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

On April 10, 2024, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule describing federal fiscal year (FY) 2025 policies and rates for Medicare's inpatient prospective payment system (IPPS) and the long-term care hospital (LTCH) prospective payment system (PPS). The proposed rule will be published in the *Federal Register* on May 2, 2024. **The public comment period on the rule will end on June 10, 2024.**

The payment rates and policies described in the IPPS/LTCH proposed rule (CMS-1808-P) affect Medicare's operating and capital payments for short-term acute care hospital inpatient services and services provided in LTCHs paid under their respective prospective payment systems. The proposed rule also sets forth rate-of-increase limits for inpatient services provided by certain "IPPS-Exempt" providers, such as cancer and children's hospitals and religious nonmedical health care institutions, which are paid based on reasonable costs. Unless otherwise specified, policies will be effective October 1, 2024.

CMS is also proposing 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 proposals in the rule include a requirement to report respiratory syncytial virus; a payment subsidy for small independent hospitals to maintain a buffer stock of essential medicines; and a comment solicitation on a maternal health standard to be included in Medicare's Conditions of Participation (CoP).

CMS makes many data files available to support analysis of the proposed rule. These data files are generally available at: FY 2025 IPPS Proposed Rule Home Page | CMS. Numbered tables that were historically included in the IPPS/LTCH rule are now only available on the CMS website at the above hyperlink.

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

CMS estimates that the proposed rule will increase FY 2025 combined operating and capital payments to approximately 3,090 acute care hospitals paid under the IPPS by an estimated $3.0 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.

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 2.6 percent for hospitals which successfully report quality measures and are meaningful users of electronic health records (EHR). The 2.6 percent rate increase is the net result of a market basket update of 3.0 percent less 0.4 percentage points for total factor 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	3.0%	2.6%	-0.75	1.85%	91
No EHR	75% of the MB	3.0%	2.6%	-2.25	0.35%	87
No IQR/EHR	100% of the MB	3.0%	2.6%	-3.0	-0.4%	26

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2025 payments increasing 2.4 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	+2.6
Expiration of the MDH Program and Changes to LVH Program	-0.2[1]
Total	+2.4[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. Similarly, Congress has repeatedly extended temporary provisions of the LVH program that allow more hospital to qualify than under regulations that were previously in effect.
[2] CMS targets 5.1 percent of IPPS payments as outliers but estimates that it will pay 5.101 percent more than the amount targeted in FY 2024. As a result, CMS estimates total payments will decline by 0.01 percent due to targeting 5.1 percent of total IPPS payments as outliers for FY 2025.

Table I Impact Analysis

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

Hospital Type	All Proposed Rule Changes
All Hospitals	2.4%
Urban	2.4%
Rural	1.9%
Major Teaching	2.8%

To the extent the impact on a given hospital category deviates from the national average of 2.4 percent, it suggests that there is a factor resulting in more of an impact on that category of hospital compared with all other hospitals. The impact would be redistributive from a policy that is budget neutral.

The redistributive payment changes from the DRG relative weight changes appear to be having a more significant negative impact on rural hospitals than on average across all hospitals. However, these impacts appear to be more than offset by changes to the wage index for rural hospitals. Geographic reclassification generally benefits rural hospitals relative to a baseline without geographic reclassification. Imputed floor and the rural floor can only benefit urban hospitals relative to these floors not being applied. Imputed floor is not budget neutral while rural is made budget neutral through an adjustment to hospital wage indexes.

The largest deviation from the average increase of 2.4 percent is occurring from expiration of the MDH program and changes to the LVH 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. Similarly, the LVH program would revert to a situation where fewer hospitals would qualify under regulations that were previously in effect.

Nevertheless, at this point in time, the MDH program is set to expire at the end of calendar year and changes to the LVH program will occur at the same time resulting in fewer hospital qualifying for an adjustment. CMS is showing the impact of changes to these programs for all of FY 2025—e.g., the impacts do not reflect that the programs will continue to be in place for the first quarter of FY 2025.

CMS will show the ¾ year FY 2025 impact of MDH expiration and changes to the LVH program in the final rule. CMS estimates that expiration of the MDH program will affect 114 hospitals and decrease spending $151 million for all of FY 2025. CMS estimates that an average of 600 hospitals now qualify for the LVH adjustment and fewer than 10 hospitals will qualify based on prior regulatory criteria that are scheduled to go into effect on January 1, 2025.

Other provisions having an impact include:

Rural Floor. The proposed rural floor raises the wage index of 492 urban hospitals so that it is not below the wage index for the rural area of its state. CMS calculates a proposed national rural floor budget neutrality adjustment factor of 0.985868 (-1.4 percent) applied to hospital wage indexes. CMS projects that rural hospitals in the aggregate will experience a 0.4 percent decrease in payments as a result of the rural floor budget neutrality requirement; hospitals located in urban areas would experience no average change in payments; and urban hospitals in the Pacific region can expect a 2.6 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 that establishes a floor on the wage index of 1.0 in Montana, North Dakota, South Dakota and Wyoming; and (3) the outmigration adjustment that increases the wage index for hospitals in counties where a high proportion of the hospital workers commute to work in 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 99 hospitals in Connecticut, Washington, DC, New Jersey, Puerto Rico and Rhode Island by $246 million. The frontier floor is estimated to increase payment to 41 hospitals by $52 million. The outmigration adjustment is estimate to increase payment to 196 hospitals by $55 million.

NTAP. NTAP payments are not subject to budget neutrality. CMS is proposing to continue NTAP payments for 24 technologies that remain eligible for add-on payments in FY 2025 and estimates Medicare will pay an additional $416.3 million in FY 2025.

Generally, CMS will discuss new NTAP applications in the proposed rule where a decision is required on whether the NTAP represents a substantial clinical improvement. CMS will not

make a decision until the final rule on whether to approve or disapprove these applications.

For alternative pathway applications (discussed further in section II. E), the Food and Drug Administration (FDA) approval process is considered a proxy for substantial clinical improvement. CMS is proposing to approve 15 NTAP for 14 alternative pathway applications (one applicant submitted NTAP for two indications) and estimates total expenditures of $172.7 million ($167 million for breakthrough devices and $5.6 million for qualified infection disease program (QIDP) products).

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to increase by $560 million or by 9.4 percent. Supplemental payments to Puerto Rico, Indian Health Service (IHS) and Tribal Hospitals are estimated to increase another $8 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.

Low Volume Hospitals. 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 608 fewer hospitals receiving the low volume hospital payment adjustment, resulting in lower spending of $261 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 these additional residency positions are 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 proposing changes 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 493 eligible hospitals and cost Medicare about $0.3 million in FY 2025.

Hospital Readmissions Reduction Program (HRRP). The HRRP program is estimated to reduce FY 2025 payments to an estimated 2,855 hospitals or 82.5 percent of all hospitals eligible to receive a readmissions penalty. The proposed readmissions penalty is estimated to affect 0.44

percent of payments to the hospitals. The impact section of the rule includes table I.G.07.-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 based on hospitals' performance scores. CMS includes an unnumbered table in the impact section that illustrates the proposed average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural) in FY 2023.

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

Rural Community Hospital Demonstration Program. CMS estimates costs for the Rural Community Hospital Demonstration Program at $49.5 million for FY 2025 using "as submitted" cost reports from FY 2019. CMS will use reconciled FY 2019 cost reports in the FY 2025 final rule when applying a final adjustment for budget neutrality to FY 2025 IPPS standardized amounts. Based on the "as submitted" cost reports, CMS proposes a budget neutrality adjustment for FY 2025 of -0.05 percent.

C. IPPS Standardized Amounts

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

	Update
Full Update	2.6%
No IQR	1.85%
No EHR	0.35%
No EHR/IQR	-0.4%

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

- MS-DRG recalibration, 0.997055 (a decrease of 0.29 percent);
- MS-DRG recalibration cap, 0.999617 (a decrease of 0.04 percent);
- Wage index, 0.999957 (a decrease that rounds to 0.00 percent);
- Geographic reclassification, 0.976773 (a decrease of 2.32 percent);
- Increase in wage indexes below the 25th percentile budget neutrality of 0.997498 or -0.25 percent;
- 5 percent cap on wage index reductions, 0.997162 or -0.28 percent;
- The outlier offset factor is 0.949 or -5.1 percent; and
- The rural community hospital demonstration program adjustment is 0.999513 or -0.05

percent.

Of the adjustments above, MS-DRG recalibration and wage index are maintained on the standardized amount from year to year. The prior year adjustments for geographic reclassification, wage indexes below the 25th percentile, transitioning reductions to the wage index, the outlier adjustment, and rural community hospital demonstration project are removed from the FY 2024 standardized amount before the FY 2025 adjustments are applied. The net increase in the standardized amount results as follows:

Factor	Net Change
Update	2.6%
DRG Recalibration	0.29%
DRG Recalibration Cap	-0.04%
Wage Index	0.00%
Geographic Reclassification	0.56%
25th Percentile	0.01%
5% Cap on Wage Index Reductions	-0.25%
Outlier	0.00%
Rural Community Hospital	0.01%
Net Change*	2.6%

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

The proposed increase in the capital rate is 2.5 percent from $503.83 to $516.41. The combined increase in the proposed operating standardized amount and the capital rate is 2.58 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=2.6%	Reduced Update Failed IQR = 1.85%	Reduced Update Failed EHR =0.35%	Reduced Update Failed IQR and EHR = -0.4%
Wage Index >1.0				
Labor (67.6%)	$4,506.29	$4,473.35	$4,407.47	$4,374.53
Non-Labor (32.4%)	$2,159.81	$2,144.02	$2,112.45	$2,096.66
WI<=1.0				
Labor (62%)	$4,132.98	$4,102.77	$4,042.35	$4,012.14
Non-Labor (38%)	$2,533.12	$2,514.60	$,2,477.57	$2,459.05
National Capital Rate (All Hospitals)	$516.41			

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 proposes to adopt an outlier threshold for FY 2025 of $49,237, an increase of 15.2 percent and $6,487 from the FY 2024 amount. CMS projects that the proposed 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 0.957708 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 December 2023 update to the FY 2023 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data is the December 2023 update of the Provider-Specific File (PSF).

Charge Inflation. CMS proposes to continue 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	$574,544,024,043	6,958,255	$82,570.13
FY 2024	$593,444,028,889	6,901,312	$85,990.03
Annual Rate of Increase			1.04142
Squared for 2 Years of Inflation			1.084555

CCRs. As it has done in the past, CMS is proposing to adjust the CCRs from the December 2023 update of the PSF by comparing the percentage change in the national average case weighted operating CCR and capital CCR from the December 2022 update of the PSF to the national average case weighted operating CCR and capital CCR from the December 2023 update of the PSF.

These data are shown in the table below.

	December 2022 PSF	December 2023 PSF	% Change	Factor
Operating	0.246416	0.254624	3.33%	1.03331
Capital	0.018005	0.017765	-1.33%	0.98667

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 bill 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.

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 proposed rule, CMS is using the December 2023 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 2024). It then subtracts that amount (expressed as percentage points) from the 5.1 percent of total operating IPPS payments that CMS is targeting as outlier payments for the payment year.

CMS estimates that FY 2019 reconciliation would result in hospitals being owed $34,513,755 or -0.04 percent of IPPS payments. As a result, CMS proposes subtracting -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 proposed outlier threshold (from $49,601 to $49,237) 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 $2,056,344 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 5.23 percent of actual total MS-DRG payments or 0.12 percentage points more than the target of 5.1 percent—the amount the standardized amount was reduced by to fund outliers. Following long-standing policy, the agency will not make retroactive adjustments to ensure that total outlier payments for FY 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 this proposed rule, CMS estimates that, using FY 2023 data, outlier payments will be 0.01 percentage points higher (or 5.101 percent) than the 5.1 percent targeted and removed from the standardized amounts to fund outlier payments.

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

A. Adoption of the MS-DRGs

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-DRG. CMS refers readers to past rulemaking for more details about the MS-DRGs.

B. Changes to Specific MS-DRG Classifications

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

Beginning with FY 2024 MS-DRG classification change requests, CMS changed the deadline to request changes to the MS-DRGs to October 20 of each year and changed the process for submitting MS-DRG classification change requests. MS-DRG change requests are only accepted 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.

