare PIP, in collaboration with the CDC and ONC. It outlined several goals, and asked commenters to consider and provide feedback on certain issues for consideration in future rulemaking. It acknowledges receiving many comments on the RFI regarding public health reporting and data exchange, which it may consider to inform potential future rulemaking proposals.

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[108] See 45 CFR 170.315(g)(10).
[109] See 45 CFR 170.215(b)(1)(ii).
[110] See 89 FR 1199. The Insights Condition requires developers of certified health IT to report on measures that provide information about the use of specific certified health IT functionalities by end users.
[111] NIST SP 800-66r2. The guidance is for health care entities on implementing requirements of the HIPAA Security Rule.
[112] 89 FR 8909-8927.

X. Other Provisions

A. Transforming Episode Accountability Model (TEAM)

1. General Provisions

In this section, CMS lays out the general operating provisions governing its implementation of mandatory payment models under its waiver authority under Section 1115A of the Act. To implement TEAM, CMS finalizes regulations in a new subpart E of 42 CFR Part 512. These include applicable definitions (§512.505), the requirements of model participants to cooperate with evaluating and monitoring the model's performance (§512.584), CMS' rights to use data collected during the model's fielding to monitor and evaluate the model (§512.588) (including provisions to protect proprietary data), remedial actions CMS may take in the event model participants fail to comply with applicable requirements (§512.592), and model participants' obligation to report bankruptcies, change in ownership, and other conditions (§512.595).

The only comments CMS received on this section of the proposed rule related to its proposed limitations on administrative and judicial review, and a separate comment asking CMS to change its proposed timeline for bankruptcy notifications. However, CMS made no changes to this material in light of these comments, and is finalizing the general TEAM provisions as proposed.

2. Transforming Episode Accountability Model (TEAM) – Introduction

Under its 1115A waiver authority, in the April 2024 proposed rule, CMS proposed a mandatory 5-year episode-based payment model (January 1, 2026 – December 31, 2030) to evaluate participating hospitals' performance on cost and quality metrics for five surgical episode categories: coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion. CMS proposed this model within the CMMI strategic refresh framework,[113] and has developed it in light of the agency's experience with the Bundled Payments for Care Improvement (BPCI) Initiative, the BPCI Advanced Model, and the Comprehensive Care for Joint Replacement (CJR) Model, as well as comments received in response to the Episode-based Payment Model request for information (RFI) published in July 2023.[114] CMS contended that TEAM is expected to improve on these prior models and produce greater success in improving patient outcomes and lower costs by reducing fragmentation of care. CMS reiterates at length the evidence base underlying bundled payment models generally, as well as the results of testing of the prior Medicare models (*e.g.*, BPCI, CJR) that it discussed at length in the proposed rule.[115]

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[113] Innovation Center Strategy Refresh: https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper

[114] https://www.federalregister.gov/documents/2023/07/18/2023-15169/request-for-information-episode-based-payment-model

[115] Most of these models produced no net savings to the Medicare program, after accounting for provider reconciliation payments.

CMS discusses general comments on its proposed TEAM. CMS characterizes these comments as generally supportive, although several commenters asked for an extension of the comment period, or asked for separate rulemaking for TEAM and future models. Some commenters expressed concerns about the mandatory nature of TEAM, and indicated that TEAM exposed hospitals to too much financial risk. CMS responded to these comments indicating that it will proceed to implement TEAM pursuant to the proposed timeline, but has changed some of its proposals in light of comments received; CMS is not finalizing other proposals, but will instead adjudicate these in future rulemaking.

3. Provisions of Transforming Episode Accountability Model

CMS proposed that the TEAM performance period would be January 1, 2026 – December 31, 2030. **The agency indicates that many commenters asked for a delay in the TEAM start date, but it is nevertheless finalizing the start date and performance period as proposed**.

Proposed model participants would be limited to acute care hospitals paid under the IPPS, as defined in section 1886(d)(1)(B) of the Act.[116] CMS indicates that "a few commenters" supported the proposed definition of TEAM participant. Some commenters suggested adding Critical Access Hospitals, physicians or physician group practices, or ambulatory surgical centers as TEAM participants. Comments were mixed on whether or not hospitals participating in the AHEAD model should be included in or excluded from TEAM. In this rule, **CMS finalizes the definition of TEAM participant as proposed (which would also exclude hospitals in Maryland), but with a slight modification to account for hospitals eligible to voluntarily opt into TEAM.[117] CMS is allowing overlap between hospitals participating in TEAM and also participating in the AHEAD model**.

CMS proposed that TEAM participation would be mandatory for hospitals in selected CBSAs in order to avoid selection issues that arise in voluntary models. While CMS proposed that participation in TEAM be mandatory for selected hospitals, the agency considered, and sought comment on, whether to create a voluntary opt-in participation arm of the model.

CMS states that a few commenters supported the mandatory nature of TEAM. Numerous commenters, however, requested that TEAM be made voluntary, and that TEAM participants be allowed to select individual episode categories. Some commenters asserted that TEAM's scope exceeds CMS' statutory authority, with one asserting that in proposing TEAM, CMS "is in violation of the Fifth Amendment of the United States Constitution and the Medicare statute."[118] Many commenters suggested that CMS exclude safety net hospitals from TEAM, arguing that they are unable to incur the additional costs required to build the infrastructure necessary to

[116] Maryland hospitals under the Total Cost of Care (TCOC) model would be excluded from participating in the TEAM.

[117] The voluntary opt-in would be available on a one-time basis to hospitals currently participating in BPCI Advanced or the CJR models, that continue in those models until the last day of the models' last performance periods, that are not located in geographic areas mandated for TEAM participation.

[118] CMS responded indicating that the agency's "testing of payment and service delivery models, including TEAM, complies with section 1115A of the Act and other governing laws and regulations, including the U.S. Constitution."

succeed in TEAM, and that they will be disproportionately burdened and penalized if required to participate on a mandatory basis. Despite the strong objections of these commenters, **CMS is finalizing its proposal to make TEAM participation mandatory for IPPS hospitals in the selected geographic areas.**

CMS proposed that TEAM participants exclusively (and not other providers and suppliers involved in the care provided during an episode) would bear sole financial accountability for performance under the model. In the case of episodes involving multiple hospitalizations, financial accountability would fall to the TEAM participant that initiated the episode. **CMS received several comments on this proposal, but is finalizing the requirement to hold the TEAM participant financially accountable for episodes as proposed.**

CMS proposed three tracks in TEAM, defined by varying levels of potential risk and reward. Track 1 would be available only in Performance Year (PY) 1 for all TEAM participants and would have only upside financial risk with quality adjustment applied to positive reconciliation amounts. Track 2 would be available in PYs 2 through 5 to a limited set of TEAM participants, including safety net hospitals, and would have two-sided financial risk with quality adjustment to reconciliation amounts. Lastly, Track 3 would be available in PYs 1 through 5 for all TEAM Participants and would have two-sided financial risk with quality adjustment to reconciliation amounts.

CMS proposed a one-year glide path to two-sided risk for TEAM participants in an effort to ensure that TEAM participants have time to prepare for two-sided financial risk. All TEAM participants would be allowed to select between one of two tracks for the first performance year of TEAM. For PY 1, a TEAM participant could elect to participate in either Track 1 or Track 3. For PY 1, Track 1 would have upside-only financial risk provided through reconciliation payments, subject to a 10 percent stop-gain limit and a Composite Quality Score (CQS) adjustment percentage of up to 10 percent, which would allow TEAM participants to be rewarded for quality improvement and episode costs, but not be held financially accountable if spending exceeds the reconciliation target price. CMS proposed that Track 3 would have two-sided financial risk in the form of reconciliation payments or repayment amounts, subject to 20 percent stop-gain and stop-loss limits and a CQS adjustment percentage of up to 10 percent.

Because some participants are less able to take on substantial financial risk, CMS proposed to allow certain TEAM participants[119] who start in Track 1 in PY 1 to elect Track 2 in PY 2 and remain in Track 2 for the duration of the model. (Such hospitals could voluntarily elect to move into Track 3.)

Table X.A.-01, reproduced below, summarizes the proposed TEAM tracks.

TABLE X.A.-01 – SUMMARY OF TEAM PARTICIPATION TRACKS

Track	Performance Year (PY)	Team Participant Eligibility	Financial Risk
Track 1	PY 1	All TEAM participants	• Upside risk only (10% stop-gain limit)

[119] Safety net hospitals, rural hospitals, Medicare-dependent hospitals (MDHs), sole community hospitals (SCH), and essential access community hospitals as defined under 42 CFR 412.109.

Track 1	PYs 1-3	TEAM participants that are safety net hospitals	• Upside risk only (10% stop-gain limit) • CQS adjustment percentage of up to 10% for positive reconciliation amounts
Track 2	PYs 2-5	TEAM participants that meet one of following hospital criteria: • Safety net hospital • Rural hospital • Medicare Dependent Hospital • Sole Community Hospital • Essential Access Community Hospital	• Upside and downside risk (5% stop-gain/stop-loss limits) • CQS adjustment percentage of up to 10% for positive reconciliation amounts and CQS adjustment percentage of up to 15% for negative reconciliation amounts
Track 3	PYs 1-5	All TEAM participants	• Upside and downside risk (20% stop-gain/stop-loss limits) • CQS adjustment percentage of up to 10% for positive and negative reconciliation amounts

CMS indicates that comments were generally supportive of the approach to give participants a glide path to taking on two-sided risk, but that most commenters wanted a longer glide path (*e.g.*, remaining in Track 1 for two years, rather than only one as proposed, either for some or for all participating hospitals). Many commenters thought the level of downside risk was too great, especially given the proposed 3 percent discount off of the episode target prices (see discussion of X.A.3.d, below). One commenter suggested that CMS make advance investment payments to participants in rural or underserved areas; CMS declined to act on this suggestion.

In response to these comments, CMS is modifying its proposal to allow safety net hospitals to remain in Track 1 only in PY 1, finalizing instead a policy that would allow them to remain in Track 1 for an additional two years (PY 2 and PY 3) (§§512.505, 512.520, and 512.550 (3)(3)(i)[120]).

a. Approach to Select TEAM Participants and Statistical Power

CMS proposed to identify model participants by first selecting geographic areas, and then requiring all hospitals (except for those hospital types specifically excluded, above) in the geographic area to participate. Geographic areas would be identified and selected using stratified random sampling to improve the statistical power of subsequent evaluations. Geographic areas would be defined on the basis of core-based statistical areas (CBSA), using the designations in OMB Bulletin 23-01 issued on July 21, 2023. Certain CBSAs would be excluded: those in Maryland (in whole or in part), and those in which hospitals generated no episodes in the five episode categories between January 1, 2022, and June 30, 2023. (The final rule lists the 803 CBSAs eligible for selection in TEAM in Table X.A.-03.)

CMS proposed to stratify CBSAs into groups based on average historical episode spending, the number of hospitals, the number of safety net hospitals, and the CBSA's exposure to prior CMS bundled payment models (and proposed to oversample CBSAs that have limited previous exposure to CMS' bundled payment models and CBSAs with a higher number of safety net hospitals). CMS would stratify each of these categories into "high" and "low" groups, resulting

[120] 512.550(3)(3)(i) is verbatim from the final rule, but it appears to be incorrect.

in 16 unique combinations, but also proposed to create a 17th stratum to group CBSAs with a very high number of safety net hospitals. CMS estimates that it would select approximately 25 percent of eligible CBSAs for participation in TEAM through this method. The 17 selection strata and their relationship to the dimensions discussed above are represented in Table X.A.-04 in the final rule, reproduced with modifications below.

TABLE X.A.-04: SELECTION STRATA AND THEIR PROPOSED SELECTION PERCENTAGES

Selection strata	Number of safety net hospitals in the CBSA	CBSA's past exposure to CMS' bundled payment models	Average spend for a broad range of episode categories in the CBSA	Number of hospitals within the CBSA	Selection percentage for CBSAs in strata
1	Low	Low	Low	Low	1/4
2	Low	Low	Low	High	1/4
3	Low	Low	High	Low	1/4
4	Low	Low	High	High	1/4
5	Low	High	Low	Low	1/5
6	Low	High	Low	High	1/5
7	Low	High	High	Low	1/5
8	Low	High	High	High	1/5
9	High	Low	Low	Low	1/3
10	High	Low	Low	High	1/3
11	High	Low	High	Low	1/3
12	High	Low	High	High	1/3
13	High	High	Low	Low	1/4
14	High	High	Low	High	1/4
15	High	High	High	Low	1/4
16	High	High	High	High	1/4
17	Very High	High	High	High	1/2
18 (new)	N/A	N/A	N/A	N/A	1/5

Commenters expressed various concerns about CMS' proposed approach to selecting TEAM participants, ranging from the oversampling of safety net hospitals, the use of CBSAs as the geographic unit of selection, the inclusion of low-volume hospitals in TEAM, and the goal of including 25 percent of eligible CBSAs in TEAM. In response to comments, CMS is finalizing its approach to selecting mandatory CBSAs and TEAM participants, with modifications. Specifically, given the new voluntary opt-in of hospitals participating in BPCI Advanced and CJR into TEAM, and the potential impacts of such opt-in on evaluation bias, CMS is creating a new selection stratum consisting of 93 CBSAs with at least one hospital participating in BPCI Advanced or CJR as of January 1, 2024, in states that are participating in AHEAD (except Maryland). Given that these CBSAs are relocated from other selection strata, there will still be 803 eligible CBSAs with 2,718 IPPS hospitals eligible to be selected for TEAM. **CMS is finalizing the 18-strata approach in this final rule. CMS publishes in this final rule the final list of CBSAs eligible for selection into TEAM in Table X.A.-05. From this list, CMS has selected 188 CBSAs that will be selected for participation in TEAM, and published this list**

for the first time (it was absent from the proposed rule; a point of criticism by some commenters) in Table X.A.-07 in the final rule (not reproduced here).

b. Episodes

CMS proposed limiting the episode categories under TEAM to those included in BPCI Advanced. These categories consist of both surgical and medical high-expenditure, high-volume care delivered to Medicare beneficiaries. CMS also wanted to ensure that the episodes in the model include post-acute care services. Given these criteria, CMS proposed to test five episode categories in TEAM: Coronary Artery Bypass Grafting (CABG), Lower Extremity Joint Replacement (LEJR), Surgical Hip and Femur Fracture Treatment (SHFFT), Spinal Fusion, and Major Bowel Procedure. These episode categories would be identified by Medicare Severity-Diagnosis Related Group (MS-DRG) during the anchor hospitalization or, for hospital outpatient procedures, by their Healthcare Common Procedure Coding System (HCPCS) codes. (The selected episode categories and billing codes are summarized in Table X.A.-08, reproduced below.)