CMS received the following requests to modify the GROUPER logic in a number of cardiac MS-DRGs under Major Diagnostic Category (MDC0 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 form 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 notes for these requests, the complexity of the GROUPER logic for these MS-DRGs requires more extensive analyses to identify and evaluate all of the data relevant to assess these potential modifications. CMS notes, 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 continues to believe that atherectomy is

distinct from coronary lithotripsy in that each of these procedures are defined by clinically distinct definitions and objectives. CMS believes 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 the proposals in this rule, CMS is posting a test version of the ICD-10 MS-DRG GROUPER Software, Version 42 on its website. This test software reflects the proposed GROUPER logic for FY 2025; it includes the new diagnosis and procedure codes effective for FY 2025 and does not include the diagnosis codes that are invalid beginning in FY 2025. CMS is also making 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 finalized that beginning with the 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 is making 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. The draft FY 2025 ICD-10 MCE Version 42 Manual file is available on the CMS IPPS website. Any questions, comments, or recommendations regarding the MCE should be sent to CMS at MSDRGClassificationChange@cms.hhs.gov.

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 2022 update of the FY 2022 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

[1]85 FR 58448

weights by avoiding low volume counts for the NonCC level MS-DRGs. CMS noted that the application of the NonCC subgroup criteria may result in modifications to certain MS-DRGs that are currently split into three severity levels and result in MS-DRGs that are split into two severity levels.

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

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

[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.

For analysis of requests to create a new MS-DRG, CMS evaluates the most recent year available of MedPAR claims data. For evaluation of requests to split an existing base MS-DRG into severity levels, CMS analyzes the most recent 2 years of MedPAR data. CMS uses 2 years of data to reduce changes related to an isolated year's data fluctuation. CMS first evaluates if the creation of a new CC subgroup is warranted to determine if all criteria are satisfied in a three-way split. The base MS-DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each subgroup is analyzed in relation to the other two subgroups using the volume (Criteria 1 and 2), average cost (Criteria 3 and 5), and reduction in variance (Criteria 5). If the criteria fail, CMS will determine if criteria are satisfied for a two-way split. A base MS-DRG is initially subdivided into two subgroups: "with MCC" and "without MCC" or with "CC/MCC" and "without "CC/MCC and each subgroup is analyzed to the other using the 5 criteria. If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for the base MS-DRG. If the three-way split fails on any one of the five criteria and meets all of the five criteria for both two-way splits, CMS would apply the two way split with the highest R2 value. CMS notes that if the request is to split an existing base MS-DGR into severity levels and the request is for one of the two-way splits, CMS will not also evaluate the criteria for a three-way split.

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 (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".

CMS does 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 states that "Other Immunotherapies" is intended to encompass the group of therapies that are currently available and to enable appropriate MS-DRG for any future therapies that may also fit into this category. CMS will continue to evaluate these issues as part of its annual analysis of this MS-DRG. CMS does not propose to revise the title for Pre-MDC MS-DRG 018.

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

a. Logic for MS-DRGs 023 through 027

CMS reviews 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. 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.

[5] 88 FR 58661 through 58667

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

CMS received two comments about its ongoing analysis of MS-DRGs 023-027. One commenter recommended that CMS should not use the surgical approach (e.g., open versus percutaneous) as a factor for the analysis because both approaches have the same risk of intracranial bleeding, infusion, and brain swelling. The commenter also did not support the reassignment of ICD-10-PCS procedure codes describing LITT. Another commenter supported the current logic for these MS-DRGs because of the clinical and resource similarities of the procedures assigned to these MS-DRGs.

CMS appreciates these comments. It continues the analysis of the claims data for MS-DRGs 023 through 027 and continues to **welcome comments on other factors it should consider in the potential restructuring of these MS-DRGs.**

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.

CMS analyzed claims data for MS-DRGs 023-027 and for cases reporting excision of brain tumor and IORT. The data shows there are no cases reporting the use of IORT with brain tumor excision; CMS is unable to evaluate whether IORT directly impacts resource utilization (see table in the proposed rule).

For FY 2025, CMS proposes 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 requested 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.

CMS summarizes its review of this request (see tables in the proposed 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 (Percutaneous and Other Intracardiac Procedures). As shown in the proposed rule, 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.

CMS proposes to create a new MS-DRG for cases reporting a LAAC procedure and a cardiac ablation procedure. CMS evaluated the criteria to create subgroups but the data did not support any subdivision.

For FY 2025, CMS proposes 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 proposes 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 discusses a proposed modification of the surgical hierarchy, 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

[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.

[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.

CMS summarizes its review of this request (see tables in the proposed 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 are greater than the average costs of all cases in these MS-DRGs. Based on the small number of cases, CMS continues 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) were 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 agrees that all these procedures all share an indication of heart failure (clinically coherent) and demonstrate comparable resource utilization. CMS proposes to reassign cases reporting procedure codes describing the implantation of a BAROSTIM system to MS-DRG 276, even if there is no MCC reported.

For FY 2025, CMS proposes 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 proposes 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 proposed 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 believes that sharing a single MS-DRG would eliminate any final incentive for hospitals to choose between the two procedures. CMS discusses similar prior requests from the FY 2015 and FY 2020 IPPS final rule.

CMS summarizes its review of this request (see tables in the proposed rule). CMS states the data analysis show 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 continues to believe that endovascular cardiac valve replacement and supplemental procedures are clinically coherent in their currently assigned MS-DRGs. CMS notes 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.

For FY 2025, CMS proposes 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 clarifies 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 thinks this request is 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 proposed rule) to MS-DRG from MS-DRGs 228 and 229 (Other Cardiothoracic Procedures).

CMS summarizes its review of this request (see tables in the proposed rule). The analysis indicates 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 does 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.

For FY 2025, CMS proposes 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 proposed 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 proposed 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).

CMS summarizes its review of its analysis for the eight ICD-10-PCS procedure codes assigned to MS-DRGs 347-349 and compares this information to claims data from MS-DRGs 329-331. CMS notes 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 notes that these eight procedure codes do not describe procedures on a stoma but are specific to intestinal anatomy and believes 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 notes that these codes do not describe procedures on a stoma but are specific to intestinal anatomy.

For FY 2025, CMS proposes the reassignment of 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.

CMS summarizes its review of the second and third logic lists (see tables in the proposed rule) and believes 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.

For FY 2025, CMS proposes 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 the FY 2024 IPPS final rule, CMS noted that the aprevo customized interbody fusion device technology was approved for new technology add-on payments for FY 2022 and FY 2023. For FY 2024, CMS finalized continuing the new technology add-on payments for the transforaminal lumbar interbody fusion (TLIF) indication for aprevo; as discussed in section II.E, for FY 2025 CMS proposes to discontinue the new technology add-on payment. The new technology add-on payment for the indications for anterior lumbar interbody fusion (ALIF) and lateral lumbar interbody fusion (LLIF) were discontinued in FY 2024.

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).

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. However, due to the concerns expressed by the requestor about the suspected inaccuracies of the coding, CMS was concerned about the reliability of the claims data and believed further review is warranted. For FY 2024, CMS maintained the current structure of MS-DRGs 453-460.

In addition, in response to the manufacturer's comment expressing concerns about the reliability of the Medicare claims data due to miscoding, CMS stated that in order for CMS to consider

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

using non-MedPAR data, the data must be independently validated and CMS must be able to independently review the medical records and verify that a particular procedure was performed for each of the cases that reported the procedure. In advance of this proposed rule, the manufacturer provided CMS with a list of providers it has an explicit relationship with to assist CMS in the ongoing review of this request.

For FY 2025, CMS summarizes its extensive review of this issue (summarized in tables in the proposed rule). CMS updates 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 are miscoded. Based on its analysis and clinical review, CMS does not believe the reassignments for spinal fusion using an aprevo customized interbody fusion device is appropriate. CMS notes 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 also reported multiple MCC and CC conditions. CMS believes 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 provides 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 believes 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 believes 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 believes new MS-DRGs are 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 discusses its analysis of this proposal, including application of all five criteria to create subgroups for the base MS-DRG.

For FY 2025, CMS proposes 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).

The proposed logic for cases assigned to these proposed MS-DRGs is displayed in Tables 6P2d – 6P.2h. CMS also proposes 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 proposes to maintain the current structure of MS-DRGs 456-458. CMS plans to continue to evaluate potential refinement of these spinal fusion MS-DRGS. **CMS seeks comments on other factors that should be considered in the potential restructuring of these MS-DRGs.** Comments for future rulemaking may be submitted by October 20, 2024 to MEARIS at https://mearis.cms.gov/public/home.

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).

For FY 2025, CMS proposes 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).

CMS summarizes its review of this issue. CMS notes 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 is 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 proposes 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.

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 are 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).

CMS summarizes 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 concludes the data analysis shows 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 proposes a new MS-DRG for cases describing a type of acute leukemia with an O.R. procedure. CMS discusses 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 proposes 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 proposes 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 proposes 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 notes 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 proposes to designate these 189 codes as non-O.R. procedures affecting the MS-DRG. CMS discusses a proposed modification of the surgical hierarchy in section II.C.15 of the proposed rule (discussed below in section 14).

CMS also proposes to revise the titles for MS-DRGs 834-836 from "Acute Leukemia without Major O.R. Procedures" to "Acute Leukemia". CMS believes this will better reflect the GROUPER logic that will no longer include ICD-10-PCS codes designated as O.R. procedures.

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 is not proposing to move any cases reporting procedure codes from MS-DRGs 981t

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

CMS has a list of procedures that are considered O.R. procedures. CMS discusses how historically this list was developed using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.)

CMS describes the current process used to determine whether and in what way each ICD-10-PCS procedure code on a claim impacts the MS-DRG assignment. First, each procedure code is either designated as an O.R. or non-O.R. procedure. Second, each O.R. procedure is further classified as either extensive or non-extensive. Third, each non-O.R. procedure is further classified as either affecting or not affecting the MS-DRG assignment (CMS refers to these as "non-O.R. affecting the MS-DRG"). For new procedure codes that have been finalized through the ICD-10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS-DRG, CMS' clinical advisors recommend the MS-DRG assignment which are listed in Table 6B (New Procedure Codes) and subject to public comment. CMS notes these proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes.

In the FY 2020 IPPS proposed rule, CMS discussed its plans to conduct a multi-year comprehensive, systematic review of the O.R. and non-O.R. ICD-10-PCS procedure codes. CMS believes there may be other factors, such as resource utilization, besides whether or not a procedure is performed in an operating room for determining these designations. 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. **CMS continues to encourage comments on any other factors to consider in its refinement efforts to recognize and differentiate consumption of resources for the ICD-10 MS-DRGs**.

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, makes proposals related to (1) laparoscopic biopsy of intestinal body parts and (2) laparoscopic biopsy of gallbladder and pancreas.

The reader is referred to the proposed rule for a discussion of these proposals.

12. Proposed Changes to the MS-DRG Diagnosis Codes

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

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] 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 proposes to finalize the nine guiding principles list above. CMS' evaluations to determine the extent to which the presence of a

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

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.

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.

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 discusses its analysis which shows 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 shows that for diagnosis codes Z59.11, Z59.12, Z59.812 and Z59.819 shows the resources

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

involved are more aligned with a NonCC severity level. CMS notes that these diagnosis codes have recently become effective and believes 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 discusses 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 proposes to change the severity level designation for the seven inadequate housing/housing instability from NonCC to CC. CMS notes that if SDOH Z codes are not consistently reported in inpatient claims data, its ability to measure the impact on resource use may not adequately reflect additional resources expended by hospitals. 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 proposed rule lists that 37 ICD-10-CM diagnosis codes that describe causally specified delirium.

CMS summarizes its review of this issue. CMS concludes 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 notes 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 proposes to maintain the severity designation of these 37 codes for causally specified delirium as CCs. CMS states that while there is a lack of consistent claims data to 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. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2025

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

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

c. Proposed CC Exclusions List for FY 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 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

[12] 52 FR 33143

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 proposed rule:

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.		

CMS believes this additional information about the suppression logic may further assist users of the ICD-10 MS-DRG GROUPER software and related materials.

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 discusses 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 proposes 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 proposes to refine how the suppression logic is displayed under Appendix C-Part C and proposes 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 proposed additions and deletions to the CC Exclusion list:

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

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

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

Table 6A	New Diagnosis Codes
Table 6B	New Procedure Codes
Table 6C	Invalid Diagnosis Codes
Table 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. Proposed Changes to Surgical Hierarchies

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

Based on the proposed changes for FY 2025, CMS proposes 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. These proposals are summarized below in tables reproduced from the rule.

Proposed Surgical Hierarchy: MDC 05	
MS-DRG 215	Other Heart Assist System Implant
MS-DRG 212	Concomitant Aortic and Mitral Valve Procedures
MS-DRGs 216-221	Cardiac Valve and Other Major Cardiothoracic Procedures
MS-DRGs 231-236	Coronary Bypass
Proposed New MS-DRG 317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation
MS-DRG 275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
Proposed New Title MS-DRG 276	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator
MS-DRG 277	Cardiac Defibrillator Implant without MCC
MS-DRGs 266-267	Endovascular Cardiac Valve Replacement and Supplement Procedures
MS-DRGs 268-269	Aortic and Heart Assist Procedures
MS-DRGs 228-229	Other Cardiothoracic Procedures
MS-DRGs 319-320	Other Endovascular Cardiac Valve Procedures
MS-DRGs 270-272	Other Major Cardiovascular Procedures
MS-DRGs 239-241	Amputation for Circulatory System Disorders Except Upper Limb and Toe
MS-DRGs 242-244	Permanent Cardiac Pacemaker Implant
MS-DRG 245	AICD Generator Procedures
MS-DRG 265	AICD Lead Procedures
MS-DRGs 273-274	Percutaneous and Other Intracardiac Procedures
MS-DRGs 323-325	Coronary Intravascular Lithotripsy
MS-DRGs 321-322	Percutaneous Cardiovascular Procedures with Intraluminal Device
MS-DRGs 250-251	Percutaneous Cardiovascular Procedures without Intraluminal Device
MS-DRGs 278-279	Ultrasound Accelerated and Other Thrombolysis
MS-DRGs 252-254	Other Vascular Procedures
MS-DRGs 255-257	Upper Limb and Toe Amputation for Circulatory System Disorders
MS-DRGs 258-259	Cardiac Pacemaker Device Replacement
MS-DRGs 260-262	Cardiac Pacemaker Revision Except Device Replacement
MS-DRG 263	Vein Ligation and Stripping
MS-DRG 264	Other Circulatory O.R Procedures

Proposed Surgical Hierarchy: MDC 08	
Delete MS-DRGs 453-455	Combined Anterior and Posterior Spinal Fusion
Proposed New MS-DRGs 426-428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New MS-DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical
Proposed New 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
Proposed New MS-DRGs 447-448	Multiple Level Spinal Fusion Except Cervical
Proposed New Title MS-DRGs 459-460	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
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

Proposed Surgical Hierarchy: MDC 08	
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

Proposed Surgical Hierarchy: MDC 17	
MS-DRGs 820-822	Lymphoma and Leukemia with Major O.R. Procedures
Proposed New MS-DRG 850	Acute Leukemia with Other Procedures
MS-DRGs 823-825	Lymphoma and Non-Acute Leukemia with Other Procedures
MS-DRGs 826-828	Myeloproliferative disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures
MS-DRGs 829-830	Myeloproliferative disorders or Poorly Differentiated Neoplasms with Other 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 rule.

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

16. 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. Currently, MS-DRGs 222-227 are on the list. The table below, reproduced from the rule, lists the existing MS-DRGs subject to this policy. CMS proposes that if the applicable proposed MS-DRG changes are finalized, it will make conforming changes to this list.

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG**	**MS-DRG Title**
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC
MDC 01	023	Craniotomy with Major Device Implant/Acute Complex CNS PDX with MCC or Chemo Implant
MDC 01	024	Craniotomy with Major Device Implant/Acute Complex CNS PDX without
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 file (fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year) from the 2nd year preceding the ratesetting year (e.g., FY 2023 for FY 2025). It also uses Medicare cost report data from the 3rd year preceding the ratesetting year (e.g., FY 2022 for FY 2025).

In developing relative weights for FY 2025, CMS proposes to use:

- FY 2023 MedPAR data: Bills received through December 31, 2023 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 6,887,902 million Medicare discharges regrouped using the FY 2025 proposed MS-DRG classifications.
- FY 2022 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2022 cost reporting periods, using the December 31, 2023 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 proposed 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 Proposed Rule Home Page | CMS. (Select file #4 under FY 2025 Proposed Rule Data files, "FY 2025 Proposed Rule: HCRIS Data File (ZIP)".)

In cases where an MS-DRG with a higher severity level has a lower weight than its base or lower severity level MS-DRG (known as non-monotonicity), CMS will calculate a single weight for both MS-DRGs based on their combined cases. For FY 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 proposed CCRs in comparison to the final FY 2024 CCRs are shown in the following table:

Group	Final FY 2024 CCR	Proposed FY 2025 CCR
Routine Days	0.417	0.417
Intensive Days	0.351	0.364
Drugs	0.18	0.182
Supplies & Equipment	0.303	0.302
Implantable Devices	0.269	0.270
Inhalation Therapy	0.153	0.163
Therapy Services	0.268	0.269
Anesthesia	0.072	0.075
Labor & Delivery	0.416	0.385
Operating Room	0.16	0.162

Group	Final FY 2024 CCR	Proposed FY 2025 CCR
Cardiology	0.086	0.089
Cardiac Catheterization	0.102	0.106
Laboratory	0.102	0.103
Radiology	0.128	0.129
MRIs	0.067	0.068
CT Scans	0.033	0.033
Emergency Room	0.153	0.155
Blood and Blood Products	0.245	0.253
Other Services	0.34	0.341

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 proposes 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."

CMS estimates that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($116,831) were 34 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($342,684). Accordingly, CMS proposes a payment adjustor of 0.34 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. The data underlying these adjustments will be updated for the FY 2025 final rule.

Proposed Cap for Relative Weight Reductions. Beginning in FY 2023, CMS adopted a 10 percent cap on reductions to the relative weights in a single year. CMS is proposing to continue that policy for FY 2025.

Other Issues. CMS proposes normalizing the relative weights by an adjustment factor of 1.92287 so that the average case weight after recalibration is equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself does not increase or decrease total payments under the IPPS.

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

[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

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 proposed cost thresholds are included in the data files associated with the FY 2025 proposed 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;
        - 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.

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

- 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 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

[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

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 will consider the presentations made at the town hall meeting and written comments received by December 18, 2023. Where applicable, CMS summarizes comments at the end of each discussion of the individual applications in this proposed rule. Comments that are unrelated to the "substantial clinical improvement" criterion are not summarized in this proposed rule. Commenters can resubmit their comments in response to proposals in this proposed rule.

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

Section "X" codes are ICD-10-PCS codes used to identify new medical services and technologies. Information regarding "X" codes can be found on the CMS web site at https://www.cms.gov/medicare-icd-10/2021-icd-10-pcs. CMS notes that after Section "X" codes have served their purpose, proposals to delete them and create new codes in the body of ICD-10-PCS would be addressed at ICD-10 Coordination and Maintenance Committee meetings. CMS also notes that codes for new technologies that are consistent with the current ICD-10-PCS codes may still be created within the current ICD-10-PCS structure.

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

CMS discusses the proposed 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

[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.

additional year only if the 3-year anniversary date of the product's entry onto the US market occurs in the latter half of the fiscal year (70 FR 47362).

Conditional approval of DefenCath™ (a formulation of taurolidine/heparin). CMS conditionally approved DefenCath for FY 2024 new technology add-on payments under the alternative pathway for certain antimicrobial products, subject to the technology receiving FDA marketing authorization by July 1, 2024. DefenCath received FDA marketing authorization on November 15, 2023 and was eligible to receive new technology add-on payments in FY 2024 beginning with discharges on or after January 1, 2024. CMS proposes to continue new technology add-on payments for DefenCath for FY 2025.

Proposed Continuation of Technologies. Table II.E.-01 in the proposed rule (see table extract below) lists the 24 technologies CMS proposes to continue new technology add-on payments for FY 2024 because the 3-year anniversary date of entry into the U.S. market occurs on or after April 1, 2024. The complete table in the proposed rule also includes the proposed maximum NTAP amount for FY 2025, codes used to identify cases eligible for NTAP, and previous related final rule citations.

Proposed 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
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

Proposed 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
20	Phagenyx® System	04/12/2023	10/1/2023	04/12/2026
21	REZZAYO™ (rezafungin for injection)	03/22/2023	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

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

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.

The summary below provides a high-level discussion of the remaining 12 new technology assessment; readers are advised to review the proposed 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 in the proposed rule are available at https://mearis.cms.gov/public/publications/ntap. In addition, separate tables listing the ICD-10-CM codes, ICD-10-PCS codes, and/or MS-DRGs related to the analysis of the cost criterion for certain applications are available with the information posted on the CMS website.[28]

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

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 believes 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). **CMS invites comments on the appropriate ICD-10-CM diagnosis codes to identify the indication of SCD for the new technology add-on payment, if approved**.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that Casgevy is not substantially similar to other currently

[28] 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.

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 states 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.

CMS notes 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 notes 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 believes 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). If CMS determines these technologies are substantially similar, the newness period would begin on December 8, 2023, the data both products received FDA approval for SCD. **CMS is interested in information on how these two technologies may differ with respect to the newness criterion**.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant included two cohorts to identify potential patients who may be eligible for Casgevy. The first cohort included all cases in MS-DRG 014 (Allogeneic Bone Marrow Transplant) to account for the low volume of SCD or transfusion-dependent beta thalassemia (TDT) cases. The second cohort included cases in MS-DRG 014 with any diagnosis code of SCD or TDT; the applicant combined the cost analysis for SCD and TDT because of the low volume of cases. A table in the proposed rule, summarizes the 4 scenarios the applicant used based on different removal of drug charges. The applicant concluded 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 proposed rule summarizes the applicant's assertions.

CMS discusses several concerns regarding whether Casgevy meets the substantial clinical improvement criterion. CMS notes 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. CMS notes that the data presented at the American Society of Hematology (ASH) meeting in December 2023 indicates that 44 people received Casgevy for SCD and only 30 participants were evaluable for primary and key secondary endpoints because they were followed for at least 16 months post infusion. Of the patients followed, the applicant stated 96.7% of patient achieved the primary efficacy endpoint (free of severe VOCs for at least 12 consecutive months) and 100% achieved the key secondary efficiency endpoint (no in-patient hospitalizations for severe VOCs for at least 12 consecutive months). The applicant also noted a safety profile consistent with myeloablative busulfan and autologous hematopoietic stem cell transplantation (HSCT). CMS notes, however, that the provided evidence did not include peer-reviewed literature that directly assessed the use of Casgevy for SCD. CMS is concerned that the small study population may limit generalizability to the Medicare population and it is unable to identify where the study took place. CMS is also concerned that the short follow-up duration is insufficient to assess improvements in long-term clinical outcomes.

CMS notes that the applicant did not provide data supporting the assertion that Casgevy significantly improves clinical outcomes relative to services or technologies previously available.

CMS is also concerned about the claim that Casgevy avoids certain serious risks of side effects associated with existing potentially curative treatment options for SCD, including Lyfgenia. CMS does not think the package insert for Lyfgenia indicating the potential risk of insertional oncogenesis based on the clinical trial is sufficient for claiming a distinction. In addition, **CMS is interested in additional information** about the frequency and clinical relevance of side effects such as severe infection, hematologic malignancy, bleeding events, and death for Casgevy and allo-HSCT.

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 believes 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). **CMS invites comments on the appropriate ICD-10-CM diagnosis codes to identify the indication of SCD for the new technology add-on payment, if approved**.

As summarized in a table in the proposed 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 states 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.

CMS is 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 discusses similarities between Casgevy and Zynteglo and believes these technologies may be substantially similar to each other. CMS notes 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 is interested in information on whether Casgevy is substantially similar to existing technologies and meets the newness criterion**.

Cost. The analysis for the cost criterion is the same analysis discussed above for the SCD indication. The applicant concluded 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 proposed rule summarizes the applicant's assertions.

CMS discusses several concerns regarding whether Casgevy meets the substantial clinical improvement criterion. CMS notes 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 above 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 is 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.

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.[29] The applicant also submitted an application for FY 2024 that it withdrew prior to the issuance of the FY 2024 IPPS final rule.[30]

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 proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated there are no other treatment options available with the same mechanism of action as DuraGraft®. 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 is concerned that the mechanism of action of DURAGRAFT® may be the same or similar to other vein graft storage solutions such as various saline, blood, and electrolyte solutions.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. CMS notes that although DuraGraft replaces solutions currently used for flushing and storage, the applicant did not remove any charges for prior technology. The applicant concluded that DuraGraft meets the cost criterion.

Substantial Clinical Improvement. The applicant stated that DuraGraft® significantly reduces clinical complications associated with vein graft following coronary artery bypass grafting (CABG) surgery. The applicant asserted there is no other product or technology that reduces the incidence of peri-operative myocardial infarction. The applicant provided 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.

CMS discusses concerns with the information provided, many of them similar to prior concerns discussed in the FY 2024 PPS proposed rule. It is concerned that some of the studies (Szalkiewicz and Perrault) used a relatively small sample size (166 and 125 patients respectively) as compared to the number of potentially eligible patients. As provided by the applicant, about 400,000 CABG surgeries as performed annually and approximately 60% will be performed on Medicare beneficiaries. CMS is also concerned about the relatively short follow-up periods in these studies (4 days and 12 months respectively). CMS notes that both authors

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

30 88 FR 26795 through 26803

indicated limitations with these studies and that larger cohorts and longer-term evaluation is needed. CMS is interested in whether similar clinical results would have been achieved with a larger patient sample and over a longer follow up period.