TABLE X.A.-08: EPISODE CATEGORIES AND BILLING CODES

Episode Category Billing Codes (MS-DRG/HCPCS)
LEJR: MS-DRG 469, 470, 521, 522. HCPCS 27447, 27130, 27702
SHFFT: MS-DRG 480, 481, 482
CABG: MS-DRG 231, 232, 233, 234, 235, 236
Spinal fusion: MS-DRG 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 472, 473. HCPCS 22551, 22554, 22612, 22630, 22633
Major bowel procedure: MS-DRG 329, 330, 331

Subsequent to the proposed rule, CMS issued a correction notice on May 31, 2024 (CMS-1808-CN). In that notice, CMS clarified that any proposed changes to the spinal fusion MS-DRGs elsewhere in the IPPS rule that were subsequently finalized would be reflected in the TEAM spinal fusion episode category, should TEAM be finalized as well.

CMS indicates that commenters were generally supportive of the episodes selected for TEAM, although many commenters suggested that TEAM participants be allowed to select episodes, rather than be required to participate in all five categories. Some commenters suggested setting separate target prices for inpatient and outpatient episodes (rather than a single target price as proposed by CMS). CMS declined to act on these suggestions. Other commenters noted that episodes initiated on an emergent basis were likely more expensive than non-emergent episodes, and suggested that CMS carve out emergent cases from TEAM episodes. CMS considered this suggestion, **but instead is finalizing a change to the TEAM risk adjustment methodology (see X.A.3.d.(4) of the final rule preamble) to address this concern**.

In the proposed rule, CMS sought comment on the definitions of the individual episode categories (lower-extremity joint replacement, SHFFT, CABG, spinal fusion, and major bowel procedure). Comments were varied, with some supporting, some opposing, and some suggesting technical and clinical modifications to the proposed episode categories. Commenters in particular argued that CMS should not include LEJR in TEAM, given that hospitals' broad participation in BPCI, BPCI Advanced, and CJR has already removed much of the cost variation for this

procedure. In addition, many commenters argued that the spinal fusion episode category be excluded from TEAM. **In light of comments on all of the episode categories, CMS is finalizing LEJR as proposed; it is finalizing SHFFT largely as proposed; it is finalizing the CABG episode category as proposed; it is finalizing the spinal fusion episode category to reflect the revised spinal fusion MS-DRGs (see section II.6.b of this final rule);[121] and it is finalizing the major bowel procedure episode category as proposed. The full list of MS-DRGs and HCPCS codes is codified at §512.510.**

CMS proposed to define TEAM episodes as consisting of all Part A and Part B services (with some exceptions (§512.525(f)), beginning with an inpatient admission ("anchor hospitalization" or outpatient procedure ("anchor procedure"), and ending 30 days after discharge or after the anchor procedure. These include physician services, hospital services, post-acute care, therapy, laboratory tests, durable medical equipment, most Part B drugs, and hospice. **CMS is finalizing the definition of "included services" as proposed.** Comments on the proposed 30-day episode length were varied, with some commenters supporting the 30-day episode, and others arguing for either longer or variable episode lengths, but in this final rule **CMS is finalizing its proposed policy for a 30-day post-discharge episode length at § 512.537 without modification.**

Excluded services would be the same exclusions that were in effect for BPCI Advanced: items and services that are clinically unrelated to the anchor hospitalization or anchor procedure; hospital admissions and readmissions for specific categories of diagnoses, such as oncology, trauma medical admissions, organ transplant, and ventricular shunts determined by MS–DRGs, defined Major Diagnostic Categories (MDC);[122] and new technology add-on payments for drugs, technologies and services identified by value code 77 on IPPS claims. OPPS pass-through payments for certain medical devices and drugs paid outside of the MS-DRG (such as hemophilia clotting factors) are also proposed to be excluded, as well as other low-volume, high-cost drugs and biologics. **CMS is finalizing its list of TEAM exclusions as proposed, without modification.**

c. Quality Measures and Reporting

CMS proposed that TEAM would incorporate quality measures that focus on care coordination, patient safety, and patient reported outcomes (PROs), which the agency believes represent areas of quality that are particularly important to patients undergoing acute procedures. CMS proposed three initial measures for TEAM: for all TEAM episodes, a Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) and a CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135); and for LEJR episodes, a Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618). Performance on these measures would inform the calculation of the TEAM participant's composite quality score

[121] The spinal fusion episode category will be composed of anchor admissions starting with MS-DRGs 402, 426, 427, 428, 429, 430, 447, 448, 450, 451, 471, 427, and 473, and anchor (outpatient) procedures identified by HCPCS codes 22551, 22554, 22612, 22630, and 22633.

[122] MDC 02 (Diseases and Disorders of the Eye), MDC 14 (Pregnancy, Childbirth, and Puerperium), MDC 15 (Newborns), and MDC 25 (Human Immunodeficiency Virus).

(CQS). Reconciliation payments to TEAM participants would be adjusted based on their performance on these measures throughout the duration of the model.

In addition, CMS is considering the future use of three measures on the 2023 Measures Under Consideration (MUC) list:[123] Hospital Harm – Falls with Injury (MUC2023-048), 30-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (MUC2023-049), and Hospital Harm – Postoperative Respiratory Failure (MUC2023-050). CMS specifically sought comment on the potential for these three measures to replace the CMS PSI 90 measure beginning in 2027.

CMS proposed that TEAM participants would use existing Hospital IQR program processes to report data for calculating these measures; using an existing process would require no additional administrative burden for participants. Participants' performance on the measures would be publicly reported, with PY 1 measure scores reported in 2027, and each year's performance reported annually with a one-year lag thereafter for the duration of the model.

CMS indicates that commenters were generally supportive of the proposed measures, particularly appreciating that these are currently collected as part of the existing Hospital Inpatient Quality Reporting (IQR) program. Incongruously, however, other commenters were concerned about the administrative burden that these measures would pose for TEAM participants, and requested that CMS use a claims-based measure set similar to BPCI Advanced. Some commenters expressed concern that two of the proposed measures are not specific to any of the TEAM episodes, and expressed particular objection to the CMS PSI 90 measure. **After considering these comments, CMS is finalizing its proposed quality measures for TEAM without modification at §512.547. In addition, CMS is finalizing the proposed Hospital Harm and Failure-to-Rescue measures to be used within the Hospital IQR program without modification. These measures will be incorporated into TEAM during its second performance year. CMS is also finalizing, without modification, its proposals regarding the form and timing of the submission of quality measure data, and the public display of these measures.** CMS indicates that it will consider other changes to quality reporting under TEAM in future rulemaking.

d. Pricing and Payment Methodology

CMS will use experience from CJR and BPCI Advanced to inform the calculation of episode target prices under TEAM, with the goal of a target price methodology that blends the most successful elements of each of these model iterations, striking a balance of predictability and accuracy.

In the April proposed rule, CMS proposed at §512.540 to use three years of baseline data, trended forward to the performance year, to calculate target prices at the level of MS-DRG/HCPCS episode type and region. CMS proposed to roll the three-year baseline forward for

[123] Centers for Medicare & Medicaid Services. (December 1, 2023). 2023 Measures Under Consideration (MUC) List. Available at: https://mmshub.cms.gov/sites/default/files/2023-MUC-List.xlsx; see also Centers for Medicare & Medicaid Services. (December 2023). Overview of the List of Measures Under Consideration. Available at: https://mmshub.cms.gov/sites/default/files/2023-MUC-List-Overview.pdf

each year of the model and laid out the specific data used for each performance year at proposed §512.540(b)(2). Within each three-year baseline period, CMS proposed to adjust spending for the first two years of the period to trend it forward to the most recent (3rd) year of the baseline period. Spending in the third year would be weighted at 50 percent in the calculation of target prices (spending in year 1 would be 17 percent and year 2 would be 33 percent). These baseline trend factor adjustments would be calculated at the MS-DRG/HCPCS episode type and region level.

Commenters were concerned that the proposed benchmarking methodology would result in a "ratchet" effect, which would make it difficult for TEAM participants to keep their costs below the episode target price, especially small providers or those serving socially disadvantaged populations. CMS argued that changes to the risk adjustment methodology and the application of a new capped 3 percent retrospective trend factor would mitigate such difficulties. After consideration of the comments received, **CMS is finalizing at §512.540(b)(2)(3) the proposal to use 3 years of baseline episode spending, rolled forward for each performance year, with more recent baseline years weighted more heavily, to calculate target prices in TEAM.**

The agency proposed to group episodes from the baseline period by applicable MS-DRG for episode types that include only inpatient hospitalizations, and by applicable MS-DRG or HCPCS code for episode types that include both inpatient hospitalizations and outpatient procedures. For episodes types that include both inpatient hospitalizations (identified by MS-DRGs) and outpatient procedures (identified by HCPCS codes), HCPCS codes would be combined for purposes of target pricing with the applicable MS-DRG representing an inpatient hospitalization without Major Complications and Comorbidities, as CMS expects those beneficiaries to have similar clinical characteristics and costs. CMS proposed to cap high-cost outlier episodes at the 99th percentile for each of the 24 proposed MS-DRG/HCPCS episode types and 9 regions (which CMS proposed to define as the 9 U.S. Census Divisions).

CMS proposed to use average standardized spending for each MS-DRG/HCPCS episode type in each region as the benchmark price for that MS-DRG/HCPCS episode type for that specific region, resulting in 216 MS-DRG/HCPCS episode type/region-level benchmark prices. CMS proposed that TEAM participants would be provided the regional prices as episode targets, rather than hospital-specific or a blend of regional/hospital-specific prices. **In this rule, CMS is finalizing its proposal to provide regional target prices to all TEAM participants for each performance year during the model performance period, where region is defined by the U.S. Census Divisions.**

The agency proposed to apply a prospective trend factor and a discount factor (3 percent) to benchmark prices (as well as a prospective normalization factor) to calculate preliminary target prices. The prospective trend factor would represent expected changes in overall spending patterns between the most recent calendar year of the baseline period and the performance year, based on observed changes in overall spending patterns between the earliest calendar year of the baseline period and the most recent year of the baseline period. The discount factor would represent Medicare's portion of potential savings from the episode. Many commenters, however, were concerned that the prospective trend factor would result in inaccurate target prices (specifically target prices that would be too low). Unduly low target prices, coupled with the

proposed 3 percent discount factor (which many commenters strenuously opposed), would produce target prices that would be unduly low and make it difficult for participants to succeed under TEAM.

In light of public comments expressing these concerns, CMS made two changes to its initial proposal. First, **the agency is finalizing a modified version of its proposed target price calculation method to include a 3 percent capped retrospective trend factor adjustment applied during reconciliation to construct reconciliation target prices**, which the agency describes as follows.

> "While the prospective trend calculates average regional episode spending that occurred during the baseline period, the retrospective trend factor calculates realized average regional episode spending that occurred during the performance year. Thus, the retrospective trend factor adjustment will be calculated by taking the average regional capped performance year episode spending for each MS–DRG/HCPCS episode type divided by the average regional capped baseline period episode spending for each MS-DRG/HCPCS episode type. The retrospective trend factor adjustment will be capped at 3 percent, meaning that the maximum difference between the prospective trend and retrospective trend is 3 percent. We believe including a 3 percent capped retrospective trend adjustment will protect TEAM participants and CMS from excessive risk, while balancing predictability and stability for TEAM participants" (pp. 2047-2048 of the public inspection version of the final rule).

Second, CMS has lowered the discount factor to 2 percent for LEJR, SHFFT, and spinal fusion episodes, and to 1.5 percent for CABG and major bowel procedure episodes (see section X.A.3.d.(3)(g) of the final rule for full discussion).

CMS proposed to risk adjust episode-level target prices at reconciliation by beneficiary age, the beneficiary's Hierarchical Condition Count (HCC), and social risk, loosely drawing on the agency's experience with risk adjustment under CJR. CMS proposed to calculate risk adjustment multipliers prospectively at the MS-DRG/HCPCS episode type level based on baseline data, and hold those multipliers fixed for the performance year. To ensure that risk adjustment does not inflate target prices overall, the agency further proposed to calculate a prospective normalization factor based on the data used to calculate the risk adjustment multipliers. The prospective normalization factor would be applied, in addition to the prospective trend factor and discount factor described previously, to the benchmark price to calculate the preliminary target price for each MS-DRG/HCPCS episode type and region. CMS proposed that the prospective normalization factor would be subject to a limited adjustment at reconciliation based on TEAM participants' observed performance period case mix, such that the final normalization factor would not exceed ±5 percent of the prospective normalization factor.

CMS also proposed a low-volume threshold policy under TEAM for purposes of reconciliation. This low volume threshold would apply to total episodes across all episode categories in the baseline period for a given PY. If a TEAM participant did not meet the proposed low volume threshold of at least 31 total episodes in the baseline period for PY 1, CMS would still reconcile their episodes, but the TEAM participant would be subject to the Track 1 stop-loss and stop-gain

limits for PY 1. If a TEAM participant did not meet the proposed low volume threshold of at least 31 total episodes in the applicable baseline periods for PYs 2-5, they would be subject to the Track 2 stop-loss and stop-gain limits for PYs 2-5. **Many commenters expressed concerns about the proposed low-volume threshold; in response CMS repeatedly states that it is withdrawing this proposal and will propose alternatives to it in future rulemaking.**

Risk Adjustment and Normalization. For TEAM, CMS proposed to use a modified version of the risk adjustment methodology used in CJR. CMS will calculate risk adjustment coefficients at the MS-DRG/HCPCS episode type level. CMS also proposed to use an HCC count variable (TEAM HCC count), collecting HCCs from the FFS claims for each beneficiary starting 90 days before the anchor hospitalization/procedure. Lastly, CMS proposed to use a variable to account for social risk composed of three elements: (1) fully dually eligible for Medicare/Medicaid, (2) position of the beneficiary's geographic residence on the distribution of Area Deprivation Index (ADI) values (>the 80th percentile for national ADI, and the 8th decile for state ADI), and (3) whether or not the beneficiary qualifies for the Part D Low-Income Subsidy (LIS).