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

New Technology Town Hall. The applicant submitted a response to data presented during the Town Hall meeting comparing isolated CABG patients from the DuraGraft Registry in Europe to a propensity-matched control group from the Society of Thoracic Surgeons (STS) Registry Adult Cardiac Surgery Database. In response to CMS' question about why two propensity match models were used in the propensity match comparison of the EU DuraGraft Registry to the STS Registry, the applicant explained that the goal of propensity matching is to balance patient and technical factors of mortality throughout the observation period and to correct for differences that may be encountered in the U.S. and Europe. The applicant also provided additional information about the use of propensity matching in this comparison.

d. ELREXFIO™ (elranatamab-bcmn)

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.[31]

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP2310176PV9B.

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 proposed 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

[31] 88 FR 26803 through 26809

therapy. Specifically, the applicant stated that current treatment options (XPOVIO®, BLENREP, ABECMA®, CARVYKTI™, and traditional chemotherapy agents) are not bispecific antibodies. The applicant discusses differences between ELREXFIO and two other bsAbs approved for patients with RRMM, TECVAYLI®, and TALVEY™.

CMS continues to believe that the mechanism of action for ELREXFIO may be the same or similar to TECVAYLI; CMS approved a new technology add-on payment for FY 2024 for TECVAYLI. CMS believes both are bispecific antibodies with distinct binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T cell receptor. Although the applicant asserted that ELREXFIO has a unique complementarity-determining region (CDR) sequence (the region of the AB that recognizes and binds to target epitopes) that is critical to the mechanism of action because it impacts how the drug targets cancer cells, it is unclear how these differences result in a substantially different mechanism of action from TECVAYLI. In addition, the applicant asserted that ELREXFIO differs from TECVAYLI because the two are based on different immunoglobulin isotypes and with the lower effector function of IgG2, ELREXFIO should only activate T-cells in the presence of BCMA and thus should only stimulate an immune response in the tumor. CMS notes that this difference may relate to the risk of adverse events from ELREXFIO administration and may relate to an assessment of substantial clinical improvement and not substantial similarity. CMS also believes that both biologics may treat the same or similar disease (RRMM) in the same or similar patient population (patients who have previously received a PI, an IMiD, and an anti-CD38 antibody) and would be assigned to the same MS-DRG. In response to the applicant's claim EXREXFIO is different from TECVAYLI because the prescribing information includes a new subpopulation, patients that had received prior BCMA-directed therapy, CMS believes that the lack of inclusion of this population in the prescribing information for TECVAYLI does not specifically exclude this patient population. CMS notes that if it determines ELREXFIO is substantially similar to TECVAYLI, the newness period would begin on November 9, 2022, the date TECVAYLI became commercially available.

CMS also believes ELREXFIO may be substantially similar to TALVEY (the application for TALVEY is discussed below in section *k*). The applicant for TALVEY stated it is a biAb approved 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. TALVEY recruits CD3-expressing T cells to myeloma cells that express GPRC5D, resulting in activation of the T cell receptor pathway and lysis of GPRC5D-expressing MM cells. CMS notes that if ELREXFIO is determined to be substantially similar to TALVEY and not TECVAYLI, the newness period for ELREXFIO would begin on August 9, 2023 (the date TALVEY received FDA approval).

CMS is interested in information on how these technologies may differ from each other with respect to the substantial similarity and newness criteria, to help CMS determine whether ELREXFIO is substantially similar to TALVEY and/or TECVAYLI.

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

Substantial Clinical Improvement. The applicant stated that ELREXFIO is a substantial clinical improvement over existing technologies because it is a new treatment option for patients with RRMM who are refractory to or otherwise ineligible or unable to access existing therapies, it significantly improves clinical outcomes, has a manageable safety profile, and has a shorter hospitalization than TECVAYLI and TALVEY. The applicant provided nine studies to support its assertions and 12 background articles about RRMM and comparator technologies. A table in the proposed rule summarizes the applicant's assertions.

CMS discusses concerns with the information provided. CMS is concerned that the evidence presented that ELREXFIO does not identify a specific population that would benefit from ELREXFIO and would not be eligible for or benefit from other therapies for late-line RRMM. CMS notes the prescribing information for TALVEY also includes efficacy data for patients with prior BCMA-directed therapy exposure and reiterates that the lack of inclusion of this population in the prescribing information for TECVAYLI does not exclude the use of the drug in these patients. CMS also notes that other treatments, including TECVAYLI and TAKVEY, are also options for patients unable to access or receive CAR T-cell therapy. CMS also does not believe the evidence presented demonstrates that ELREXFIO is safer and has improved efficacy relative to other comparable therapies and is concerned that the claim that ELREXFIO offers fewer hospitalization days is not supported with evidence that this improves access to treatment and that other factors, such as age, may contribute to this finding.

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. CMS states 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 discusses 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 notes 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 requests 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 proposed 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 is 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 questions if the device constitutes a difference mechanism of action because it is Doppler ultrasound technology. CMS also believes 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 believes 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.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that FloPatch FP 120 meets the cost criterion.

CMS notes that the applicant limited their cost analysis to cases with a diagnosis of septicemia or severe sepsis but is concerned that cases using the technology would map to other DRGs and questions whether these cases should also be included in the cost analysis.

Substantial Clinical Improvement. The applicant stated that FloPatch 120 represents a substantial clinical improvement because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments; diagnoses a medical condition in a patient population where that condition is currently undetectable; and significantly improves clinical outcomes. The applicant provided five studies and seven background articles. A table in the proposed rule summarizes the applicant's assertions.

CMS discusses several issues related to the evidence supporting the substantial clinical improvement assertions including concerns that the study submitted are single-site studies based on a small patient population and do not provide evidence showing how the use of the technology to make a diagnosis affects the management of patients. CMS is interested in additional evidence that assesses the impact of FloPatch FP120 compared to existing technologies and demonstrates improved clinical outcomes.

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 proposed 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 seeks comments on whether reformatting the delivery mechanism for a drug represents a new mechanism of action for drug-device combination technologies and what factors should be considered 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.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded 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 proposed rule summarizes the applicant's assertions.

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

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 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 proposed 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 notes 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 states 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 notes that any payment would be contingent on CMS' coverage of the item and any restrictions on the coverage would apply.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that Lantidra meets the cost criterion. CMS notes that the cost analysis only included MS-DRG 639 (Diabetes without CC/MCC) and is 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.

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.

CMS discusses concerns with the information provided and requests 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 is

concerned about the small number of patients evaluated at year 6 and notes 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 is also interested in data demonstrating that Lantidra improves clinical outcomes including reduced mortality.

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.[32]

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

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 is 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 proposed 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

[32] 86 FR 25272 through 25282 and 87 FR 28244 through 28257

unresectable or metastatic melanoma who have been previously treated with at least one systemic therapy.

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

CMS discusses concerns about the information provided and notes that these are similar to concerns previously raised. CMS remains 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 is also concerned that the study population is not representative of the Medicare population. CMS is interested in additional information comparing AMTAGVI to existing treatments. CMS is also concerned that it is not clear how the impact of high-dose IL-2, which has been used to treat metastatic melanoma and is given as a post-treatment to AMTAGVI, impact the treatment effects and adverse effects reported 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 is 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 proposed 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, CMS believes that Lyfgenia may have the same or similar mechanism of action as Casgevy. Both gene therapies use modified autologous CD34+ HSPC therapies for the treatment of SCD. CMS notes that both may use the same or similar mechanism of action to reduce the amount of sickling hemoglobin to reduce and prevent VOEs, would be assigned to the same MS-DRG, and treat the same or similar patient population and disease. CMS notes that if it determines the technologies are substantially similar, it believes the newness period would begin on December 8, 2024 (the date both technologies received FDA approval for SCD).

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

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

CMS is concerned the information provided does 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 requests 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 is 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.

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. The online application posting contains the complete list of ICD-10-CM codes.

As summarized in a table in the proposed 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 is concerned that according to the 510(k) application, the Quicktome Software Suite may be equivalent to StealthViz, its predicate device. **CMS is 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.

CMS notes 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 is 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 observes 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 states 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 is 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 continues to be interested in comments related to determining newness for technologies that use AI, an algorithm, or software. Specifically, CMS is interested on the following issues:

- How these technologies may be considered for the purpose of identifying a unique mechanism of action;
- How updates to AI, an algorithm, or software would affect an already approved technology or a competing technology;
- Whether software changes for an already approved technology would be considered a new mechanism of action; and
- Whether an improved algorithm by competing technologies would represent a unique mechanism of action if the outcomes were the same as an already approved AI new technology.

Cost. CMS summarizes the analysis provided to demonstrate the technology meets the cost criterion. The applicant concluded that Quicktome Software Suite meets the cost criterion. CMS notes 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.

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 notes 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 proposed rule summarizes the applicant's assertions.

CMS discusses concerns with the information provided. CMS does 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 is interested in additional information demonstrating the direct impact of using the Quicktome Software Suite on reducing neurological or cognitive deficits post-surgery. CMS also questions whether the findings are generalizable to the Medicare population.

CMS continues to be interested in comments related to how it should evaluate substantial clinical improvement for technologies that use AI, an algorithm, or software, including issues related to algorithm transparency and how CMS should consider these issues in its assessment of substantial clinical improvement. CMS states that algorithm transparency refers to whether, and the extent to which, clinical users are able to access a consistent, baseline set of information about the algorithms they use to support their decision making and to assess such algorithms for fairness, appropriateness, validity, effectiveness, and safety.[33]

k. TALVEY™ (talquetamab-tgvs)

[33] Department of Health and Human Services (December 13, 2023). HHS Finalizes Rule to Advance Health IT Interoperability and Algorithm Transparency/HHS.gov, accessed 2/20/2024.

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. 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 proposed 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.

As previously discussed in section *d*, CMS is concerned that TALVAY may be substantially similar to ELREXFIO and may also have a similar mechanism of action as TECVAYLI. CMS notes that both ELREXFIO and TECVAYLI are bsAbs that use binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor. CMS questions how binding to a different protein, GPRC5D, on the tumor cells results in a different mechanism of action compared to BCMA targeting biAbs. In addition, although the applicant claimed that TALVEY results in a distinct adverse event profile, CMS considers this related to an assessment of substantial clinical improvement rather than substantial similarity.

CMS notes that if it determines that TALVAY is substantially similar to TECVAYLI, the newness period would begin on November 9, 2022 (the date TECVAYLI became commercially available). If CMS determines that TALVEY is substantially similar to ELREXFIO and not TECVAYLI, the newness period for TALVEY would begin on August 9, 2023 (the date TALVEY received FDA approval). **CMS is interested in information on how these technologies may differ with respect to the newness criterion**.

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

Substantial Clinical Improvement. The applicant stated that TALVAY meets the substantial clinical improvement criterion because it offers a treatment option for patients that cannot receive other therapies since its indication is less restrictive and it may be more immediately accessible than the BCMA CAR T-cell therapies. The applicant also stated that TALVEY improves clinical outcomes and provides a therapeutic option with a lower severe infection rate. The applicant provided eight studies; CMS notes that it considers 4 as background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS is concerned the applicant did not compare TALVEY and CAR T-cell therapy and is interested in evidence comparing that effects of these treatments on mortality and other clinical outcomes. CMS notes that conclusions based on a comparison of clinical trials are difficult to interpret because of the numerous confounding variables that potentially exist between the clinical trials. Thus, CMS questions whether adverse rates observed in the clinical trials of one drug can be directly compared to the rates in clinical trials of another drug. CMS is interested in additional evidence demonstrating that TALVEY significantly improves clinical outcomes compared to BCMA biAbs in heavily pre-treated naïve to prior biAbs and CAR T-cell therapy that adjusts for the effects of confounding factors.

l. Odronextamab, First Indication: Relapsed or Refractory Diffuse Large B-Cell Lymphoma (R/R DLBCL)

Regeneron Pharmaceuticals submitted an application for odronextamab, the first fully-human Cluster of Differentiation (CD) 20xCD3 bsAb with an IgG4-based structure in B Cell non-Hodgkin lymphoma (B-NHL) that is designed to simultaneously bind to two types of antigens, CD20 found on normal and cancerous B cells, and CD3 found on T-cells. This simultaneous engagement results in the activation of T cells, generating cytotoxic T-cells that destroy the targeted cells. The application for odronextamab for use in relapsed or refractory follicular lymphoma (R/R FL) is discussed below in section *m*.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP23101LHBUG.

Newness. The applicant anticipates a BLA decision from FDA for adults with R/R DLBCL after at least two prior therapies, including patients with or without prior CAR T-cell therapy before May 1, 2024. The applicant submitted a request for a unique ICD-10-PCS code for odronextamab. The online application posting provides a complete list of ICD-10-CM codes provided by the applicant. CMS believes the relevant codes to identify R/R DLBCL would be codes included in ICD-10-CM subcategory C83.3- (Diffuse large B-cell lymphoma).

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that odronextamab has a unique mechanism of action because it elicits an immune response through the blocking effect of the IgG4-based structure. The applicant also asserted that odronextamab is the only bsAb that shows efficacy in patients with R/R DLBCL with or without prior CAR T-cell therapy. The applicant noted that odronextamab may have a similar mechanism as EPKINLY™ and COLUMVI™ for the treatment of adult patients with R/R DLBCL after two or more prior lines of systemic therapy but odronextamab is the only fully human, IgG4-based bsAb in B-NHL.[34] The applicant also asserts that it treats a new patient subpopulation: adult patients with two or more prior therapies after transplantation or CAR T-cell therapy. CMS notes, however, the applicant stated that both EPKINLY and COLUMVI may also be used for patients with R/R DLBCL after disease progression post-transplant or CAR T-cell therapy.

CMS is concerned that odronextamab and EPKINLU and COLUMVI may all be substantially similar to each other as they may use the same or similar mechanism of action, would be

[34] CMS approved new technology add-on payments for FY 2024 for EPKINLY and COLUMVI (88 FR 58835).

assigned to the same MS-DRG and treat the same or similar population and disease. If CMS determines this technology is substantially similar to EPKINLY and COLUMVI, the newness period would begin on May 19, 2023 (the date EPKINLY received FDA approval).). **CMS is interested in information on how these technologies may differ with respect to the newness criterion**.

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

Substantial Clinical Improvement. The applicant stated that odronextamab meets the substantial clinical improvement criterion because it offers a treatment option for patients that are ineligible for CAR T-cell therapy and represents a substantial clinical improvement over existing technologies and improves clinical outcomes. The applicant provided three studies and nine background articles. A table in the proposed rule summarizes the applicant's assertions.

CMS discusses concerns with the information provided. CMS is concerned the applicant did not compare odronextamab with EPKINLY and COLUMVI. CMS reiterates its concern that conclusions based on a comparison of clinical trials are difficult to interpret because of the numerous confounding variables that potentially exist between the clinical trials. Thus, CMS questions whether the differences between these technologies equate to clinically meaningful improvements for patients treated with odronextamab as compared to rates for existing treatments. CMS also is concerned that the applicant did not present any evidence comparing long-term outcomes of odronextamab to existing technologies.

m. Odronextamab, Second Indication: Relapsed or Refractory Follicular Lymphoma (R/R FL)

Regeneron Pharmaceuticals submitted an application for odronextamab, the first fully-human Cluster of Differentiation (CD) 20xCD3 bsAb with an IgG4-based structure in B Cell non-Hodgkin lymphoma (B-NHL) that is designed to simultaneously bind to two types of antigens, CD20 found on normal and cancerous B cells, and CD3 found on T-cells. This simultaneous engagement results in the activation of T cells, generating cytotoxic T-cells that destroy the targeted cells. The application for odronextamab for use in R/R DLBCL is discussed above in section *l*.

The online application posting is available at https://mearis.cms.gov/public/publications/ntap/NTP231017YATW9.

Newness. The applicant anticipates a BLA decision from FDA for adults with R/R FL after at least two prior therapies before May 1, 2024. The applicant submitted a request for a unique ICD-10-PCS code for odronextamab. The online application posting provides a complete list of ICD-10-CM codes provided by the applicant. CMS believes the relevant codes to identify R/R FL would be codes included in ICD-10-CM subcategory for Follicular lymphoma: C82.0- through C82.6, C82.8- and C82.9.

As summarized in a table in the proposed rule, for the first criterion (same or similar mechanism of action), the applicant stated that odronextamab has a unique mechanism of action because it elicits an immune response through the blocking effect of the IgG4-based structure. The applicant also asserted that odronextamab is the only bsAb that shows efficacy in patients with

FL Grade 3b and offers consistent efficacy in other high-risk subgroups of patients with R/R FL. The applicant noted that odronextamab may have a similar mechanism as Lunsumio™ another IgG bsAb engaging CD3xCD20 therapy which treats the same population of R/R FL adult patients with two or more prior therapies; CMS approved the application for new technology add-on payments for Lunsumio in FY 2024.[35] CMS notes that the FDA-approved labeling for Lunsumio does not include any sub-population of patients within the eligible R/R FL adult patients.

CMS is concerned that odronextamab and Lunsumio may be substantially similar to each other as they may use the same or similar mechanism of action, would be assigned to the same MS-DRG and treat the same or similar population and disease. If CMS determines this technology is substantially similar to Lunsumio, the newness period would begin on December 22, 2022 (the date Lunsumio received FDA approval). **CMS is interested in information on how these technologies may differ with respect to the newness criterion**.

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

Substantial Clinical Improvement. The applicant stated that odronextamab meets the substantial clinical improvement criterion because it will expand access to heavily, pretreated, highly refractory patients for whom existing therapies are not adequate and significantly improves clinical outcomes relative to other technologies, including Lunsumio. The applicant provided three studies and eight background articles. A table in the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

CMS discusses concerns with the information provided. CMS reiterates its concern that conclusions based on a comparison of clinical trials are difficult to interpret because of the numerous confounding variables that potentially exist between the clinical trials. Thus, CMS questions whether the differences between these technologies equate to clinically meaningful improvements for patients treated with odronextamab as compared to rates for existing treatments. CMS is also interested in additional information comparing outcomes between odronextamab and existing therapies such as Breyanzi® which is also approved for patients with FL Grade 3B with RR disease after two or more lines of systemic therapy.

6. 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

[35] 88 FR 58844

CMS when the application is submitted.[36] 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 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). Of the remaining 14 applications, 12 of the technologies received a Breakthrough Device designation from FDA and two applications were designated as a QIDP. There were no applications for technologies approved through the LPAD pathway from FDA.

CMS provides background information on each application and proposes whether or not each technology would be eligible for new technology add-on payment for FY 2025 based on whether the technology meets the cost criterion. For the Breakthrough Devices Program, the new technology add-on payment is the less of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case. For QIDPs and LPADs, the new the new technology add-on payment is the less of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS-DRG payment for the case.

In addition, the publicly posted FY 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 proposed rule are available at https://mearis.cms.gov/public/publications/ntap. In addition, separate tables listing the ICD-10-CM codes, ICD-10-PCS codes, and/or MS-DRGs related to the analysis of the cost criterion for certain applications are available in Table 10 associated with the information posted on the CMS website.[37]

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

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.

[36] 88 FR 58948 through 58958

[37] 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 online application posting is available at https://mearis.cms.gov/public/publciations/ntap/NTP231017D5AA7.

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. 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 is 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. Subject to the applicant adequately address this concern, CMS would agree that the technology meets the cost criterion.

Based on preliminary information, the applicant anticipates the total cost of the Annalise Enterprise CTB Triage – OH to the hospital to be $371.37 per patient. The applicant stated that hospitals will acquire the technology on a subscription-based model, will an annual cost of $180,000 per hospital. The average cost per patient per hospital will vary based on the volume of NCCT cases for which the software is used. Additional information about how the cost per case was calculated is provided in the proposed rule. 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.

Subject to the applicant addressing CMS' cost analysis, CMS proposes to approve the Annalise Enterprise CTB Triage – OH for new technology add-on payments for FY 2025. CMS proposes the maximum new technology add-on payment for a case involving the use of the technology would be $241.39 for FY 2025 (65 percent of the average cost of the technology).

CMS continues to welcome comments as to the appropriate method to determine a cost per case for technologies sold on a subscription basis, including comments on whether the cost analysis should be updated based on the most recent subscriber data for each year for which the technology may be eligible for add-on payment.

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 anticipates a 510(k) decision from FDA before May 1, 2024. The applicant submitted a request for an ICD-

10-PCS code for the technology. 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.

Subject to the technology receiving FDA marketing authorization by May 1, 2024, CMS proposes to approve the ASTar System for new technology add-on payments for FY 2025. 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. CMS proposes the maximum new technology add-on payment for a case involving the use of the technology would be $97.50 for FY 2025.

c. cefepime-taniborbactam

Venatorx Pharmaceuticals submitted an application for cefepime-taniborbactam an investigational ß-lactam antibiotic/ß-lactamase inhibitor combination for the treatment of complicated urinary tract infections (cUTI). The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2310168RYEB.

The applicant stated that cefepime-taniborbactam received QIDP designation from FDA on February 4, 2022 for cUTI, complicated intra-abdominal infections (cIAI), hospital-acquired bacterial pneumonia (HABP), ventilator-associated bacterial pneumonia (VABP) and melioidosis. The applicant is seeking approval from FDA for the treatment of patients 18 years or older for cUTI, including pyelonephritis caused by designated susceptible gram-negative bacteria and cases with concurrent bacteremia. The applicant anticipates an NDA decision before July 1, 2024 and expects commercial availability immediately after FDA approval. The applicant submitted a request for a unique ICD-10-PCS code. The online posting contains the complete list of applicable ICD-10-CM codes. CMS notes that cefepime-taniborbactam is eligible for conditional approval for new technology add-on payments.

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

Subject to the technology receiving FDA marketing authorization as a QIDP by July 1, 2024, CMS proposes to approve cefepime-taniborbactam for new technology add-on payments for FY 2025. Ceferpime-taniborbactam is eligible for conditional approval, if the technology does not receive FDA marking authorization by July 1, 2024, provided it receives FDA marketing authorization before July 1, 2025. If FDA marketing authorization is received before July 1, 2025, the new technology add-on payment for cases using ceferpime-taniborbactam would be effective for discharges beginning in the first quarter after FDA market authorization is granted. If FDA marketing authorization is received on or after July 1, 2025, no new technology add-on payments would be made for FY 2025.

The applicant did not provide an estimate for the cost of cefepime-taniborbactam. A new technology add-on payment would be limited to the lesser of 75% of the average cost of the technology, or 75% of the costs in excess of the MS-DRG for the case.

d. 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. 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 proposes to approve the EVOQUE System for new technology add-on payments for FY 2025. Based on preliminary information the total cost of the system will be $49,000 per patient. CMS proposes that the maximum new technology add-on payment for a case involving the EVOQUE system would be $31,850 for FY 2025.

e. 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 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 proposes to approve the TAMBE Device for new technology add-on payments for FY 2025. 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 to a hospital is anticipated to be $72, 675. CMS proposes that the maximum new technology add-on payment for a case involving the TAMBE Device would be $47,238.75 for FY 2025.

f. 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.[38] The online application is available at 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 proposes to approve the LimFlow System for new technology add-on payments for FY 2025. The applicant anticipated the total cost to the hospital to be $25,000 per patient. CMS proposes that the maximum new technology add-on payment for a case involving the LimFlow System would be $16,250.

g. 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

[38] 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).

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 proposes to approve the Paradise Ultrasound Renal Denervation System for new technology add-on payments for FY 2025. The applicant anticipated the total cost to the hospital to be $23,000 per patient. CMS proposes that the maximum new technology add-on payment for a case involving the technology would be $14,950.

h. 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 proposes 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. CMS proposes that the maximum new technology add-on payment for a case involving the technology would be $6,337.50 for FY 2025 (65% of $9,750).

i. restor3d TIDAL™ Fusion Cage

Restor3d submitted an application for the TIDAL Fusion Cage, a porous cage used to aid in healing fractures, bone voids, absent bone, or surgical resections in conjunction with an intramedullary nail for tibio-talo-calcaneal (TTC) Fusions of the ankle. The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP2310167MCW9.