In responding to the proposed rule, *many* commenters expressed concerns about CMS' proposed approach to risk adjustment under TEAM, and argued that a more robust approach was necessary. In response to these concerns, CMS conducted additional regression analyses, and convened a technical expert panel to inform refinement of the TEAM risk adjustment. **CMS has substantially altered its proposed risk adjustment approach, and is now finalizing an approach that involves episode-category specific risk adjusters.** Beneficiary age, HCC count, and beneficiary social risk are common to the risk adjusters for all five episodes; hospital bed size, hospital safety net status, prior post-acute care use, long-term care use, dementia, disability, and a procedure-related variable are used in the risk adjustment for several of the episode categories. In addition, CMS uses 11 to 16 HCCs unique to each episode category.[124] **The full list of risk adjusters that the agency is finalizing appears on pages 2076-2080 of the public inspection version of the final rule. The agency is finalizing its approach to calculating and applying the normalization factor as proposed. CMS has withdrawn its proposed 90-day lookback period for capturing beneficiary-specific HCCs, and indicates that it will revisit this specific issue in future rulemaking.**

Process for Reconciliation. CMS proposed at §512.550 to conduct an annual reconciliation calculation that would compare performance year spending on episodes that ended during that PY with reconciliation target prices for those episodes to calculate a reconciliation amount for each TEAM participant, similar to the process used in CJR. CMS would conduct the reconciliation six months after the end of the performance year. **CMS received no comments on its proposal to conduct one reconciliation annually, and is finalizing these provisions as proposed. Comments on the timeline for reconciliation were supportive, so CMS is finalizing its proposal to conduct the reconciliation six months after the end of the performance year.**

Composite Quality Score. CMS proposed, as part of the annual reconciliation process, to adjust the difference between the TEAM participant's performance year spending and their

[124] 11 HCCs are identified for use in CABG, 16 HCCs for SHFFT, 12 for Major Bowel Procedure, 12 for LEJR, and 12 for Spinal Fusion.

reconciliation price (the reconciliation amount) by its Composite Quality Score (CQS), an approach similar to that used in CJR and BPCI Advanced.

As noted above, the quality measures used in TEAM would be collected through the CMS Hospital IQR program and the Hospital-Acquired Condition (HAC) reduction program. CMS proposed to convert raw quality measure scores into scaled quality measure scores by comparing the raw quality measure score to the distribution of raw quality measure score percentiles among the national cohort of hospitals, which would consist of TEAM participants and hospitals not participating in TEAM, in the CQS baseline period (CMS proposed CY 2025 as the baseline period for the duration of TEAM), so that each measure has a scaled quality measure score between 0 and 100 for each episode category.

CMS proposed that prior to calculating the CQS, the quality measures would be weighted based on the volume of episodes for a TEAM participant. A normalized weight would be calculated by dividing the TEAM participant's volume of episodes for a given quality measure by the total volume of all the TEAM participant's episodes. This calculation would be applied to all quality measures for the TEAM participant (see Table X.A.-06 in the proposed rule). CMS asserted that it is important to volume weight the quality measures so that more weight is given to the quality measures that apply to more episode categories. CMS proposed to then take the quality measures' normalized weights and combine them with the scaled quality measure scores to determine the weighted scaled score by multiplying each quality measure's scaled quality measure score by its normalized weight to create weighted scaled scores for a TEAM participant. The weighted scaled scores would then be added together to construct the CQS for the TEAM participant.

Comments on the proposed CQS were mixed, with several opposing CMS' proposal that a TEAM participant would need a perfect score of 100 on a quality measure to receive their full reconciliation payment amount. In light of comments received, **CMS is finalizing its CQS proposals with slight modification:** the Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) measure, CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135) measure, and the Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO-PM) (CMIT ID #1618) will use a CY 2025 baseline (as proposed), but the Hospital Harm – Falls with Injury (CMIT ID #1518) measure, the Hospital Harm – Postoperative Respiratory Failure (CMIT ID #1788) measure, and the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (CMIT ID #134) measure will use a CQS baseline period of CY 2026. **CMS is also slightly modifying its scaled score proposal for inverse quality measures, assigning a scaled score of 0 if the TEAM participant has a raw quality measure score greater than the maximum of the raw quality measure scores in the CQS baseline period and assigning a scaled quality measure score of 100 if the TEAM participant has a raw quality score less than the minimum of the raw scores in the CQS baseline period.**

Calculating the Reconciliation Payment Amount or Repayment Amount. CMS proposed to retrospectively calculate a TEAM participant's actual episode performance based on the episode definition, after the completion of each performance year. CMS would cap performance year

spending at **the high-cost outlier cap that it is finalizing in §512.540(b)(4) of this final rule**. Any performance year episode spending amount above the high-cost outlier cap would be set to the amount of the high-cost outlier cap. CMS would then compare each TEAM participant's performance year spending to its reconciliation target prices, and define the reconciliation amount as the dollar amount representing the difference between the reconciliation target price and performance year spending for each MS-DRG/HCPCS episode type, prior to adjustments for quality, stop-gain/stop-loss limits, and post-episode spending. The agency would adjust the reconciliation amount for quality performance, and then apply stop-loss and stop-gain limits (discussed above) to calculate the Net Payment Reconciliation Amount (NPRA).[125] **CMS is finalizing its proposals at §512.550(c)-(g) for calculating the reconciliation payment amount or repayment amount without modification.**

CMS proposed to apply the CQS adjustment percentage to any reconciliation amount (positive or negative). The percentage adjustments would vary as a function of the model participant's Track, as indicated in Table X.A.-13 of the final rule, reproduced below.

TABLE X.A.-013 – TEAM CQS ADJUSTMENT PERCENTAGE FORMULAS

Track	Reconciliation Amount	CQS Adjustment Percentage Formula
Track 1	Positive Reconciliation Amount	CQS adjustment percentage = (10%-10% * (CQS/100))
Track 2	Positive Reconciliation Amount	CQS adjustment percentage = (10%-10% * (CQS/100))
Track 2	Negative Reconciliation Amount	CQS adjustment percentage = (15% * (CQS/100))
Track 3	Positive Reconciliation Amount	CQS adjustment percentage = (10%-10% * (CQS/100))
Track 3	Negative Reconciliation Amount	CQS adjustment percentage = (10% * (CQS/100))

CMS received no comments on the calculation and application of the CQS, and is finalizing these policies without modification as proposed.

Limitations on NPRA. CMS proposed to phase in risk in TEAM. Track 1 TEAM participants would not be subject to downside risk in performance year 1, but would be subject to a stop-gain limit of 10 percent. CMS proposed that Track 2 TEAM participants would be subject to downside and upside risk with symmetric stop-gain and stop-loss limits of 10 percent for PYs 2-5. Since Track 3 would be designed for TEAM participants with prior experience in value-based care or those who are prepared to accept greater financial risk in the first year of TEAM, CMS proposed that TEAM participants who opt into Track 3 would be subject to both upside and downside risk, with symmetric stop-gain and stop-loss limits of 20 percent for all performance years. Many commenters asked CMS for lower financial risk for rural hospitals in TEAM. **In response, CMS is finalizing a change to the proposed Track 2 stop-loss and stop-gain limits, reducing the limits from 10 percent to 5 percent**.[126]

Participant Responsibility for Increased Post-Episode Payments. To mitigate any potential incentives for hospitals to defer necessary care to the period after the 30-day post-anchor hospitalization/anchor procedure window, CMS proposed to calculate total Part A and Part B spending in the 30-day period following the completion of each episode, whether or not the

[125] This amount would be adjusted by a post-episode spending calculation, discussed later in the proposed rule.
[126] This change would apply not just to rural hospitals, but to all hospitals (*e.g.*, safety net hospitals) eligible for Track 2.

spending is related to the defined episode. CMS proposed that starting in PY 1 for Track 3 TEAM participants, and PY 2 for Track 2 TEAM participants, if the TEAM participant's average post-episode spending exceeds a defined threshold (three standard deviations from the regional average 30-day post-episode spending), the amount above the threshold would be subtracted from the reconciliation amount or added to the repayment amount for that performance year. The amount above the threshold would not be subject to the stop-loss limits proposed elsewhere in the proposed rule. **CMS is finalizing this proposal.**

Reconciliation Payments and Repayments. For the PY 1 reconciliation process for Track 1 TEAM participants, CMS proposed to combine a TEAM participant's NPRA and post-episode spending amount, and if positive, the TEAM participant would receive the amount as a one-time lump sum reconciliation payment from Medicare. If negative, the TEAM participant would not be responsible for repayment to Medicare. For TEAM participants in Track 3 for PY 1, and Track 2 or Track 3 for PYs 2-5, if the amount is positive, the TEAM participant would receive the amount as a one-time lump sum reconciliation payment from Medicare. If the amount is negative, Medicare would hold the TEAM participant responsible for a one-time lump sum repayment. CMS would collect the one-time lump sum repayment in a manner that is consistent with all relevant federal debt collection laws and regulations. **After consideration of the comments received, CMS is finalizing without modification at §512.550(g)(2)-(3) the proposed provisions for lump sum reconciliation payments and repayment amounts.**

Appeals Process. At proposed §512.560, CMS proposed a first-level appeal process for TEAM participants to contest matters related to payment or reconciliation, such as the calculation of the TEAM participant's reconciliation amount or repayment amount as reflected on a TEAM reconciliation report, the calculation of NPRA, and the calculation of the CQS. CMS also proposed a reconsideration review process for model participants to contest a CMS appeals determination, and lays out the procedures and timelines for reconsideration review, which would include an option for either the TEAM participant or CMS to request a review by the CMS Administrator. **CMS received no comments on its proposed first-order appeals process and thus is finalizing this provision without modification at §512.560**. **Neither did CMS receive comments on its proposed reconsideration process and therefore is finalizing this provision without modification at §512.561.**

e. Model Overlap

When providers (or beneficiaries) are involved in more than one model at the same time, CMS has previously had to define attribution, demarcation, and precedence policies to ensure that Medicare did not make duplicate payments, and to ensure that the incentives created by participation in multiple models (*e.g.*, an ACO and a bundled model) were not misaligned. However, these efforts often themselves resulted in confusing methodologies or misaligned incentives which were difficult to navigate. Participants from prior models have also cited confusion with identifying to which model(s) a beneficiary may be aligned or attributed. Yet CMS continues to believe it is important to simultaneously allow beneficiaries to participate in broader population-based and other total cost of care models, as well as episode payment models that target a specific episode with a shorter duration, such as TEAM. Therefore, CMS proposed that a beneficiary could be in an episode in TEAM by undergoing a procedure at a TEAM

participant, and be attributed to a provider participating in a total cost of care or shared savings model or program. CMS believes that allowing overlap between beneficiaries aligned to a total cost of care model who also initiate an episode in TEAM and by allowing both participants to retain savings will have a positive impact on beneficiaries by fostering a cooperative relationship between accountable care and TEAM participants where all parties have interest in providing coordinated, longitudinal care.

In the proposed rule, CMS also sought comment on an alternative proposal whereby ACO-aligned beneficiaries would be prohibited from being in a TEAM episode. CMS also solicited comment on the notion (not proposed) of requiring TEAM participants to notify an ACO that one of their aligned beneficiaries has triggered a TEAM episode, including the timeframes for such notification and any available data that could inform more effective communications between TEAM participants and participants in total cost of care models.

CMS indicates that it received considerable support for its proposal to allow overlap (participants or beneficiaries) between TEAM and other payment models, although some commenters opposed such overlap (these commenters supported the alternative proposal of prohibiting ACO-aligned beneficiaries from being in TEAM episodes). **After considering various comments, CMS is finalizing its proposals for model overlap. Regarding the notification process the agency discussed in the proposed rule, CMS indicates that comments were mixed; it states that it will address these comments and make additional proposals in future rulemaking (but not in this final rule).**

f. Health Equity

For purposes of TEAM, CMS defines safety net hospitals and rural hospitals, and flexibilities that would be afforded to these providers. Having considered several alternative definitions of safety net hospitals, CMS proposed to use the CMMI Strategy Refresh definition of safety net hospitals within TEAM. Comments were varied, but generally supportive of CMS' proposal; therefore, the agency is finalizing its proposed definition of safety net hospital at §512.505.

With respect to identifying rural hospitals, as proposed, because TEAM participants would be selected from CBSAs, by definition no rural hospitals would be explicitly included in TEAM. However, due to geographic reclassifications or rural referral center designations, CMS proposed to define rural hospitals for purposes of TEAM as an IPPS hospital that is located in a rural area as defined under §412.64; is located in a rural census tract defined under §412.103(a)(1); has reclassified as a rural hospital under §412.103; or is designated a rural referral center (RRC) under §412.96. In light of comments received, **CMS is finalizing a definition of rural hospital that includes only rural hospitals located in a rural area or rural census tract, but would not include hospitals that have reclassified to rural areas or RRCs**.

Beneficiary Social Risk Adjustment. CMS notes that it is believed that the inclusion of beneficiary social risk adjustment may provide more resources to providers who care for underserved beneficiaries to offset the additional costs often attributed to social determinants of health, and notes that several CMMI initiatives incorporate beneficiary social risk adjustment into their financial calculations or determining payment amounts. To be consistent with these

other programs, CMS proposed to incorporate and equally weight the three social risk indicators discussed earlier in TEAM's target price methodology (state and national ADI indicators, the Medicare Part D LIS indicator, and dual-eligibility status for Medicare and Medicaid). CMS describes the comments the agency received regarding beneficiary social risk adjustment (mixed, but generally supportive of concept), but oddly, the agency makes no statement regarding the finalization of its specific proposal. **The finalized version of §512.545(a)(3) is identical to the proposed version, so it appears CMS finalized the social need risk adjustment factor without modification.**

Health Equity Plans and Reporting. To further align with other CMS Innovation Center models and promote health equity, CMS proposed that TEAM participants can voluntarily submit to CMS, in a form and manner and by the date(s) specified by CMS, a health equity plan for the first performance year. These plans would identify health disparities among the TEAM participant's beneficiary population, identify health equity goals, describe the health equity plan intervention strategy, and identify health equity plan performance measures. CMS proposed that these plans would be mandatory for TEAM participants beginning in PY 2.