The restor3d TIDAL Fusion Cage System received Breakthrough Device designation from FDA on June 26, 2023 for the indication of tibiotalocalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle with critical size bone defect, in lieu of bulk allograft for various procedures. The applicant anticipates a 510(k) decision for an indication consistent with the Breakthrough Device designation before May 1, 2024. The applicant submitted a request for a unique ICD-10-PCS code. The list of applicable diagnosis codes is available on 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 proposes to approve the restor3d TIDAL Fusion Cage for new technology add-on payments for FY 2025. The applicant anticipated the cost of the restor3d TIDAL Fusion Cage to be $27,995 per patient. In addition, the application noted costs related to the Instrument Kit ($6,995), TTC Fusion Nail ($7,500) and Bone Graft ($1,500) and estimated the total cost to the hospital to be $43,990 for each procedure for each patient. CMS reiterated that when determining a new technology add-on payment, payment is based on the cost of the actual technology and not for additional costs related to the use of the device (86 FR 45146). CMS proposes that the maximum new technology add-on payment for a case involving the technology would only include the cost of the restor3d TIDAL Fusion CAGE and would be $18,196.75 for FY 2025 (65% of $27,995).

j. 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 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 proposes 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 expects the cost information prior to the final rule.

k. Transdermal Glomerular Filtration Rate (GFR) Measurement System utilizing Lumitrace

MediBeacon submitted an application for Transdermal Glomerular Filtration Rate (GFR) Measurement System utilizing Lumitrace for measuring GFR in patients with impaired or normal renal function during clinical conditions where the real time measurement of GFR (versus estimated measures) is clinically useful to patient management.[39] The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP23101671HAA.

The Transdermal GFR Measurement System received Breakthrough Device designation from FDA on October 16, 2018 for measuring GFR in patients with impaired or normal renal function. The applicant is seeking premarket approval for the same indication. The applicant stated that one ICD-10-PCS code (XT25XE5) may be used to identify procedures using the technology.

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

Subject to the Transdermal GFR Measurement System receiving FDA marketing approval consistent with its Breakthrough Designation by May 1, 2024, CMS proposes to approve the technology for new technology add-on payments for FY 2025. The applicant has not provided an estimate for the cost of the technology and CMS expects the applicant to submit cost information prior to the final rule.

l. 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 applicant anticipates a PMA decision for the same indication before May 1, 2024. 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.

[39] The applicant submitted an application for a FY 2024 new technology add-on payment but the applicant withdrew the application before the FY 2024 IPPS final rule (88 FR 58919).

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

Subject to the TriClip G4 System receiving FDA marketing approval consistent with its Breakthrough Designation by May 1, 2024, CMS proposes to approve the TriClip G4 for new technology add-on payments for FY 2025. The applicant anticipates 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. CMS proposes that the maximum new technology add-on payment for a case involving the technology would be $26,000 for FY 2025.

m. 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 proposes to approve the VADER Pedicle System for new technology add-on payments for FY 2025. The applicant anticipates the total cost of the VADER Pedicle System to be $43,340 per patient. This total cost is based on an average of five pedicle screws, two rods, and five set screws used for a spinal fusion procedure. CMS proposes that the maximum new technology add-on payment for a case involving the technology would be $28,242.50 for FY 2025.

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 proposes to approve ZEVETRA for new technology add-on payments for FY 2025. ZEVETRA is eligible for conditional approval, if the technology does not receive FDA marking authorization by July 1, 2024, provided it receives FDA marketing authorization before July 1, 2025. If FDA marketing authorization is received before July 1, 2025, the new technology add-on payment for cases using ZEVETRA would be effective for discharges beginning in the first quarter after FDA market authorization is granted. If FDA marketing authorization is received on or after July 1, 2025, no new technology add-on payments would be made for FY 2025.

The applicant anticipates the price for ZEVETRA will be $125 per vial. The recommended dosage varies depending on the condition being treated. For ABSSSI and CABP, the estimated average cost would be $3,750 for a 10-day therapy. For SAB, the estimated average cost would be $11,500. CMS proposes 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).

7. Proposed Change 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 could prove 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 agrees 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 proposes the following**:

- 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.

8. Proposed 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).[40]

CMS discusses 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 believes it is appropriate to propose an update of this policy.

CMS proposes 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 will 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.

[40] 88 FR 58948 through 58958

9. Proposed 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 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 proposes 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 notes 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.

CMS seeks comments on the proposal and whether it should make this proposed 75 percent add-on payment percentage available only to applicants that meet certain additional criteria, such as attesting to offering and/or participating in outcome-based pricing arrangements with purchasers (without regard to whether the specific purchaser availed itself of the outcome-based arrangement) or otherwise engaging in behaviors that promote access to these therapies at lower costs.

Regulatory Impact Analysis
For FY 2025, CMS proposes to continue 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 $416 billion dollars.

CMS is proposing to approve 14 technologies under the alternative pathway for FY 2025 new technology add-on payments. Based on preliminary information from the applicants, CMS estimates that the total payment for these technologies, if approved, would be approximately $172.7 million for FY 2025. 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 $167 million. This

estimate does not include the new technology add-on payments for three technologies that are part of the Breakthrough Device program because cost or volume information was not included in their applications.

CMS has not determined the potential payment impact of the 19 technologies that applied under the traditional pathway as it has not yet determined if they meet the criteria for new technology add-on payments for FY 2025.

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 weighted (by hours) 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 (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 is proposing to use these revised delineations to calculate the IPPS wage index beginning in FY 2025.

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 proposes 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 a metropolitan statistical area (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 is proposing to continue to use 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 proposes to adopt the planning regions as county equivalents for wage index purposes. The proposed rule includes an unnumbered table that shows the current county for each provider number in Connecticut, its current county and CBSA and its proposed planning area and CBSA.

Urban Counties Becoming Rural. CMS' analysis shows that a total of 53 counties (and county equivalents) and 33 hospitals that are currently part of an urban CBSA becoming rural beginning in FY 2025 under the revised OMB delineations. Other than "Lugar" hospitals (explained in the next paragraph) CMS is proposing 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 that a total of 54 counties (and county equivalents) and 24 hospitals that are currently rural becoming part of an urban CBSA beginning in FY 2025 under the revised OMB delineations. CMS is proposing 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 rural 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 and Medicare Dependent Hospital) 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 hospital designation is terminated).

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 is not proposing any additional transition for these hospitals.

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.

C. Worksheet S-3 Wage Data

The proposed rule wage index values are based on data from FY 2021 submitted cost reports. CMS is not proposing 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 presents 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.

The proposed rule calculations of the FY 2025 wage index are based on wage data of 3,075 hospitals. The data file used to construct the proposed wage index includes FY 2021 data submitted to CMS as of January 26, 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 status as of January 24, 2024.

General wage index policies are unchanged from prior years. CMS notes that it proposes to exclude 69 providers due to aberrant wage data that failed edits for accuracy. However, if data aberrancies for these providers are resolved timely, CMS will include data from these providers to set the final rule FY 2025 wage indexes.

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 proposed 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 2025 wage index timetable go to: FY 2025 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 proposed rule includes a detailed listing of these steps. CMS calculates an unadjusted national average hourly wage of $54.80.

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%

Comparison of Occupational Mix Adjusted to Unadjusted Wage Index			
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 (2,950 of 3,075) used to determine the FY 2025 proposed 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) Medicare Geographic Classification Review Board (MGCRB) reclassifications only for the wage index; 2) Urban to rural reclassifications for all IPPS purposes; 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. 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 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.

There are 610 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2025. There are 237 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2023 that will continue for FY 2025. There are 316 hospitals approved for wage index reclassification in FY 2024 that may continue for FY 2025. CMS indicates that there will be 1,163 hospitals in MGCRB reclassification status for FY 2025 (with 248 of these hospitals reclassified back to their home area).

The deadline for withdrawing or terminating a wage index reclassification for FY 2025 approved by the MGCRB is 45 days from the date of display of the FY 2025 proposed rule. This is a change from prior year policies that permitted withdrawing or terminating a wage index reclassification up until 45 days from publication of the proposed rule in the *Federal Register*.

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.

CMS does not provide the deadline for withdrawing or terminating a wage index reclassification. The last business day before 45 days from proposed rule display is May 24, 2024.

MGCRB reclassifications are effective for 3 fiscal years. Because hospitals that have been reclassified beginning in FY 2023, 2024, or 2025 were reclassified based on the current labor market delineations, if CMS adopts the revised OMB delineations beginning in FY 2025, the CBSAs to which they have been reclassified, or the CBSAs where they are located, may change. CMS details its proposals for how it will assign reclassified hospitals based on the new OMB CBSA delineations:

Urban Counties Becoming Rural or Rural Counties Becoming Urban. CMS indicates that some rural hospitals are reclassified to an area to which they would now be geographically located if it implements the new OMB CBSA delineations. In this case, CMS proposes to maintain 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.

The proposed rule identifies six hospitals that are reclassified to an urban area that would become rural under the proposed OMB delineations based on the 2020 Census. CMS indicates there would be no comparable area to where these hospitals could be reclassified, and it proposes to terminate their reclassification status (although one would be a home area reclassification and its wage index would be unaffected).

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 proposes 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 proposed 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).

Hospitals Reclassified to CBSAs where One or More Counties Move to a New or Different Urban CBSA. CMS is proposing 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 proposes 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 proposed 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 proposes to use the county to which the majority of hospitals in the group reclassification are geographically closest.

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 is proposing 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.

Instructions to Request Reassignment of Reclassified CBSA. Hospitals with current reclassifications are encouraged to verify area wage indexes in Table 2 in the appendix of the proposed rule, and confirm that the CBSAs to which they have been reclassified for FY 2025 would continue to provide a higher wage index than their geographic area wage index. As noted earlier, if a hospital is dissatisfied with its proposed geographic reclassification assignment, it may withdraw that assignment no later than 45 days from date of the proposed rule display (May 24, 2024 which is the last business day before this deadline).

The hospital may request reassignment to an alternate CBSA provided that they can document meeting the requisite proximity criteria for reassignment to an alternate CBSA that contains one or more counties (or county-equivalents) from the CBSA to which they are currently reclassified. For county-wide group reclassifications, all hospitals in the county must request the same reassignment.

Changes to the wage index by reason of reclassification withdrawals, terminations, wage index corrections, appeals and the CMS review process will be incorporated into the final FY 2025 wage index values. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, CMS refers readers to 42 CFR §412.273.

2. 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 106 percent criterion is applied to other rural hospitals within the same state, not to other hospitals in the area where the hospital is geographically located. This policy applies for the first time for geographic reclassifications applications to the MGCRB due September 1, 2021 effective October 1, 2022. CMS adopted this policy in response to adverse litigation against the agency in *Bates County Memorial Hospital v. Azar*.

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 Sole Community Hospitals (SCH), Medicare Dependent Hospital (MDH) or Rural Referral Center (RRC) status.

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 is proposing a minor technical change to the regulations to ensure that its policy always links to the latest HRSA update of the RUCA designations.

CMS is also proposing 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 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 has in the past. CMS notes that its proposed 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.

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).

Under the proposed 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 is also proposing 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 is proposing that 17 of 53 counties that that were previously urban qualify to be Lugar counties. CMS proposes 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.

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 proposed rule FY 2025 wage index for 494 urban hospitals requiring a budget neutrality adjustment factor of 0.985868 (-1.41 percent) applied to hospital wage indexes.

CMS is not proposing 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.

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.

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 $52 million in IPPS operating payments due to the frontier floor.

Outmigration Adjustment. CMS proposes 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 $55 million to 196 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. In the FY 2025 proposed rule, CMS proposes to continue this policy 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 indicates 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 indicates 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. For this reason, CMS is proposing to extend the policy for 3 more years through FY 2027. This proposal 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 0.8879. CMS is proposing to apply 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 pending 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 and remanded the policy to the agency. CMS has appealed the court's decision. A decision in that appeal is pending. CMS does not indicate what it would do in the final rule if the circuit court upholds the district court decision and finds the low wage index policy to be unlawful.

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 -0.28 percent for FY 2025.

H. Wage Index Tables

Proposed rule wage index tables 2, 3 and 4 can be found at: FY 2025 IPPS Proposed Rule Home Page | CMS. Select #2 under FY 2025 Proposed 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 the aggregate DSH payments that would be made under section 1886(d)(5)(F) of the Act without application of the ACA;
- Factor 2: The ratio of the percentage of the population uninsured in a base year prior to ACA implementation to the percentage of the population uninsured in the most recent period; and
- Factor 3: A hospital's uncompensated care costs for a given time period relative to uncompensated care costs for that same time period for all hospitals that receive Medicare DSH payments.

The statute precludes administrative or judicial review of the Secretary's estimates of the factors used to determine and distribute UCP. UCP payments are only made to hospitals eligible to receive DSH payments that are paid using the national standardized amount (SCHs paid on the basis of hospital specific rates, hospitals not paid under the IPPS and hospitals in Maryland paid under a waiver are ineligible to receive DSH and, therefore, UCP payments).