Some commenters supported CMS' health equity plan and reporting requirements. Some suggested that TEAM participants be able to choose their areas of focus; others thought the plans and reporting should be voluntary for the duration of TEAM; some were concerned about the additional administrative burden these plans would impose. **In light of comments received, CMS is finalizing a modified version of its proposal, in that development of health equity plans and reporting to CMS would be voluntary for the duration of TEAM.**

CMS similarly proposed that TEAM participants voluntarily submit beneficiary-level demographic data (including data on race, ethnicity, language, disability, sexual orientation, gender identity, sex, and other demographics) to CMS in PY 1, and that this would become mandatory in PY 2 and subsequent years. Some commenters supported this proposal, but many comments offered suggestions for different data standards or tools for data collection and reporting. Similar to the health equity plan and reporting proposal, here **CMS is finalizing that demographic data collection will be voluntary for all TEAM participants for the duration of the model, and that given issues with beneficiary potential unwillingness to provide certain information to TEAM participants, participants would not be penalized for incomplete or missing data.**

Beginning in PY 1, CMS proposed that TEAM participants would be required to screen attributed TEAM beneficiaries for at least the following four health-related social needs (HRSN) domains—food insecurity, housing instability, transportation needs, and utilities difficulty. (CMS also considered requiring TEAM participants to screen on a standardized set of HRSN domains.) CMS also proposed that TEAM participants would need to report aggregated HRSN screening data and screened-positive data for each HRSN domain for TEAM beneficiaries that received screening to CMS in a form and manner and by date(s) specified by CMS beginning in PY 1 and for all following performance years. As part of this reporting to CMS, TEAM participants would report on policies and procedures for referring beneficiaries to community-based organizations, social service agencies, or similar organizations that may support patients in accessing services to address unmet social needs.

Many of the comments CMS received in response to this proposal suggested that the HRSN screening proposed for TEAM should align with the analogous requirements under the Hospital IQR program (SDOH-1 and SDOH-2 measures[127]) in order to reduce administrative burden. Some commenters thought CMS should pay TEAM participants for HSRN screening and data collection/reporting; CMS indicated that it will consider these suggestions in future rulemaking. After evaluating comments received, **CMS is finalizing its proposed HSRN screening and reporting requirements, in a manner that follows the reporting of SDOH-1 and SDOH-2 measures in the Hospital IQR, but on a voluntary basis only.**

In addition, the agency also asked for comment on possibly providing upfront infrastructure payments (similar to the ACO Investment Model upfront payments) to qualified safety net hospital participants to further support safety net hospitals in the transformation of care delivery, and the requirements and criteria governing how such funds would be allocated.[128] CMS indicated that it received a "wide range" of comments in response to this solicitation, and that these comments will inform future rulemaking.

g. Financial Arrangements

CMS asserts that it is necessary to provide TEAM participants with flexibilities that could support their performance in TEAM and allow for greater support for the needs of beneficiaries. These flexibilities include the ability to engage in financial arrangements to share a TEAM participant's reconciliation payment amounts and repayment amounts. Such flexibilities would allow TEAM participants to share all or some of the TEAM participant's reconciliation payment amount or repayment amount. **With the proposed arrangements finalized, CMS is making a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)) is available to protect certain remuneration finalized in this section when arrangements with eligible providers and suppliers are in compliance with this rule and 42 CFR 1001.952(ii).**

For purposes of the federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), CMS proposed that the following types of providers and suppliers that are Medicare-enrolled and eligible to participate in Medicare or entities that are participating in a Medicare ACO initiative may be TEAM collaborators:

- Skilled Nursing Facility (SNF).
- Home Health Agency (HHA).
- Long-Term Care Hospital (LTCH).
- Inpatient Rehabilitation Facility (IRF).
- Physician.
- Nonphysician practitioner.
- Therapist in a private practice.

[127] SDOH – social determinants of health.
[128] Somewhat cryptically, CMS suggests that these funds would not come out of the Medicare Parts A and B Trust Funds.

- Comprehensive Outpatient Rehabilitation Facility (CORF).
- Provider or supplier of outpatient therapy services.
- Physician Group Practice (PGP).
- Hospital.
- Critical Access Hospital (CAH).
- Non-physician provider group practice (NPPGP).
- Therapy group practice (TGP).
- Medicare ACO.

CMS solicited comment on the proposed definition of TEAM collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition. Commenters suggested adding hospice, rural emergency hospitals, device manufacturers, and other types of non-physician practitioners (*e.g.*, registered dieticians) to the proposed list of TEAM collaborators. **CMS indicates that it will consider these suggestions in future rulemaking, but otherwise is finalizing the list as proposed without modification at §512.505.**

Sharing Arrangements. CMS proposed that certain financial arrangements between a TEAM participant and a TEAM collaborator be termed "sharing arrangements." For purposes of the federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), the agency proposed that a sharing arrangement would be to share reconciliation payment amounts or repayment amounts. Where a payment from a TEAM participant to a TEAM collaborator is made pursuant to a sharing arrangement, that payment would be defined as a "gainsharing payment." Where a payment from a TEAM collaborator to a TEAM participant is made pursuant to a sharing arrangement, CMS proposed to define that payment as an "alignment payment."

A TEAM participant must not make a gainsharing payment or receive an alignment payment except in accordance with a sharing arrangement. CMS proposed that a sharing arrangement must comply with the provisions of section X.A.3.g.(b) of the proposed rule[129] and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. CMS proposed that the TEAM participant and TEAM collaborator must document this agreement in writing and, per monitoring and compliance guidelines (§512.590), must make it available to CMS upon request. The written agreement must specify the following parameters of the arrangement:

- The purpose and scope of the sharing arrangement.

[129] This section would require that the sharing arrangement must be in writing, signed by the parties, and entered into before care is furnished to TEAM beneficiaries under the sharing arrangement. In addition, participation in a sharing arrangement must be voluntary and without penalty for nonparticipation. The sharing arrangement would have to require all of the individuals and entities party to the arrangement to comply with the applicable provisions of this proposed rule, if finalized, including proposed requirements regarding beneficiary notifications (proposed §512.582(b)), access to records and record retention (proposed §512.586), and participation in any evaluation, monitoring, compliance, and enforcement activities performed by CMS or its designees (proposed §512.590). The sharing arrangement must also require all individuals and entities party to the arrangement who are providers or suppliers to comply with the applicable Medicare provider enrollment requirement at §424.500, including having a valid and active TIN or NPI, during the term of the sharing arrangement.

- The identities and obligations of the parties, including specified TEAM activities and other services to be performed by the parties under the sharing arrangement.
- The date of the sharing arrangement.
- Management and staffing information, including type of personnel or contractors that will be primarily responsible for carrying out TEAM activities.
- The financial or economic terms for payment, including the following:
  - Eligibility criteria for a gainsharing payment.
  - Eligibility criteria for an alignment payment.
  - Frequency of gainsharing or alignment payment.
  - Methodology and accounting formula for determining the amount of a gainsharing payment that is solely based on quality of care and the provision of TEAM activities.
  - Methodology and accounting formula for determining the amount of an alignment payment.

The sharing arrangement must also require the TEAM collaborator to have a compliance program that includes oversight of the sharing arrangement and compliance with the requirements of the model. The agency proposed that the board or other governing body of the TEAM participant have responsibility for overseeing the TEAM participant's participation in the model, its arrangements with TEAM collaborators, its payment of gainsharing payments, its receipt of alignment payments, and its use of beneficiary incentives in the model.

Lastly, CMS proposed that the sharing arrangement must not pose a risk to beneficiary access, beneficiary freedom of choice, or quality of care so that financial relationships between TEAM participants and TEAM collaborators do not negatively impact beneficiary protections under the model. CMS proposed to require that the terms of the sharing arrangement must not induce the TEAM participant, TEAM collaborator, or any employees, contractors, or subcontractors of the TEAM participant or TEAM collaborator to reduce or limit medically necessary services to any beneficiary or restrict the ability of a TEAM collaborator to make decisions in the best interests of its patients, including the selection of devices, supplies, and treatments.

CMS sought comment on all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model would be met.

Some commenters expressed concerns about the burden of preparing sharing arrangements with large numbers of TEAM collaborators and stressed (1) the importance of hospitals sharing savings with TEAM collaborators, and (2) the importance of sufficient shared savings to offset the costs of the associated administrative burden, although there appears to be no action for CMS to take in response, beyond acknowledging receipt of these comments. Therefore, **the agency is finalizing its proposed TEAM sharing arrangements without modification at §512.565.**

Gainsharing Payment and Alignment Payment Conditions and Limitations. CMS asserts that gainsharing payment eligibility for TEAM collaborators should be conditioned on two requirements—(1) quality of care criteria; and (2) the provision of TEAM activities. With respect to the first requirement, CMS proposed that to be eligible to receive a gainsharing payment, the

TEAM collaborator must meet quality of care criteria during the performance year for which the TEAM participant earned a reconciliation payment amount that comprises the gainsharing payment. With regard to the second requirement, to be eligible to receive a gainsharing payment, or to be required to make an alignment payment, a TEAM collaborator other than a PGP, NPPGP, or TGP would need to have directly furnished a billable item or service to a TEAM beneficiary during the same performance year for which the TEAM participant earned a reconciliation payment amount or repayment amount. These requirements ensure that there is a required relationship between eligibility for a gainsharing payment and the direct care for TEAM beneficiaries during an episode for these TEAM collaborators. CMS proposed to establish similar requirements for PGPs, NPPGPs and TGPs that vary because these entities do not themselves directly furnish billable services.

CMS proposed that the amount of any gainsharing payments must be determined in accordance with a methodology that is solely based on quality of care and the provision of TEAM activities, and *not* on the *amount* of TEAM activities provided. CMS sought comment on this proposal, and also on whether the methodology must be based *solely* on these two elements, or if, alternatively, the methodology must be based *substantially* on these two elements.

CMS proposed that for each PY, the aggregate amount of all gainsharing payments that are derived from a reconciliation payment amount by the TEAM participant must not exceed the amount of the reconciliation payment amount, and lays out other parameters governing the gainsharing payments.[130] The agency also proposed that alignment payments from a TEAM collaborator to a TEAM participant may be made at any interval that is agreed upon by both parties. Alignment payments must not be issued, distributed, or paid prior to the calculation by CMS of the repayment amount and cannot be assessed in the absence of a repayment amount. The TEAM participant must not receive any amounts under a sharing arrangement from a TEAM collaborator that are not alignment payments.

CMS solicited comment on its proposed aggregate and individual TEAM collaborator limitations on alignment payments.

Commenters in various forms suggested that CMS *require* that TEAM participants share any savings with TEAM collaborators. One commenter suggested that gainsharing payments be allowed on the basis of factors other than solely the quality of care and the provision of TEAM activities; other commenters raised concerns that some of the proposed rules were unduly prescriptive and limited TEAM participants' flexibilities. After considering comments received, **CMS is finalizing its proposals for gainsharing and related policies without modification at**

[130] For example, CMS proposed certain limitations on alignment payments that are consistent with the CJR model. For a performance year, the aggregate amount of all alignment payments received by the TEAM participant from all of the TEAM participant's TEAM collaborators could not exceed 50 percent of the repayment amount. CMS believes it is important that the TEAM participant retain a significant portion of its responsibility for repayment amounts. In addition, the aggregate amount of all alignment payments from a TEAM collaborator to the TEAM participant for a TEAM collaborator other than an ACO may not be greater than 25 percent of the TEAM participant's repayment amount. The aggregate amount of all alignment payments from a TEAM collaborator to the TEAM participant for a TEAM collaborator that is an ACO may not be greater than 50 percent of the TEAM participant's repayment amount.

§512.56.

Documentation Requirements. CMS proposed detailed documentation requirements for financial arrangements, proposed mandatory records that the TEAM participant must keep, and proposed a requirement that the TEAM participant must retain and provide access to, and must require each TEAM collaborator to retain and provide access to, the required documentation. CMS sought comment about all of the requirements set out in the preceding discussion, including whether additional or different safeguards would be needed to ensure program integrity, protect against abuse, and ensure that the goals of the model are met. **CMS received no comments on its proposed documentation requirements and is finalizing them without modification**.

Distribution Arrangements. CMS proposed that certain financial arrangements between TEAM collaborators and other individuals or entities called "collaboration agents" be termed "distribution arrangements." A collaboration agent is an individual or entity that is not a TEAM collaborator and that is a PGP, NPPGP, or TGP member that has entered into a distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee. For purposes of the federal anti-kickback statute safe harbor for CMS-sponsored model arrangements (42 CFR 1001.952(ii)), CMS proposed that a distribution arrangement is a financial arrangement between a TEAM collaborator that is a PGP, NPPGP or TGP and a collaboration agent for the sole purpose of sharing a gainsharing payment received by the PGP, NPPGP or TGP.

As with gainsharing payments, CMS proposed that any payments made as distribution arrangements be made solely on the basis of quality of care and the provision of TEAM activities. The requirements CMS proposed for distribution arrangements largely parallel those proposed for sharing arrangements and gainsharing payments described above—all distribution arrangements must be in writing and signed by the parties, contain the effective date of the agreement, and be entered into before care is furnished to TEAM beneficiaries under the distribution arrangement (and *not* conditioned on the volume of services provided). Participation must be voluntary and without penalty for nonparticipation, and the distribution arrangement must require the collaboration agent to comply with all applicable laws and regulations.

CMS sought comment on these proposals, and specifically on whether there are additional safeguards or a different standard is needed to allow for greater flexibility in calculating the amount of distribution payments that would avoid program integrity risks, and whether additional or different safeguards are reasonable, necessary, or appropriate for the amount of distribution payments from a PGP to its members, a NPPGP to its members, or a TGP to its members.

Again, as with sharing arrangements, CMS proposed that a collaboration agent can only receive a distribution payment if they furnished or billed for an item or service rendered to a beneficiary during an episode that occurred during the same performance year for which the TEAM participant accrued the internal cost savings or earned a reconciliation payment amount that comprises the gainsharing payment being distributed. Further, CMS proposed that the total amount of all distribution payments in a performance year must not exceed the amount of the gainsharing payment received by the TEAM collaborator from the TEAM participant for that

performance year. Proposed documentation requirements are similar to those CMS proposed with respect to sharing arrangements.

CMS proposed that the TEAM collaborator may not enter into a distribution arrangement with any individual or entity that has a sharing arrangement with the same TEAM participant, contending that allowing both types of arrangements for the same individual or entity for care of the same beneficiary during the performance year could also allow for duplicate counting of the individual's or entity's same contribution toward model goals and provision of TEAM activities in the methodologies for both gainsharing and distribution payments. This would potentially lead to financial gain for the individual or entity that is disproportionate to the contribution toward model goals and provision of TEAM activities by that individual or entity.

CMS includes all of its proposals regarding requirements for distribution arrangements in proposed §512.568, and the agency sought comment on all of these provisions. In addition, CMS solicited comments from stakeholders on how the regulation of these financial arrangements may interact with similar regulations under the Medicare Shared Savings Program (MSSP).

Interestingly, CMS indicates that it received no comments on any of its proposals related to distribution arrangements, so **the agency is finalizing them as proposed at §512.568**.

Downstream Distribution Arrangements. For the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP, CMS proposed and sought comment on similar "Downstream Distribution Arrangements," a financial arrangement between:

- A collaboration agent that is both a PGP, NPPGP, or TGP and an ACO participant, and
- A downstream collaboration agent.[131]

These proposed requirements largely parallel those proposed for distribution arrangements and gainsharing and distribution payments at §512.565 and §512.568, and will not be described in detail here in the interest of brevity. **CMS received no comments on its general proposals for TEAM downstream distribution arrangements and is finalizing them as proposed at §512.570.** With respect to specific requirements for downstream distribution arrangements, some commenters expressed concern that downstream participants would be subject to penalties under these proposals without being eligible for savings or incentive payments. At least one commenter echoed comments made elsewhere in response to the proposed rule that hospitals participating in TEAM be required to share savings with downstream participants. **CMS did not act on these comments, and is finalizing them as proposed at §512.570.**

Beneficiary Incentives. CMS proposed that TEAM participants may choose to provide in-kind patient engagement incentives to beneficiaries in an episode, which may include items of technology, subject to certain conditions. CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii))

[131] A downstream collaboration agent is an individual who is not a TEAM collaborator or a collaboration agent and who is a PGP member, a NPPGP member, or a TGP member that has entered into a downstream distribution arrangement with the same PGP, NPPGP, or TGP in which he or she is an owner or employee, and where the PGP, NPPGP, or TGP is a collaboration agent.

is available to protect the beneficiary incentives proposed in this section when the incentives are offered in compliance with the requirements established in the final rule and the conditions for use of the anti-kickback statute safe harbor at 42 CFR 1001.952(ii). CMS proposed that any such incentives must be provided by a TEAM participant or their agent to the beneficiary, and that the incentive must be reasonably related to the beneficiary's medical care. CMS sought comment on this proposal.

With respect to technology, CMS proposed specific safeguards to prevent abuse. The agency proposed that no item or service involving technology can exceed $1000 for any TEAM beneficiary in any episode. CMS also proposed that items and services above $75 in retail value remain the property of the TEAM participant and must be returned to the TEAM participant at the end of the episode. CMS specifically solicited comment on its proposals related to technology in TEAM episodes.[132]

CMS proposed that TEAM participants can offer their beneficiaries in-kind engagement incentives, as long as they are related to the beneficiary's care and do not represent inducements to seek care from specific entities. CMS proposed that the incentives must advance one of four clinical goals of TEAM: beneficiary adherence to drug regimens, beneficiary adherence to care plans, reduction of readmissions or complications from treatment, or management of chronic conditions or diseases that may be affected by treatment of the TEAM clinical condition.

CMS proposed documentation requirements for all beneficiary incentives.

CMS indicates that commenters were generally supportive of the agency's proposals regarding beneficiary incentives, especially those aimed at encouraging adherence to recommended treatments. Several commenters were concerned about the "enhanced documentation requirements" related to technology, some of which they asserted would be "impractical or impossible to meet." **Despite these comments, and in light of other generally supportive comments, the agency is finalizing its proposals for the TEAM beneficiary incentives—including the proposed documentation requirements—as proposed at §512.575.**

Fraud and Abuse Waiver and OIG Safe Harbor Authority. CMS is not proposing to issue any waivers of fraud and abuse provisions in conjunction with TEAM. However, as indicated in the proposed rule, CMS stated that if the proposals herein are finalized, the agency expected to determine that the CMS-sponsored models safe harbor will be available to protect certain financial arrangements and incentives: the TEAM sharing arrangement's gainsharing payments and alignment payments, the distribution arrangement's distribution payments with TEAM collaborators and collaboration agents, the downstream distribution arrangements and downstream distribution payments with collaboration agents and downstream collaboration agents, and TEAM beneficiary incentives. CMS proposed to make the federal anti-kickback statute safe harbor for CMS-sponsored model arrangements available, provided that all of the financial arrangements associated with such payment meet all safe harbor requirements set forth in 42 CFR 1001.952(ii), proposed §512.565, proposed §512.568, and proposed §512.570. **As**

[132] The CMS proposal is oddly detailed in describing the steps that a TEAM participant must take to retrieve technology from a TEAM beneficiary, including the documentation of steps taken to retrieve it (or failure to retrieve it), and penalties for the beneficiary in the event the item cannot be retrieved.

discussed in section X.A.3.g.(9) of the preamble of this final rule, since the proposed beneficiary incentives are finalized, CMS also makes the determination that the Anti-Kickback Statute Safe Harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)) is available for TEAM.

h. Proposed Waivers of Medicare Program Requirements

Given the potential of TEAM to reduce Medicare spending and improve quality of care, CMS proposed to use its waiver authority under section 1115A of the Act to waive certain Medicare program rules for providers and suppliers furnishing services to TEAM beneficiaries.

CMS also discussed waiving certain requirements governing the provision of telehealth services. Under BPCI Advanced and CJR, CMS waived two requirements, thus allowing beneficiaries in urban areas to receive telehealth services, and also allowing beneficiaries to receive telehealth services in their home or place of residence. Under TEAM, CMS proposed to waive the same two provisions. CMS proposed to waive the geographic site requirements of section 1834(m)(4)(C)(i)(I) through (III) of the Act that limit telehealth payment to services furnished within specific types of geographic areas or in an entity participating in a federal telemedicine demonstration project approved as of December 31, 2000, and the originating site requirements of section 1834(m)(4)(C)(ii)(I)-(VIII) of the Act that specify the particular sites at which the eligible telehealth individual must be located at the time the service is furnished via a telecommunications system. As under BPCI Advanced and CJR, CMS proposed to create a specific set of nine HCPCS G-codes to describe the E/M services furnished to TEAM beneficiaries in their homes via telehealth, with corresponding new payment rates that would be published in the CY 2026 Medicare Physician Fee Schedule.

CMS also discussed waiving the current law requirement that a beneficiary have a 3-day hospital stay in order to qualify for coverage of subsequent skilled nursing facility care (the "SNF 3-day rule"). CMS proposed to use its 1115A waiver authority to waive this requirement for TEAM beneficiaries, but with the proviso that TEAM participants may only discharge a TEAM beneficiary to a SNF with a quality rating of three stars or higher as indicated on Medicare's Nursing Home Compare website.[133] However, TEAM participants could also discharge a beneficiary to a swing bed in an acute-care hospital or critical access hospital if that is the beneficiary's preference (MSSP allows the same leeway to ACOs). CMS proposed to monitor use of this waiver to ensure that TEAM beneficiaries are not being inappropriately prematurely discharged from the hospital.

CMS also noted that additional beneficiary protections may be needed if the SNF 3-day rule is waived. Current payment and coverage policies for SNF services based on sections 1861(i), 1862(a)(1), and 1879 of the Act include protections for beneficiaries from liability for certain non-covered SNF charges; these policies for SNF services would continue to apply under TEAM, including SNF services furnished pursuant to the SNF 3-day waiver. But based on its experience with SNF 3-day rule waiver, including under the CJR model, CMS proposed to align the use of the SNF 3-day rule waiver under TEAM with comparable provisions under CJR. The TEAM participant would be required to provide the TEAM beneficiary with a discharge

[133] https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome

planning notice outlining their potential financial liability; however, CMS proposed to make the TEAM *participant* financially liable in circumstances where the TEAM participant does not provide the beneficiary with proper notice, or otherwise violates the terms of the waiver.

Comments with respect to waivers were *extremely* varied, and at times were general (*e.g.*, that CMS should standardize its waivers across models to reduce complexity and provider administrative burden) to very specific (e.g., allowing nurse practitioners to order cardiac rehabilitation, or excluding TEAM episodes involving an IRF stay that did not meet the "60 percent rule" requirements from the calculation of that IRF's compliance with the "60 percent rule" altogether). CMS indicates that in TEAM, the agency has tried to align waivers with those in BPCI Advanced and CJR,[134] and that efforts are underway within the agency to further standardize waivers across models. With respect to the waivers CMS specifically proposed, many commenters supported the proposed telehealth waivers, including the creation of new telehealth "G codes." Commenters were similarly generally supportive of CMS' proposals with respect to waiving the SNF 3-day rule under TEAM.

For this final rule, CMS maintains the existing homebound requirement for home health care; it is finalizing the proposed telehealth waivers and corresponding HCPCS codes (§512.580(a) and §512.580(a)(3)(ii)). CMS is also finalizing at §512.580(b) the waiver of the SNF 3-day rule as proposed, including the provisions for determining qualified SNFs as proposed at §512.580(b)(3), but without inclusion of swing bed arrangements.

i. Monitoring and Beneficiary Protection

As proposed, TEAM would not limit a beneficiary's ability to choose among Medicare providers or limit Medicare's coverage of items and services available to the beneficiary. While TEAM participants may recommend preferred providers to their beneficiaries, they may not limit beneficiaries to a preferred or recommended providers list that is not compliant with restrictions existing under current statutes and regulations. Nor could TEAM participants charge any TEAM collaborator a fee to be included on any list of preferred providers.

CMS proposed that TEAM participants must require all ACOs, providers and suppliers who execute a Sharing Arrangement with a TEAM participant to share beneficiary notification materials (to be developed or approved by CMS) that detail this payment model with the beneficiary prior to discharge from the anchor hospitalization, or prior to discharge from the anchor procedure for a Medicare FFS patient who would be included under the model. TEAM participants would have to require this notification as a condition of any Sharing Arrangement. Where a TEAM participant does not have Sharing Arrangements with providers or suppliers that furnish services to beneficiaries during an episode, or where the anchor hospitalization or anchor procedure for a Medicare FFS patient who would be included under the model was ordered by a physician who does not have a Sharing Arrangement, the beneficiary notification materials would have to be provided to the beneficiary by the TEAM participant.

[134] For example, the "homebound" requirement for Medicare-covered home health care was not waived in CJR or BPCI Advanced, and CMS did not propose that it be waived for TEAM. The telehealth waivers discussed in TEAM parallel those implemented in CJR and BPCI Advanced.

Additionally, CMS proposed to require that TEAM participants require every TEAM collaborator to provide written notice, to be developed by CMS, to applicable TEAM beneficiaries of the existence of its sharing arrangement with the TEAM participant and the basic quality and payment incentives under the model. This notice would need to be provided no later than the time the beneficiary first receives services from the TEAM collaborator during the episode, or as soon as reasonably practicable thereafter.

CMS indicates that some commenters supported the proposed beneficiary notification, but others thought the burden of this notification was too high for TEAM participants and collaborators, and thus either should not be incurred at all or that CMS should be responsible for said notification. Others expressed concerns about the timing of the notifications, stating that as proposed, the notifications would be provided to beneficiaries too late to be useful in discharge planning, and that the notifications should be provided at the time of the beneficiary's first encounter with a TEAM participant. (CMS indicated it would evaluate this suggestion in future rulemaking.) Despite many commenters expressing concerns, in this rule **CMS is finalizing as proposed its proposals for beneficiary freedom of choice at §512.582(a), TEAM participant beneficiary notification at §512.582(b)(1), and TEAM collaborator notice at §512.582(b)(2).**

CMS proposed to monitor TEAM beneficiaries' access to care, evaluate service utilization under the model, and where necessary, audit hospitals whose provision of services suggests they are compromising beneficiaries' access to care. CMS proposed similar policies for monitoring quality of care provided under TEAM, and also to monitor any indications of delayed care (*e.g.*, pushing care to past the end of the 30-day TEAM episode).[135] **CMS is finalizing these proposals without modification at §512.584 (monitoring for access to care), §512.582 and §512.590 (monitoring for quality of care), and at §512.582 and §512.590 (monitoring for delayed care).**

j. Access to Records and Record Retention

CMS notes that MSSP and other CMMI models contain audit and record retention requirements that CMS proposed to replicate in TEAM. CMS proposed that the federal government would have a right to audit, inspect, investigate, and evaluate any documents and other evidence regarding implementation of TEAM, as with any other CMS Innovation Center model. Additionally, in order to align with the policy of current models being tested by CMMI, CMS is proposing that the TEAM participant and its TEAM Collaborators must maintain and give the federal government access to all documents (including books, contracts, and records) and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of the CMS Innovation Center model, including documents and other evidence regarding compliance, payments, quality measure information, utilization of services of the model, the ability of the TEAM participant to bear risk, patient safety, and any other program integrity issues.

CMS listed only one comment (supportive) received on this policy and is finalizing its proposed records access and retention policies.