B. Uncompensated Care Payments

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

OACT's January 2024 Medicare estimate of DSH payments for FY 2025 is $13.943 billion. **The proposed Factor 1 amount is seventy-five percent of this amount, or $10.457 billion.** The proposed Factor 1 for 2025 is about $442 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 proposed 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	0.9937	0.9607	12.873
2023	1.043	0.945	0.990	1.0503	1.0250	13.195
2024	1.031	0.977	1.005	1.0228	1.0349	13.656
2025	1.026	0.986	1.005	1.0046	1.0210	13.943

- 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 the total inpatient hospital discharges and the IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in other columns (such as the difference between the total inpatient hospital discharges and the IPPS discharges and the 20 percent add-on for COVID-19 discharges). The "other" column also includes a factor for Medicaid expansion due to the ACA.[41]

[41] The "Other" column also includes the estimated impacts on Medicaid enrollment; estimated change of +8.3 percent in FY 2022, +5.1 percent in FY 2023, -13.9 percent in FY 2024, and -4.3 percent in FY 2025.

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	3.0	-0.4	0.0	2.6

2. Proposed 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 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.[42]

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 8.5 percent and 8.8 percent, respectively. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates the proposed 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: 8.5 percent.
- Percent of individuals without insurance for CY 2025: 8.8 percent.
- Percent of individuals without insurance for FY 2025 (0.25 times 0.085) + (0.75 times 0.088): 8.7 percent

Proposed Factor 2 = 1-|((0.087-0.14)/0.14)| = 1 - 0.3786 = 0.6214 (62.14 percent)

CMS calculated Factor 2 for the FY 2025 proposed rule to be 0.6214 or 62.14 percent, and the uncompensated care amount for FY 2025 to be $10.457 billion x 0.6214 = $6.498 billion which is about $560 million more than the FY 2024 UCP total of about $5.938 billion; the percentage increase is 9.4 percent. The table below shows the Factor 1 and Factor 2 estimates for FY 2024 and the proposed factors for FY 2025.

[42]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

FY 2025 Proposed Change in UCP

($ in billions)

	FY 2024	FY 2025	Change	% Change
Factor 1	$10.015	$10.457	$0.442	4.4%
Factor 2	0.5929	0.6214	0.0285	4.8%
UCP*	$5.938	$6.498	$0.560	9.4%

* The UCP totals do not include supplemental payments for IHS/Tribal hospital and Puerto Rico hospitals. In FY 2025, these payments accounted for $91.1 million.

3. Proposed 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 is not proposing 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 plans 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. It is using the December 2023 HCRIS extract to calculate Factor 3 for the proposed rule, but intends to use the March 2024 update of HCRIS to calculate the final Factor 3 for the final rule.

CMS describes the steps it used to calculate Factor 3 and how it calculated uncompensated care payments for new and newly merged hospitals. Consistent with its past policy, a newly merged hospital's final uncompensated care payment would be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 would be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year.

Consistent with the methodology used in prior years, CMS provides details on the methodology it uses to trim CCRs for hospitals with aberrant uncompensated care cost data. Specifically, the statewide average CCR was applied to a small number of hospitals with potentially aberrant data; this included 10 hospitals for FY 2019 reports, 8 hospitals for FY 2020 reports, and 8 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)).

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

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

For FY 2025 and subsequent fiscal years, CMS proposes to calculate the per-discharge amount for uncompensated care payments using the average of the most recent 3 years of discharge data. CMS proposes for FY 2025 to use an average of FY 2021, FY 2022, and FY 2023 historical discharge data.[43]

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

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

In the case of hospital mergers, CMS publishes a table on the CMS Web site, in conjunction with the issuance of each fiscal year's proposed and final IPPS rules, containing a list of the mergers known to CMS and the computed uncompensated care payment for each merged hospital. Hospitals have 60 days from the date of public display of each year's proposed rule to review the tables and notify CMS in writing of any inaccuracies.[44]

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[43] 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.

[44] Comments on the list of mergers can be submitted to the CMS inbox at Section3133DSH@cms.hhs.gov. It notes that this inbox is not intended for Worksheet S-10 audit process related emails, which should be directed to the MACs.

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

As discussed in section III.B. of the preamble of this proposed rule, CMS proposes to implement 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 would have an impact on the calculation of Medicare DSH payment adjustments to certain hospitals. Specifically, hospitals with less than 500 beds that are currently in urban counties that would become rural under this proposal to adopt 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 if it finalizes the proposal to adopt 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.

D. 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 indicates 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).

E. Payment Impacts

The regulatory impact analysis presented in Appendix A of the proposed rule includes the estimated effects of the changes to uncompensated care payments and supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals for FY 2025 across all hospitals by geographic location, number of beds, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,422 hospitals that are projected to be eligible for DSH in FY 2025.

The proposed total amount of uncompensated care payments ($6.498 billion) combined with supplement payments for IHS/Tribal hospitals and Puerto Rico hospitals ($91.1 million) is $6.589 billion. This is a 9.43 percent increase from FY 2024 payments (about $568 million). Changes in FY 2024 payments are driven by proposed increases in Factor 1 and Factor 2.

The variation in the distribution of payments by hospital characteristics is largely dependent on a given hospital's reported uncompensated care costs used in the Factor 3 computation and whether the hospital is eligible to receive the supplemental payment. A percent change in payments lower than 9.43 percent indicates that hospitals within that category are projected to experience a smaller increase compared to the average for all hospitals, and a percent change greater than 9.43 percent indicates the category of hospitals is receiving a larger increase in payments than the average for all hospitals. The table below shows impacts for selected categories of hospitals, including proposed uncompensated care payments and supplemental payments combined.

Hospital Type	Dollar Difference FY 2024-FY 2025 ($ in millions)	Percent Change (%)
All Hospitals	568	9.43
Urban	523	9.20
Large Urban	325	10.44
Other Urban	198	7.70
Rural	45	13.47
Beds: 0-99 (Urban)	37	16.33
Beds: 250+ (Urban)	367	8.79

Hospital Type	Dollar Difference FY 2024-FY 2025 ($ in millions)	Percent Change (%)
Beds: 100 to 249 (Rural)	20	16.89
New England (Urban)	11	6.89
Middle Atlantic (Urban)	54	8.34
South Atlantic (Urban)	16	2.44
East South Central (Urban)	125	8.45
West North Central (Urban)	29	7.81
West South Central (Urban)	171	13.83
Pacific (Urban)	59	11.25
Middle Atlantic (Rural)	3	17.40
Pacific (Rural)	2	29.16
Puerto Rico	7	9.33
Teaching with 100 or more residents	226	9.61
Teaching with fewer than 100 Residents	175	8.20
Non-Teaching	167	10.88
Voluntary	308	8.85
Proprietary	82	9.52
Government	178	10.60

Under this proposal, rural hospitals are projected to receive an increase in uncompensated care payments of 13.47 percent compared to an increase in UCP payments of 9.2 percent for urban hospitals in FY 2025 compared to FY 2024. Urban hospitals are projected to receive smaller than average increases in uncompensated care payments and supplemental payments in most regions. Teaching hospitals with fewer than 100 residents are projected to receive a smaller than average payment increase of 8.20 percent. Nonteaching hospitals and teaching hospitals with 100 or more residents are expected to receive larger than average increases of 10.88 and 9.61 percent, respectively. Voluntary ownership hospitals are expected to receive a smaller than average increase of 8.85 percent, 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.[45] 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-

[45] 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 is proposing to add new MS-DRGSs 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 is proposing 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.

B. Inpatient Hospital Update

The proposed 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) 4th quarter 2023 forecast (with historical data through the 3rd quarter of 2023) for the hospital market basket is 3.0 percent. IGI's 4th quarter 2023 forecast of total factor productivity is 0.4 percent.

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

FY 2023	Scenario 1: Hospital Submitted Quality Data and is a Meaningful EHR User	Scenario 2: Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Scenario 3: Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Scenario 4: Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.75	-0.75
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.25	0.0	-2.25
Productivity Adjustment	-0.4	-0.4	-0.4	-0.4
Applicable Percentage Increase	**2.6**	**0.35**	**1.85**	**-0.4**

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

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 proposes 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 1.7764 (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)	1.49655
2. Middle Atlantic (PA, NJ, NY)	1.5563
3. East North Central (IL, IN, MI, OH, WI	1.6427
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7216
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6306

Census Region	CMI Value
6. East South Central (AL, KY, MS, TN	1.59315
7. West South Central (AR, LA, OK, TX	1.7814
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7804
9. Pacific (AK, CA, HI, OR, WA)	1.7821

The median regional CMIs in the proposed rule reflect the December update of the FY 2023 MedPAR containing data from bills received through December 2023. A hospital seeking to qualify as an RRC should get its hospital-specific CMI value (not transfer-adjusted) from its Medicare Administrative Contractor.

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 2026	15 miles	3,800 Total Discharges	Total Discharges<500=25%; Declining Linear Adjustment up to 3,800 discharges applied to each Medicare Discharge
CY 2026 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 hospital qualified for the LVH adjustment.

CMS is proposing 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 proposes 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 is proposing 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 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, 2024 by the September 1, 2024 deadline. 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.

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 payment methodology. 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, at this time, CMS is advising hospitals of the MDH program expiration and the potential to ameliorate the associated reduction in payment through becoming an SCH.

When the MDH program was set to expire at the end of FY 2012, CMS revised the SCH regulations to allow MDHs to apply for SCH status in advance of the expiration of the MDH program. These regulations allow SCH status to begin the day following the MDH program's expiration. In order for an MDH to receive SCH status effective 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, 2023 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.

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 they train.

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

For 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 requires that the Secretary shall initiate an application process to distribute 200 residency positions effective July 1, 2026. At least 100 of the positions made available shall 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 that required CMS to distribute an additional 1,000 resident positions. CMS' proposals follow the model it established for implementing section 126 of the CAA, 2021. The statute prohibits administrative and judicial review of CMS' implementation.

Consistent with its CAA, 2021 policies, CMS proposes 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 details all of the elements that will be required in the MEARIS application.

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 is proposing 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.

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.

- Reference Resident Level Exceeds the Hospital's Resident Limit. The "reference resident level" refers to 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).

- 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.

- Hospitals Serves Patients from Health Professional Shortage Areas (HPSA). To qualify under this criterion, residents in the hospital's residency program 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 is proposing that the program must be a psychiatry program or a subspecialty of psychiatry.

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 proposes that "a psychiatry or a psychiatry subspecialty" will include psychiatry or any of its subspecialties listed at following website: Overview (acgme.org).

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 to each qualifying hospital rounded to two decimal places for awarding a partial resident position.

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.

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, CMS is proposing that any resident positions awarded to a rural hospital must be used to expand an existing residency that is no longer with its 5 year newness period.

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 indicates 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 of the CAA, 2021 positions in years 4 and 5, CMS is proposing to prioritize hospitals qualifying under category 4 regardless of HPSA score.

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 is proposing 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.

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, CMS proposes to use the PRA for all other residents to pay for the additional residents awarded under section 4122(a) of the CAA, 2023.

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(a) of the CAA, 2023 from being included in these affiliation agreements for five years.

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 is using 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 is proposing to further 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 proposes 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 indicates that the 90 percent criterion may be more difficult for small or rural-based programs to meet. For this reason, CMS requests 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 is not proposing a specific threshold but suggests 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 indicates 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 is soliciting 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 solicits comments on whether it would make sense to define a similar period of time (for example, 10 years or 5 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 raises a similar concern about whether special provisions are necessary for small or rural-based programs and solicits comment on whether these thresholds should be different for programs that are accredited fewer than 16 positions.

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.[46] 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 requests comments on this issue.

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 requests comments on the issue.

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 McLaren St. Luke's Hospital Located in Maumee, OH (CCN 360090) and South City Hospital, located in St. Louis, MO (CCN 260210):

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
360090	McLaren St. Luke's Hospital	Maumee, OH	47580	May 9, 2023	14.93	14.93
260010	South City Hospital	St. Louis, MO	41180	November 18, 2023	67.54	74.00

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 July 9, 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 is not proposing 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

[46] 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.

(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.

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 proposes to use the 4th quarter 2023 update of the 2021 HCRIS projected forward two years to estimate 2023 payments. For 2023, CMS will be distributing $60 million in nursing and allied health education MA payments with an offset of 2.73 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.

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 where the hospital has no costs for the CAR-T product from the relative weight calculation.

CMS is proposing to adopt these same policies for FY 2025. Using the FY 2023 data for determining FY 2025 the FY 2025 IPPS relative weights, the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($116,831) were 34 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($342,684). Accordingly, CMS is proposing to adjust the payment for MS-DRG 018 by applying an adjustor of 0.34 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 will provide 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 is proposing 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.