[135] As discussed earlier, this monitoring is intrinsic to the TEAM reconciliation process, given that TEAM participants will be financially accountable for certain post-episode payments occurring in the 30 days after conclusion of the episode.

k. Data Sharing

Based on its experience with BPCI Advanced and CJR, CMS proposed under its existing authority[136] to make certain beneficiary-identifiable claims data and regional aggregate data available to participants in TEAM regarding Medicare FFS beneficiaries who may initiate an episode and be attributed to them in the model. These data would only be made available pursuant to a formal signed TEAM data sharing agreement.[137] As proposed, for the 3-year baseline period, TEAM participants would only receive beneficiary-identifiable claims data for beneficiaries that initiated an episode in their hospital or hospital outpatient department in the 3-year baseline period, and the beneficiary-identifiable claims data shared with the TEAM participant would be limited to the items and services included in the episode. CMS proposed to share these data only with TEAM participants bearing risk, not their collaborators. Data would be shared at a granular (*e.g.*, claims) or aggregated level, as requested by the TEAM participant through formal specified processes.

CMS also proposed to make three years of baseline data on Part A and Part B spending to TEAM participants for beneficiaries who would have been included in an episode had the model been implemented during the baseline period, and that this baseline data would be rolled forward and updated for each performance year of the model. These data would be shared with TEAM participants at least one month before the start of each performance year.

CMS requested comments on all aspects of its proposal to share beneficiary-identifiable claims data with TEAM participants. CMS also sought comments on the minimum data necessary beneficiary-identifiable information for TEAM participants to request beneficiary-identifiable information for purposes of conducting permissible health care operations purposes under this model, and on the regional aggregate data that it would provide to TEAM participants.

CMS received no public comments on its proposals regarding the legal authority for CMS to share beneficiary-identifiable data with TEAM participants. The agency did receive comments supportive of its proposal to share beneficiary level data with TEAM participants, although some commenters expressed reservations about participants' ability to effectively process and use

[136] Under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR 164.501, under the auspices of "health care operations."

[137] CMS proposed that the TEAM data sharing agreement would contain certain terms—that TEAM participants would agree (1) to comply with the requirements for use and disclosure of beneficiary-identifiable data that are imposed on covered entities by the HIPAA regulations and the requirements of the proposed TEAM; (2) to comply with additional privacy, security, and breach notification requirements to be specified by CMS in the TEAM data sharing agreement; (3) to contractually bind each downstream recipient of the beneficiary-identifiable data that is a business associate of the TEAM participant or performs a similar function for the TEAM participant, to the same terms and conditions to which the TEAM participant is itself bound in its data sharing agreement with CMS as a condition of the downstream recipient's receipt of the beneficiary-identifiable data retrieved by the TEAM participant under the TEAM; and (4) that if the TEAM participant misuses or discloses the beneficiary-identifiable data in a manner that violates any applicable statutory or regulatory requirements or that is otherwise non-compliant with the provisions of the TEAM data sharing agreement, the TEAM participant would no longer be eligible to retrieve the beneficiary-identifiable data and may be subject to additional sanctions and penalties available under the law. The data sharing agreement would also include other provisions, including requirements regarding data security, retention, destruction, and breach notification.

these data. CMS **is finalizing at §512.562(b)(1) and §512.562(c) the proposal to share beneficiary-identifiable data with TEAM participants as permitted under the referenced statutes and regulations**. CMS received no comments and thus **is finalizing its proposal to share regional aggregate data with TEAM participants (with minor grammatical edits)**.[138]

l. Referral to Primary Care Services

In the April proposed rule, CMS proposed that TEAM participants be required to include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure. The agency also proposed that the TEAM participant must comply with beneficiary freedom of choice requirements, as described in the Beneficiary Choice and Notification section—X.A.3.i.(2) of this final rule and codified at§ 512.582(a)—and not limit a TEAM beneficiary's ability to choose among Medicare providers or suppliers. If a TEAM participant failed to comply with requiring a referral to a supplier of primary care services during hospital discharge planning, then the TEAM participant would be subject to remedial action, as described in the Remedial Action section: X.A.1.f. of this final rule.

Comments on this proposal were mixed, with some supportive and some (seemingly more than those supporting) opposed or expressing substantial concerns, with opponents citing variability in the availability of primary care providers as an impediment to being able to comply with such a requirement. However, after consideration of the public comments received, **CMS is finalizing its proposal as proposed that TEAM participants be required to include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure at §512.564. CMS also finalizes its proposal that the TEAM participant must comply with beneficiary freedom of choice requirements and not limit a TEAM beneficiary's ability to choose among Medicare providers or suppliers**.

m. Alternative Payment Model Options

CMS proposed that TEAM would be considered an Advanced Alternative Payment Model (AAPM), and that the TEAM participant would be considered the APM entity, but that the TEAM participant's eligible clinicians may be assessed for QP determinations depending on which track the TEAM participant is in and whether the Certified Electronic Health Record Technology (CEHRT) criteria are met (89 FR 36480).

CMS indicates that comments were generally supportive of its AAPM proposals for TEAM, and thus is **finalizing the TEAM Advanced APM options and the associated requirements at §512.522, as well as the proposed definitions for the AAPM option and non-AAPM option at §512.505**.

[138] CMS is also finalizing its proposals regarding protecting beneficiary-specific data, the contents of a TEAM data sharing agreement, and related technical provisions.

n. Interoperability

In the proposed rule (89 FR 36482), CMS stated that it would like to support TEAM participants' HIT interoperability efforts that could lead to best practices across the U.S. health care landscape. However, CMS did not want to create duplicate efforts or place unnecessary burden on TEAM participants. CMS in this rule does not describe the comments it received in response to its aspirational comments on interoperability (other than thanking commenters for their input) and notes that any further proposals related to interoperability included in TEAM will be done in future notice and comment rulemaking.

o. Evaluation Approach

CMS proposed to evaluate TEAM using a methodology for TEAM consistent with the standard CMMI evaluation approaches the agency has taken in other projects such as the BPCI initiative, BPCI Advanced and the CJR model, and other CMMI models. Specifically, the evaluation design and methodology for the proposed TEAM would be designed to allow for a comparison of historical patterns of care among the TEAM participants to any changes made in these patterns in response to TEAM. In addition, the overall design would include a comparison of TEAM participants with hospitals not participating in TEAM to help the agency discern simultaneous and competing provider and market level forces that could influence evaluation findings. CMS discusses analytic parameters of the TEAM evaluation, including analytic techniques, statistical methods, data to be collected and analyzed, and evaluation questions.

CMS proposed that the TEAM evaluation period would encompass the entire 5-year model performance period, and up to two years after. CMS indicates it is planning to evaluate TEAM on an annual basis.

Commenters suggested additional sub-topics and sub-groups of beneficiaries that CMS might pursue in evaluating TEAM. Others expressed concerns about the potential burden of being required to participate in the evaluation of TEAM. However, after considering comments received, **CMS is finalizing its proposed approach to evaluating TEAM without modification**.

p. Decarbonization and Resilience Initiative

In the April 2024 proposed rule, CMS discussed a proposal for a voluntary Decarbonization and Resilience Initiative within TEAM to assist hospitals in mitigating the effects of hospital carbon emissions on health outcomes, health care costs and quality of care. The voluntary initiative would have two elements: technical assistance for all interested TEAM participants and a proposed voluntary reporting option to capture information related to Scope 1 and Scope 2 emissions as defined by the Greenhouse Gas Protocol (GHGP) framework,[139] with the potential

[139] Janet Ranganathan, Laurent Corbier, Pankaj Bhatia, Simon Schultz, Peter Gage, & Kjeli Oren. The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard (Revised Edition). World Business Council for Sustainable Development and World Resources Institute. 2004. https://ghgprotocol.org/sites/default/files/standards/ghg-protocol-revised.pdf

to add Scope 3 in future years. CMS asserts that the surgical episodes under TEAM represent opportunities for hospitals to become more energy efficient.

In the proposed rule, CMS reviewed key studies documenting the effects of climate change and greenhouse gas (GHG) emissions on health, and the current administration's efforts to address climate-related threats to health. (CMS repeats this review in this final rule.)

The GHGP framework referenced by CMS includes three "scope levels." For purposes of this proposed rule, CMS provides examples of the health care-related elements of each scope level:

- Scope 1: Direct emissions. Direct GHG emissions from sources that are owned or controlled by an organization or company. For health care, Scope 1 captures health care operations such as direct facilities emissions, anesthetic gases, and GHG emissions from leased or owned vehicles.
- Scope 2: Indirect emissions from purchased energy. GHG emissions from the generation of purchased electricity consumed by the organization or company. For health care facilities, Scope 2 includes purchased or acquired electricity, and steam, heat, or cooling consumed by the reporting organization or company.
- Scope 3: Other indirect GHG emissions. Scope 3 allows for the treatment of all other indirect emissions. Scope 3 incorporates upstream and downstream emissions in the supply chain. For health care, Scope 3 may include purchased pharmaceuticals and chemicals, medical devices and supplies, food, water, waste, employee and patient transportation, and additional emissions outside of Scopes 1 and 2.

CMS stated in the proposed rule that given the established impact GHG emissions have on Medicare, Medicaid, and CHIP beneficiary health, the agency proposed to collect data on GHG emissions, through voluntary reporting, as part of its monitoring and evaluation of TEAM. CMS proposed to assist TEAM participants in measuring their GHG emissions, reporting these metrics, and sharing benchmark data on GHG emissions through Individualized Feedback Reports.

Under the first element of the initiative (technical assistance) CMS indicated it would provide three types of support to interested TEAM participants: developing approaches to enhance organizational sustainability and resilience; transitioning to care delivery methods that result in lower GHG emissions and are clinically equivalent to or better than previous care delivery methods (for example, switching from Desflurane to alternative inhaled anesthetics); and identifying and using tools to measure emissions and associated measurement activities.

Under the second element of the initiative (voluntary reporting), CMS proposed that TEAM participants could elect to report metrics and questions related to emissions to CMS on an annual basis following each performance year. TEAM participants that elect to report on all the initiative metrics and questions to CMS, in the form and manner required by CMS, would be eligible for benefits such as receiving individualized feedback reports and public recognition as well as potentially achieving operational savings. CMS proposed four areas for reporting: (1) Organizational Questions; (2) Building Energy Metrics; (3) Anesthetic Gas Metrics; and (4) Transportation Metrics. CMS proposed specific metrics under each of these four areas. CMS also

proposed a set of questions that TEAM participants opting into the initiative would be required to answer.

Looking to the future, CMS also included a request for information (RFI) on Scope 3 metrics and Metered-dose Inhalers (MDI).

CMS proposed that TEAM participants electing to participate in the Decarbonization and Resilience Initiative would report information to CMS annually no later than 120 days after the end of each performance period, in a form and manner to be specified by CMS.

CMS proposed that TEAM participants who elect to report all the metrics identified would receive individualized feedback reports and be eligible to receive public recognition for their commitment to decarbonization. In addition to these proposed benefits, CMS contended that TEAM participants may receive additional indirect benefits from engaging in the voluntary reporting portion of the Decarbonization and Resiliency Initiative.

CMS solicited comments on all elements of its proposed voluntary Decarbonization and Resilience Initiative. In addition, CMS included an RFI on future incentives for participation in the initiative, noting that while the agency is not currently proposing any bonus payments or payment adjustments for participating in the initiative, it is considering doing so in future years.

CMS indicates that many commenters expressed strong support for the proposed decarbonization initiative, with some commenters suggesting that incentives (such as explicit dedicated CMS funding) and penalties be added to the initiative given its potential impacts, and one commenter recommended tying emissions reductions to Medicare payments. Some commenters recommended that the decarbonization initiative be implemented on a faster track, and that it be opened up to all hospitals, not just TEAM participants. (CMS does not describe any negative comments submitted in response to the proposed initiative.) As a result, **CMS in this rule is modifying §512.598(a) to not only allow TEAM participants to voluntarily report on metrics and respond to questions to CMS for their acute care hospital, but to also allow TEAM participants to report on metrics and respond to questions that include the TEAM participant's hospital corporate affiliates. With this modification, CMS will finalize the proposal defining this initiative, as well as its proposed forms of technical assistance.**[140]

Lastly, CMS summarizes comments it received in response to its RFI on Scope 3 reporting (measuring upstream and downstream reporting of greenhouse gas emissions), and on future incentives for participation in the voluntary decarbonization and resilience initiative, and notes that this information will inform future rulemaking.

q. Termination of the TEAM

In the April 2024 proposed rule, CMS stated that the general provisions relating to termination of models by CMS in 42 CFR 512.596 would apply to the TEAM. CMS indicated that the agency would provide written notice to TEAM participants specifying the grounds for termination and

[140] CMS also responds to numerous technical suggestions, requests for clarifications, *et cetera*. The agency defers some of the requested actions to future rulemaking.

the effective date of such termination or ending. As provided by section 1115A(d)(2) of the Act and §512.594, termination of the model under section 1115A(b)(3)(B) of the Act would not be subject to administrative or judicial review.

CMS received no comments on the TEAM termination proposal and therefore finalizes this provision without modification.

4. Collection of Information Requirements

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, CMS asserted that the information collection requirements contained in this proposed rule for TEAM need not be reviewed by the Office of Management and Budget.

CMS received no comments on the proposed information collection requirements, and therefore finalizes this provision without modification.

5. Regulatory Impact Analysis

Under TEAM, participants would continue to bill Medicare under the traditional FFS system for items and services furnished to Medicare FFS beneficiaries. The TEAM participant may receive a reconciliation payment from CMS if Medicare FFS expenditures for a performance year are less than the reconciliation target price, subject to a quality adjustment. TEAM would not have downside risk for Track 1 and TEAM participants would only be accountable for performance year spending below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount. For Tracks 2 and 3, TEAM would be a two-sided risk model that requires TEAM participants to be accountable for performance year spending above or below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount or a repayment amount.

CMS posits that TEAM will have direct effects on the Medicare program, given that it is a mandatory payment model under which participants will have an incentive to reduce Medicare spending. In the first performance year of the program, CMS anticipates that TEAM will cost the Medicare program $38 million, contending that most participants will begin participation in Track 1, which carries no downside risk (see Table I.G.12.-01 of the final rule, reproduced below). In subsequent years, TEAM participants would be subject to both upside and downside risk. Applying the proposed stop-loss and stop-gain percentage limits to each track in each subsequent year of the program, CMS estimates that TEAM participants will pay CMS more in repayments (in instances where the TEAM participant's episode costs are higher than the baseline amount) than CMS will pay out by way of reconciliation payments (when the TEAM participant's episode costs are lower than the baseline amount). Over the course of the 5-year duration of the model, CMS estimates that CMS will pay TEAM participants $442 million,

TEAM participants would pay CMS $622 million, and that TEAM would save the Medicare program approximately $481 million over the five performance years (2026 through 2030).

CMS assumes that episode volume will change at the same rate as projected Medicare FFS enrollment as indicated in the 2023 Medicare Trustees Report.[141]

CMS assumes that baseline spending per episode will increase by 1.5 percent annually over the course of the model's lifespan. On the basis of the historical performance of the CJR model, CMS estimates that TEAM participants will reduce episode spending within a range of 0 to 3 percent.

TABLE I.G.12.-01: PROJECTED FINANCIAL IMPACTS OF TEAM (IN MILLIONS)

	2026	2027	2028	2029	2030
TEAM episode spending	$5,715	$5,828	$5,943	$6,058	$6,163
(+) Reconciliation payment amounts (positive)	$95	$93	$82	$82	$90
(+) Repayment amounts (negative)	$0	-$130	-$150	-$175	-$167
- Baseline episode spending	$5,773	$5,887	$6,003	$6,119	$6,225
Impact	$38	-$96	-$129	-$154	-$140
Impact as % of Baseline	**0.7%**	**-1.6%**	**-2.1%**	**-2.5%**	**-2.2%**

CMS' estimates of the impact of TEAM do not include the effects of TEAM beneficiary overlap with total cost of care models (*i.e.*, ACOs), but CMS states that it would not expect such overlap to have a meaningful effect on TEAM's financial impacts.

With respect to impacts on Medicare beneficiaries, CMS holds that because of the incentives in TEAM's design, beneficiaries in the model should experience improved quality of care, outcomes, transitions, *et cetera*. CMS does not expect that TEAM will have any negative impacts on beneficiaries given the safeguards built into the program. CMS also notes that TEAM will not change Medicare FFS payments or beneficiary copayments, deductibles, or coinsurance.

CMS assumes that TEAM will have no spillover effects on the non-Medicare market, but notes that this assumption is subject to "considerable uncertainty."

B. Provider Reimbursement Review Board (PRRB)

The PRRB is a five-member administrative tribunal that adjudicates disputes over Medicare payment for certain providers of services in the Medicare program. Board Members may serve for a maximum of two 3-year terms and must be knowledgeable in the area of cost reimbursement.

Since the PRRB was created in 1974, Medicare has transitioned from payment systems based on cost reimbursement to prospective payment systems. These changes in reimbursement have led to changes in the types of cases adjudicated by the Board, the complexity of the matters that come before the Board, and often, the amount of time required to bring matters to resolution.

[141] https://www.cms.gov/oact/tr/2023

CMS proposed to:

1. Require Board Members to be knowledgeable in the area of payment to Medicare Part A providers rather than cost reimbursement.
2. Permit a Board Member to serve no more than three consecutive terms, instead of two.
3. Permit a Board Member who is designated as Chair in their second or third consecutive term to serve a fourth consecutive term to continue leading the Board as Chair.

The first proposal intends to align the qualifications to be a Board member with the statutory requirement in section 1878(h) of the Act. This change will also reflect that Medicare largely pays providers of services on the basis of prospective payment systems and not cost reimbursement.

The second and third proposals recognize that serving on the Board requires a job change—something a prospective member may be unwilling to do for a maximum of six years of employment. Over time, CMS states that it has been increasingly challenging to attract a large pool of qualified candidates who have relevant skills and experience in matters that come before the PRRB.

CMS cited other reasons in the proposed rule for allowing longer terms such as the time necessary to learn the duties of the job and the benefit of retaining institutional knowledge. Further, CMS noted that the cases the Board may hear frequently involve nuanced issues that implicate highly specialized and complex areas of law. Permitting Board Members to serve more than two consecutive terms would allow them greater opportunity to follow the landscape of issues under judicial review.

While CMS proposed that Board Members serve a maximum of three consecutive terms, it also considered a policy that would allow Board Members to serve four consecutive terms (12 years in total). Under the alternative proposal, CMS considered allowing the Chair to serve an additional two or three consecutive terms to provide a longer period to gain experience prior to ascending to the role of Chair.

Several comments supported CMS' proposals and a few comments were opposed. Opposing comments indicated concern about members with 9 to 18-year terms becoming entrenched. CMS was asked to explore higher pay as incentive to recruit Board members. Other commenters cautioned that the relaxation of term limits would deprive the Board of the regular infusion of fresh experience and perspectives that new Board Members bring. Some commenters thought the effective date of October 1, 2024 for longer terms for Board members created the appearance that CMS was rewarding the Board for decisions favorable the agency.

CMS responded that turnover on the Board occurs with regularity, which has disruptive impacts on the Board's productivity and efficiency. However, CMS also recognizes the commenters' concerns about permitting a Board Member to serve as long as 12 to 18 years. CMS will not be finalizing the proposals to have Board Members serve more than three consecutive 3-year terms at this time. CMS responded emphatically that the timing of the changes to regulations are unrelated to any decisions that the Board.

C. Maternity Care Request for Information (RFI)

In the proposed rule, CMS requested comment on differences between hospital resources required to provide inpatient pregnancy and childbirth services to Medicare patients relative to non-Medicare patients. Medicare's rates for childbirth services will be based on the 13 percent of beneficiaries that are under 65 and eligible for Medicare based on disability, having ESRD or amyotrophic lateral sclerosis. This population is likely to be very different than non-Medicare patients in need of childbirth and maternity services.

To the extent that the resources required differ between patient populations, CMS also requested information on the extent to which non-Medicare payers, or other commercial insurers, may be using the IPPS as a basis for determining their payment rates for inpatient pregnancy and childbirth services and the effect, if any, that the use of the IPPS as a basis for determining payment by those payers may have on maternal health outcomes (such as the rate of low-risk cesarean deliveries).

Commenters provided a wide range of feedback on CMS's RFI. Below is sample of some of those points:

- Medicare payment rates are generally not perceived to be a driver of practice patterns in maternity care.
- Medicare payment rates are often used as a benchmark by state Medicaid programs for setting rates.
- The resources to treat Medicare beneficiaries may differ from the resources required to treat a non-Medicare population.
- The current MS-DRG structure and weights do not adequately reflect the resource consumption of maternity care services.

CMS will consider these comments in its ongoing efforts to reduce maternal health disparities and improve maternal health outcomes during pregnancy, childbirth, and the postpartum period of maternal health.

D. Changes to the Payment Error Rate Measurement (PERM)

CMS measures Medicaid and CHIP improper payments through the Payment Error Rate Measurement (PERM) program. Section 202 of Division N of the Further Consolidated Appropriations Act, 2020 (FCAA, 2020) required Puerto Rico to publish a plan, not later than 18 months after the FCAA's enactment, for how Puerto Rico would develop measures to comply with the PERM requirements. Puerto Rico published this plan on June 20, 2021. It was approved by the CMS Administrator on June 22, 2021. CMS proposed to remove the prior exclusion of Puerto Rico from the PERM program now that it has developed measures to comply with PERM

requirements. There were no comments on this proposal that CMS is finalizing with a minor technical correction to a statutory cite.

E. CoP Requirements for Hospitals and CAHs to Report Acute Respiratory Illnesses

1. Background.

CoPs are health and safety requirements that apply to hospitals and CAHs. The CoPs require that hospitals and CAHs, respectively, have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections and other infectious diseases and for the optimization of antibiotic use through stewardship.

2. Continued Respiratory Illness Reporting in a Modified Form.

During the COVID-19 PHE, CMS required that hospitals and CAHs report specified information about COVID-19 in a format and frequency specified by the Secretary. CMS later required that, beginning at the conclusion of the COVID–19 PHE declaration and continuing until April 30, 2024, hospitals and CAHs electronically report information about COVID–19, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection in a standardized format.

In the proposed rule, effective October 1, 2024, CMS proposed to revise the hospital and CAH infection prevention and control and antibiotic stewardship programs CoPs to extend a modified form of the current COVID-19 and influenza reporting requirements that will include data for RSV and reduce the frequency of reporting for hospitals and CAHs. CMS proposed requiring reporting of the following data elements:

- Confirmed infections of respiratory illnesses, including COVID-19, influenza, and RSV, among hospitalized patients;
- Hospital bed census and capacity (both overall and by hospital setting and population group (adult or pediatric)); and
- Limited patient demographic information, including age.

The proposal would require that hospitals and CAHs report these data weekly (either in the form of weekly totals or snapshots of key indicators) through a CDC-owned or supported system. Given the five-month lag between the expiration of the earlier reporting requirement and the effective date of the one being proposed, CMS encouraged hospitals and CAH to voluntarily continue reporting this information.

CMS received overwhelming support from patients and community members on these proposals. Many commenters recommend publishing the collected data to an easily accessible location, such as HealthData.gov. In response, CMS indicated that the Centers for Disease Control (CDC) will continue to post updated weekly data aggregated by state on data.CDC.gov.

Hospital associations expressed concern about the appropriateness of data reporting as a CoP requirement. These comments emphasized that establishing CoPs may threaten access to

Medicare participation, facility financial viability, access to care, operational efficiency and hinder infection prevention efforts. They suggested voluntary disclosure could lead to long-term automated, efficient data sharing. CMS disagrees and notes that reporting has dropped from near complete reporting by all US hospitals each week to only around 35 percent of hospitals reporting since reporting became voluntary.

Some commenters suggest delaying the compliance date to give hospitals more time to be prepared to report the required data. CMS responded that the finalized policy is a reduction from the already familiar required reporting that ended in April 2024. Nevertheless, CMS is delaying the effective date of the CoP requirement from October 1, 2024 to November 1, 2024 thereby providing a 90-day delay between public availability of this rule and the effective date of the requirements.

Commenters requested clarity regarding the data elements required for reporting, including the respiratory pathogens, limited demographic information, hospital census and capacity data, as well as how CMS intends to use the data to ensure hospitals have enough resources for compliance. In addition, commenters urged CMS to establish a modern automated, standardized reporting and collection system for providers and to partner with CDC, the Assistant Secretary for Planning and Response (ASPR), and the Office of National Coordinator. Such a platform would provide a single place where all the proposed data elements could be captured.

CMS responded that the proposed reporting requirements were written in a manner that would allow for maximum flexibility by covering a broad array of services and entities. The National Health Safety Network (NHSN) is actively engaged in developing approaches to data collection that can be automated and thus reduce the manual burden of reporting by healthcare facilities. To reduce burden, CMS will work with the CDC to ensure hospitals can continue to use existing, established systems to report data.

A significant number of commenters indicated that the reporting requirements were too burdensome, time consuming, and duplicative. Infection data may be already reported through other mandatory mechanisms, including manual case reporting, electronic case reporting and CDC's National Syndromic Surveillance Program (NSSP).

CMS acknowledged the potential burden of proposed reporting requirements and will continue to maintain the reporting requirements in more or less the form in use up through April 30, 2024. Further, CMS, CDC, and ASPR will also take steps to encourage state and local partners to utilize HHS adopted health IT standards such as the United States Core Data for Interoperability that are already supported by existing systems for data exchange, which would further reduce burden on health care systems.

Many comments advocated daily data submission. Others supported weekly or snapshot data from one day per week to reduce administrative burden. CMS clarified that weekly reporting would encapsulate daily data, but the facility would submit it once a week. Snapshot data would be reported once per week but would not be aggregate data—it would be a snapshot of what is occurring on that day. The majority of commenters supported weekly data reporting.

CMS agrees that snapshot reporting makes sense for bed census and capacity data, as well as total confirmed existing infections of respiratory illnesses, including COVID-19, influenza, and RSV, among hospitalized patients. However, CMS will continue to require reporting of a limited set of respiratory disease and hospital capacity data on a weekly basis.

For FY 2025, the information collection will include:

One-Day-a-Week Snapshot	Weekly Total New Hospital Admissions
• Staffed bed capacity and occupancy including adult and pediatric • Hospitalizations prevalence by respiratory illness and bed type	• Total new hospital admissions for adult and pediatric patients by age range, over a defined weekly period

CMS is finalizing its proposal to require ongoing respiratory illness reporting in a modified form as proposed but effective November 1, 2024 instead of October 1, 2024. Beginning November 1, 2024, hospitals and CAHs must electronically report this information to CDC's NHSN or other CDC-owned or CDC-supported system, as determined by the Secretary.

3. Soliciting Input on Collecting Data by Race and Ethnicity

The proposed rule indicated that timely, complete data on racial and ethnic differences in hospitalizations can assist in assuring the health and safety of individuals receiving health care services to the greatest extent possible. For that reason, CMS solicited comment on expanding the scope of demographic information collection to further support improvements in clinical outcomes while also protecting privacy and the safety of demographic groups.

There were many comments on the difficulties hospitals would have collecting demographic data including the lack of uniform requirements across states in terms of what questions are asked and how they are asked, the response options available, and how and when data is collected. Comments stressed the importance of creating definitions and categories so that there is a standard classification for the entire nation.

In response, CMS indicated that it is not expanding the collection of demographic data at this time due to the need to further refine this concept and the need to begin data collection of other elements by November 1, 2024. Nevertheless, CMS acknowledges that not collecting this data would represent a gap in epidemiological information.

4. Proposal to Collect Additional Elements During a PHE

CMS' proposal to require the acute respiratory illness reporting previously discussed is connected to any declared public health emergency. If there is a declared federal, state or local PHE for infectious disease or the Secretary determines an event that is significantly likely to become a PHE for infectious disease, CMS further proposed that hospitals be required to:

- Report data up to a daily frequency without notice and comment rulemaking.
- Report additional or modified data elements relevant to infectious disease PHE including but not limited to:

- Confirmed infections of the infectious disease, facility structure and infrastructure operational status;
- Hospital/ED diversion status; staffing and staffing shortages; supply inventory shortages (for example, equipment, blood products, gases);
- Medical countermeasures and therapeutics; and
- Additional, demographic factors.

Public comments on this proposal were mixed. Some stakeholders noted that the value of reporting respiratory illness data during a PHE outweighed the administrative burden and suggested that there should be incentives for hospitals to provide even more data during a PHE. However, commenters also noted that increased reporting during a PHE would significantly burden hospitals during a vulnerable and resource-constrained period. Hospital associations shared significant concern regarding the proposed flexibility provided to the Secretary to request increased reporting if there was a "likely threat" of a PHE.

In the face of future illness emergencies, CMS anticipates stakeholders—including health care systems—will continue to need data on how respiratory illnesses are affecting and burdening the health care system. In the event of a PHE, HHS will provide proper notification to hospitals and CAHs to activate increased PHE reporting and indicate the frequency and required additional elements that are necessary for reporting based on the specific circumstances at the time. CMS recognizes the concerns raised regarding the proposal to also require increased PHE reporting if there is a "likely threat" of a PHE. In response to the concerns raised, CMS is withdrawing the proposal that the Secretary may require increased reporting if the threat of a PHE is significantly likely.

5. Collaboration.

CMS, CDC, and ASPR will work with hospitals, health systems, and state, territorial, local and tribal agencies to streamline federal, state, and local reporting burden by using a technical exchange mechanism for reporting. CDC and ASPR, together with ONC, would also take steps to encourage state and local partners to utilize the same HHS-adopted health IT standards for data exchange, which would further reduce burden on health care systems.

6. RFI on Health Care Reporting to the National Syndromic Surveillance Program.

CDC's NSSP is a collaboration among CDC, other federal agencies, local and state health departments, and academic and private sector partners who have formed a Community of Practice. They collect, analyze, and share electronic patient encounter data received from emergency departments, urgent and ambulatory care centers, inpatient health care settings, and laboratories.

The electronic health data are integrated through a shared platform; the BioSense Platform. The public health community uses analytic tools on the platform to analyze data received as early as 24 hours after a patient's visit to a participating facility. Public health officials use these timely and actionable data to detect, characterize, monitor, and respond to events of public health concern.

Currently, CDC receives data from 78 percent of the non-federal emergency departments across 50 states, Washington D.C., and Guam. Recognizing the tremendous value that these data offer in providing a fast and broad look at the trends and patterns of illness and injury across the county, CDC is seeking to close the remaining participation gap to ensure all communities served by acute care hospitals and CAHs are well represented in CDC's NSSP.

Syndromic surveillance is not a part of any condition of participation but the continued growth of national syndromic surveillance would benefit hospitals, health care, and public health. CMS requested public comment in the proposed rule on what else can be done to ensure that this effort can continue to make progress and that this critical data source is available at all levels of public health to support health care preparedness, public health readiness, and responsiveness to existing and emerging health threats.

CMS received varied responses and suggestions in response to this comment solicitation. A commenter stated that NSSP is already a measure under the Public Health and Clinical Data Exchange objectives in the Medicare Promoting Interoperability Program (PIP). CMS appreciates that hospital and CAH attestation to participate in syndromic surveillance reporting is a required measure under the PIP's Public Health and Clinical Data Exchange Objective. However, inclusion in that program, while a valuable incentive, has not been sufficient to close the current participation gap. CMS will consider the other comments it received as it develops future policy.

XI. Medicare Payment Advisory (MedPAC) Recommendations

In its March 2024 Report to Congress, MedPAC recommended an update to hospital IPPS and outpatient prospective payment system rates by the amount specified in current law plus 1.5 percent. Consistent with the statute, CMS is applying an IPPS update for FY 2025 that is equal to the Secretary's estimate of the hospital market basket (3.4 percent) less the 10 year average of total factor productivity (-0.5 percent) for a total update of 2.9 percent provided the hospital submits quality data and is a meaningful EHR.

MedPAC is concerned that its recommended update may be insufficient to ensure the viability of Medicare safety-net hospitals. It recommended redistributing disproportionate share hospital (DSH) and uncompensated care payments using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommended adding $4 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to Congress transitional approaches for an MSNI policy. CMS responds that its authority under section 1886(r) of the Act requires that it distribute DSH and uncompensated care payments according to a formula specified in statute.

Table I.—Impact Analysis: FY 2025 Operating IPPS

	Number of Hospitals[1]	Hospital Rate Update (1)[2]	FY 2025 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2025 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2025 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of Imputed Floor, the Frontier Wage Index, and Outmigration Adjustment (6)[7]	MDH Expiration (7)[8]	All FY 2025 Changes (8)[9]
All Hospitals	3,082	2.9	0.0	0.0	0.0	0.0	0.3	-0.1	2.8
By Geographic Location:									
Urban hospitals	2,392	2.9	0.0	0.0	-0.2	0.1	0.4	-0.1	2.8
Rural hospitals	690	2.9	-0.2	0.6	2.4	-0.7	0.1	-0.7	2.6
Bed Size (Urban):									
0-99 beds	645	2.9	-0.3	0.4	-2.0	1.3	0.5	-1.6	1.1
100-199 beds	682	2.9	-0.1	0.0	-0.8	1.1	0.4	-0.3	2.6
200-299 beds	421	2.9	0.0	-0.1	-0.2	0.6	0.4	0.0	2.8
300-499 beds	394	2.9	0.0	0.1	0.3	0.2	0.3	0.0	2.7
500 or more beds	248	2.8	0.1	-0.1	0.0	-0.8	0.4	0.0	3.2
Bed Size (Rural):								0.0	0.0
0-49 beds	341	2.8	-0.3	0.4	1.7	-0.7	0.2	-1.4	1.6
50-99 beds	182	2.9	-0.3	0.3	2.7	-0.7	0.3	-1.6	1.4
100-149 beds	91	2.9	-0.2	0.5	2.4	-0.7	0.0	-0.2	2.8
150-199 beds	44	2.9	-0.1	0.6	2.3	-0.7	0.0	0.0	3.5
200 or more beds	32	2.9	-0.2	1.2	2.7	-0.9	0.1	0.0	3.8
Urban by Region:									
New England	106	2.9	0.0	-1.6	7.0	0.0	0.6	-0.1	4.2
Middle Atlantic	280	2.9	0.0	-1.6	-0.1	-0.5	0.8	-0.1	1.1
East North Central	367	2.9	0.1	0.4	-0.5	-0.2	0.1	-0.3	4.6
West North Central	156	2.9	-0.1	0.1	-1.7	-0.9	0.6	0.0	2.7
South Atlantic	396	2.9	0.0	1.5	-0.7	-0.1	0.4	-0.1	4.4
East South Central	142	2.9	0.0	2.3	-1.8	-0.9	0.1	0.0	4.7
West South Central	358	2.9	0.1	1.2	-1.9	-0.9	0.1	-0.1	3.7
Mountain	179	2.9	-0.1	1.1	0.0	0.1	0.3	0.0	2.4
Pacific	356	2.8	0.1	-1.7	0.0	2.3	0.1	0.0	0.1
Rural by Region:									
New England	21	2.9	-0.1	0.1	2.7	-0.9	0.0	-1.4	2.2
Middle Atlantic	52	2.9	-0.2	2.0	6.1	-1.1	0.3	-0.2	4.4
East North Central	110	2.9	-0.2	0.2	3.5	-0.7	0.1	-1.7	2.1
West North Central	77	2.9	-0.4	0.0	0.3	-0.3	0.4	-0.3	2.0
South Atlantic	112	2.9	-0.3	0.4	1.3	-0.7	0.1	-0.9	1.6
East South Central	132	2.8	-0.1	1.5	2.0	-0.9	0.0	-0.5	3.6
West South Central	120	2.8	-0.2	0.5	2.5	-0.8	0.0	-0.4	3.1
Mountain	42	2.7	-0.3	0.3	-0.2	-0.2	0.4	0.0	2.5
Pacific	24	2.9	-0.2	0.0	2.6	-0.5	0.0	0.0	1.5
Puerto Rico									
Puerto Rico Hospitals	52	2.9	-0.3	-2.1	-3.4	-0.7	0.8	0.0	2.3
By Payment Classification:									
Urban hospitals	1,714	2.9	0.0	0.0	-2.4	1.6	0.6	0.0	2.4
Rural areas	1,368	2.9	0.0	0.0	1.9	-1.2	0.1	-0.2	3.1
Teaching Status:									
Nonteaching	1,832	2.9	-0.1	0.1	-0.6	1.3	0.3	-0.4	2.3
Fewer than 100 residents	958	2.9	-0.1	0.2	0.0	0.0	0.4	-0.1	2.9
100 or more residents	292	2.8	0.2	-0.4	0.4	-0.9	0.4	0.0	3.0
Urban DSH:									
Non-DSH	331	2.9	-0.3	0.0	-2.3	0.6	0.6	-0.2	2.6

	Number of Hospitals[1]	Hospital Rate Update (1)[2]	FY 2025 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	FY 2025 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2025 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of Imputed Floor, the Frontier Wage Index, and Outmigration Adjustment (6)[7]	MDH Expiration (7)[8]	All FY 2025 Changes (8)[9]
100 or more beds	1,015	2.9	0.0	0.0	-2.5	1.7	0.6	0.0	2.4
Less than 100 beds	368	2.9	-0.1	0.1	-2.5	1.9	0.4	-0.4	2.4
Rural DSH:									
Non-DSH	83	2.8	-0.1	0.2	3.5	-1.3	0.2	-1.7	2.0
SCH	242	2.8	-0.2	0.1	0.4	-0.1	0.0	0.0	2.9
RRC	791	2.9	0.0	-0.1	2.0	-1.2	0.1	-0.1	3.2
100 or more beds	39	2.9	0.1	0.6	-0.9	-1.3	0.1	-0.5	4.0
Less than 100 beds	213	2.8	-0.1	0.7	3.7	-1.3	0.5	-5.1	-1.8
Urban teaching and DSH:									
Both teaching and DSH	581	2.9	0.0	0.0	-2.5	1.1	0.8	0.0	2.4
Teaching and no DSH	52	2.9	-0.2	-0.3	-2.2	0.0	0.8	-0.3	2.1
No teaching and DSH	802	2.9	0.0	0.0	-2.5	2.8	0.3	0.0	2.4
No teaching and no DSH	279	2.9	-0.3	0.2	-2.3	1.0	0.4	-0.1	2.9
Special Hospital Types:									
RRC	155	2.9	0.0	1.2	1.8	0.3	0.3	-0.7	3.0
RRC with Section 401 Reclassification	579	2.9	0.1	-0.1	2.2	-1.3	0.1	-0.1	3.3
SCH	244	2.8	-0.4	0.1	0.3	-0.2	0.1	0.0	2.6
SCH with Section 401 Reclassification	34	2.9	0.0	0.0	0.2	-0.1	0.0	0.0	3.1
SCH and RRC	119	2.9	-0.3	0.2	1.0	-0.4	0.1	0.0	2.8
SCH and RRC with Section 401 Reclassification	46	2.9	-0.4	0.2	0.1	-0.1	0.0	0.0	2.7
Type of Ownership:									
Voluntary	1,906	2.9	0.0	-0.1	0.2	-0.1	0.4	-0.2	2.7
Proprietary	755	2.9	-0.1	0.7	-0.4	1.2	0.2	-0.1	3.3
Government	420	2.8	0.1	-0.3	-0.7	-0.3	0.1	-0.1	2.6
Medicare Utilization as a Percent of Inpatient Days:									
0-25	1,362	2.9	0.1	0.2	-0.4	-0.1	0.2	0.0	2.9
25-50	1,615	2.9	-0.1	-0.1	0.4	0.1	0.5	-0.3	2.7
50-65	65	2.9	-0.4	-1.5	-1.6	3.0	0.6	-0.2	1.2
Over 65	16	2.5	-2.5	0.5	0.1	-0.3	2.2	-1.0	0.0
Medicaid Utilization as a Percent of Inpatient Days:									
0-25	1,910	2.9	-0.1	0.2	0.1	-0.1	0.3	-0.2	2.8
25-50	1,044	2.9	0.1	-0.2	0.0	0.0	0.3	0.0	2.8
50-65	99	2.8	0.2	-1.0	-1.4	2.2	0.1	0.0	1.1
Over 65	29	2.5	0.3	-0.3	-1.9	2.7	0.2	0.0	0.8
FY 2025 Reclassifications:									
All Reclassified Hospitals	1,059	2.9	0.0	0.0	2.2	-1.0	0.1	-0.2	3.1
Non-Reclassified Hospitals	2,023	2.9	0.0	0.0	-2.6	1.2	0.6	-0.1	2.5
Urban Hospitals Reclassified	902	2.9	0.0	-0.1	1.9	-1.0	0.1	-0.2	3.1
Urban Non-reclassified Hospitals	1,501	2.9	0.0	0.0	-3.2	1.6	0.7	0.0	2.4
Rural Hospitals Reclassified Full Year	279	2.9	-0.2	0.8	2.7	-0.8	0.0	-0.4	3.0
Rural Non-reclassified Hospitals Full Year	400	2.8	-0.2	0.4	1.8	-0.7	0.4	-1.1	2.0
All Section 401 Reclassified Hospitals:	729	2.9	0.1	-0.1	1.9	-1.2	0.1	-0.2	3.1
Other Reclassified Hospitals (Section 1886(d)(8)(B))	51	2.9	-0.1	0.7	6.7	-1.3	0.0	-1.8	1.9

[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 2023, 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 2.9 percent update to the national standardized amount and the hospital-specific rate (the 3.4 percent market basket rate-of-increase reduced by 0.5 percentage point for the productivity adjustment).
[3] This column displays the payment impact of the changes to the Version 42 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2023 MedPAR 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 0.99719 and 0.999874.
[4] This column displays the payment impact of the update to wage index data using FY 2021 cost report data. This column displays the payment impact of the application of the wage budget neutrality factor. The wage budget neutrality factor is 1.000114.
[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2025 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2025. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.962791.
[6] This column displays the effects of the rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index 0.977499.
[7] This column shows the combined impact of (1) the imputed floor for all-urban states; (2) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (3) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.
[8] This column displays the impact of the expiration of the MDH status on January 1, 2025, a non-budget neutral payment provision.
[9] This column shows the estimated change in payments from FY 2024 to FY 2025.