J. Maintaining Access to Essential Medicines

1. Overview

The proposed rule indicates 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 proposes 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 proposal 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 proposes 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 proposes 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' proposed 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. Proposed List of Essential Medicines

CMS proposes 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 proposes 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 seeks 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 is requesting 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 requests 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 is proposing that eligible hospitals for this policy are those with 100 beds or fewer and are independent. The 100 bed criterion is consistent with the MDH provisions that identify a small hospital as under 100 beds. CMS proposes that the 100 bed determination for eligibility for the policy will be same cost reporting period during which the hospital is seeking the separate payment. CMS proposes that an "independent hospital" is one that is not part of a chain organization as defined for purposes of hospital cost reporting.

The proposed rule indicates that 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 requests comment 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 is proposing that eligible hospitals maintain a 6 month buffer stock of essential medicines in shortage although it requests comment on whether to transition to this policy over two years. During the first year, eligible hospitals would be required to maintain a 3 month buffer stock. During the second year, eligible hospitals would be required to maintain a 6 month buffer stock.

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' proposal will 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 requests comment on a number of items that may be considered allowable costs for the proposed 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 is proposing 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 the 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.

K. Hospital Readmissions Reduction Program (HRRP)

The HRRP is established under section 1886(q) of the Act.[47] 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 are no proposals or updates in the proposed rule for the HRRP.
The estimated percentage of hospitals that will be penalized under the HRRP for the FY 2025 HRRP is 82.52 percent (2,356 of the 2,855 hospitals), with total penalties for all such penalized hospitals estimated to be 0.44 percent of total payments for such hospitals.[48]

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

In the rule, CMS proposes to:

- Adopt the updated Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (and scoring modifications) beginning with the FY 2030

[47] 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.

[48] See Table I.G.7.-01 in Appendix A of the proposed rule. CMS bases its analysis on the proportion of dual-eligible stays among Medicare FFS and managed care stays between July 1, 2019 and June 30, 2022 (i.e., the FY 2024 HRRP's applicable period), which is the most recently available data at the time of publication of the rule. CMS plans to include in the FY 2025 IPPS/LTCH PPS final rule an updated estimate of the financial impact for the FY 2025 HRRP applicable period (July 1, 2020 through June 30, 2023).

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 proposed 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.

- Modify the scoring of the HCAHPS Survey measure from the FY 2027 through FY 2029 program years so that hospitals would be 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 dimensions of the survey that would remain unchanged for the FY 2027 through FY 2029 program years. These updated scoring modifications are proposed in section IX.B.2.f of the proposed 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 is shown in Table 16 of the rule. The estimates were calculated using the FY 2024 program year's Total Performance Scores. The analysis shows that for the 2,474 hospitals an average net percent positive payment adjustment of 0.136 percent. There is no estimated change in burden associated with the proposals since the proposals use data that are already submitted to CMS for other quality programs or payment purposes (or that will be required to be submitted to CMS under other quality programs, as proposed in the rule).

1. Background

a. Program Overview[49]

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.

[49] 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.

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 $1.7 billion, based on the December 2023 update of the FY 2023 MedPAR file.[50]

2. Previously Adopted Quality Measures for the HVBP Program

No changes are proposed to the FY 2025 and FY 2026 measure sets.

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[51] #	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			

[50] The agency is publishing proxy value-based incentive payment adjustment factors in Table 16 of the rule, calculated using the FY 2024 program year's TPSs (the most recently available scores available to hospitals to review). The proxy adjustment factors will not be used to adjust hospital payments. CMS intends to provide updated tables in the FY 2025 IPPS/LTCH PPS final rule (and on the CMS website in Fall 2024) that will reflect the March 2024 update to the FY 2023 MedPAR file and the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2025 HVBP.

[51] Consensus-based entity identifier number for endorsed measures.

Measure	CBE[51] #	2025	2026-2030
Clinical Outcomes 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	0166	X	X
3-Item Care Transition measure (CTM)	0228		
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 proposed rule, several updates are proposed with regard to the HCAHPS Survey in the Hospital VBP Program, including modifying scoring while the updated version of the measure would be adopted in the Hospital IQR Program for the FY 2027 through FY 2029 program years. CMS is also proposing to adopt the updated version of the measure and to modify 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 proposed HCAHPS Survey dimensions for the HVBP Program.

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.

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										

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
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 proposed rule, CMS proposes that for the FY 2027, FY 2028, and FY 2029 program years, it would only score on the 6 dimensions of the HCAHPS Survey that would be unchanged from the current version. In section IX.B.2.g of the rule, CMS proposes to adopt 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 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 proposed rule.

As described in section IX.B.2.g of the rule, the agency is also proposing to adopt 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 proposes a method to enable hospitals to report a single survey for both Programs. Under section IX.B.2.f of the rule, CMS proposes 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 would be excluded while the proposed updated survey would be publicly reported under the Hospital IQR Program for one year, as required by statute. Scoring would be modified to score hospitals only on the following 6 HVBP Program dimensions of the survey (which would 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 would be modified such that the achievement points (0-10) and improvement points (0-9) would be calculated for each of the 6 remaining dimensions, the larger of which would be summed up across the dimensions, resulting in a base score of 0-60 points (as compared to 0-80 points). That score would 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) would be calculated without change and added to the normalized base score (as is currently) for a total score that ranges from 0-100 points.

M. Hospital-Acquired Conditions (HAC) Reduction Program

CMS does 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 2,945 hospitals, 736 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[52]

CMS does not propose any additions to or removals from the measure set. There are currently the following 6 measures in the HAC Reduction Program for FY 2025 and subsequent years:

- 5 Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) hospital-associated infection (HAI) measures:

[52] 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.

    - 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).

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. Proposed FY 2025 Budget Neutrality Adjustment

CMS proposes to continue to use its general budget neutrality methodology applied in previous years. It identifies 23 hospitals currently participating in the program. Using data from "as submitted" cost reports with a cost report end date in CY 2022, CMS estimates that the demonstration program will cost $49,522,206, which will be incorporated into the budget neutrality offset adjustment for FY 2025.

As of the date of publication of the proposed rule, not all the finalized cost reports for the 26 hospitals that completed cost reporting periods beginning in FY 2019 under the demonstration payment methodology are available; all those finalized cost reports are needed to reconcile actual and estimated costs of the demonstration for that fiscal year. CMS expects all of those finalized cost reports to be available by the time of the final rule; thus, it proposes to include the difference

between the actual and estimated costs of the demonstration for FY 2019 as determined from finalized cost reports within the budget neutrality offset amount in the final rule.

The total budget neutrality adjustment for FY 2025 is estimated to be $49,522,206. The overall amount may change if there are any revisions before the final rule to the data used to formulate this estimate, and CMS expects to revise the budget neutrality offset amount when it calculates the actual costs of the demonstration for FY 2019 upon receipt of all finalized cost reports for that fiscal year.

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 is proposing a national capital Federal rate of $516.41 for FY 2025.

Update Factor:

For FY 2025, CMS will increase the national capital Federal rate by 3.0 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 less real case mix nets to 0.0 percent, CMS is not proposing to apply an 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 proposing to make 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 proposing to make 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		2.5
Intensity		0.0
Case-Mix Adjustment Factors:		

CMS FY 2025 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE		
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		3.0

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 percent -0.21 percent (0.9577/0.9598-1). Thus, the outlier adjustment decreases the FY 2025 capital federal rate by 0.21 percentage points.

The geographic adjustment factor (GAF) is a function of the hospital wage index. As such, CMS has been reflecting changes to the wage data as well as its policy changes to the wage index (increasing the wage indexes that are below the 25th percentile and providing a 5 percent cap on reductions to certain wage indexes) in the budget neutrality adjustment.

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

- Isolate the impact of just the change to the wage data (e.g., without the increase to the lowest quartile wage indexes or the 5 percent cap on reductions to the wage index).
- Isolate the impact of the increase in the lowest quartile wage indexes and 5 percent cap on wage index decreases.

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

To remove the prior year budget neutrality adjustment for the increase in the lowest quartile wage index and the 5 percent cap on the wage index, CMS proposes to divide the capital Federal rate by 0.9964, which was the effect of these policy adjustments in FY 2024.

CMS then proposes to continue with its 2-step approach to determining GAF budget neutrality as follows:

- Isolate the impact of just the change to the wage data (e.g., without the increase to the lowest quartile wage indexes or the 5 percent cap on reductions to the wage index). CMS

determined a budget neutrality adjustment of 1.0029 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 0.9943 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 0.9969. The incremental adjustment for the 10 percent cap on reductions to the DRG relative weights is 0.9996. The total adjustment is 0.9965 (0.9969 x 0.9996) 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 0.9994 (0.9965 x 1.0029, or -0.06 percent). The quartile/cap adjustment of 0.9943 (or -0.57 percent) is then applied.

Proposed Rule Calculation:

The proposed rule includes the following chart to show how each of the factors and adjustments affect the computation of the FY 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	1.03	1.03	3.0
GAF/DRG Adjustment Factor*	N/A	0.9994	0.9994	-0.06
Quartile/Cap Adjustment Factor**	0.9964	0.9943	0.9979	-0.21
Outlier Adjustment Factor**	0.9598	0.9577	0.9979	-0.21
Capital Federal Rate	$503.83	$516.41	1.0250	2.50

* 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 0.9994 (or -0.06 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 0.9979 (or -0.21 percent). The net change to the Quartile/Cap adjustment is 0.9943/0.9964 or 0.9979 (-0.21 percent).

Considering the update factor and the budget neutrality adjustments, CMS is proposing to adopt a national capital Federal rate for FY 2025 of $516.41, a 2.5 percent increase over the FY 2023 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 are also paid reasonable costs subject to a limit.

The annual update to the TEFRA limit is based on IGI's 2023 4th quarter forecast of the hospital market basket for FY 2025 with historical data through the 3rd quarter of 2023 and is 3.0 percent.

B. Critical Access Hospitals (CAHs)

The Frontier Community Health Integration Project (FCHIP) Demonstration[53] is designed to develop and test new models of care by permitting enhanced reimbursement for telemedicine, nursing facility, ambulance, and home health services. Ten CAHs in Montana, Nevada, and North Dakota participated in the 3-year demonstration beginning August 1, 2016. Section 129 of the CAA, 2021 extended the FCHIP for another five years in the cost reporting year beginning January 1, 2022. Among the 10 CAHs eligible to participate in the demonstration project in the extension period, five have elected to continue their participation.

The demonstration was intended to be budget neutral through reduced transfers and admissions to other health care providers that offset any increase in payments under the waivers. However, if that is not the case, CMS would recoup any additional expenditures attributable to the FCHIP through a reduction in payments to all CAHs nationwide beginning with FY 2020. CMS found that the initial period of the demonstration was budget neutral and no reduction in payments to CAHs was necessary.

For the extension period, CMS proposed the same application of budget neutrality if the demonstration is found to increase costs—through an adjustment to payments for all CAHs nationwide. However, CMS adopted a policy to make this adjustment in a single fiscal year rather than over three fiscal years as was its policy for the initial period (although the budget neutrality adjustment was unneeded for the initial period). CMS believes a one-year period is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data and/or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.
CMS is not proposing to make any budget neutrality adjustment in FY 2025 for the FCHIP demonstration project.

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

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

A. Background

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 proposes 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.[54] 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 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

[54] 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.

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, and CMS proposes to revise paragraph (4) of §412.23(e) to codify this policy that has heretofore been explicitly stated in the preamble of certain final rules. It proposes other technical changes (reordering and revising provisions in paragraphs (3) and (4) of §412.23(e)) to clarify which provisions apply to existing LTCHs and which apply to hospitals seeking classification as LTCHs. The agency states that its proposed revisions do not reflect any change to current policies.

Summary of Proposed Changes to LTCH PPS Rates for FY 2025*	
Standard Federal Rate, FY 2024	$48,116.62
Proposed Rule Update Factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+2.8%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+2.8% (1.028)
Net update LTCHs not reporting quality data	+0.8% (1.008)
Proposed Rule Adjustments	
Proposed area wage index budget neutrality adjustment	0.9959347
Proposed Standard Federal Rate, FY 2025	
LTCHs reporting quality data ($48,116.62 x 1.028 x 0.9959347)	$49,262.80
LTCHs not reporting quality data ($48,116.62 x 1.008 x 0.9959347)	$48,304.38
Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$90,921
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$49,237
Impact of Proposed Policy Changes on LTCH Payments in FY 2025	
Total estimated impact	1.6% (≈ $41 million)
LTCH standard federal payment rate cases (71% of LTCH cases)	1.2% (≈ $26 million)
Site neutral payment rate cases (29% of LTCH cases)**	4.7% (≈ $14 million)
*More detail is available in Table IV, "Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments For LTCH PPS Standard Federal Payment Rate Cases for FY 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 proposes to continue to apply the same MS-DRG classification system used for the IPPS payments to the LTCH PPS in the form of MS-LTC-DRGs. Other MS-DRG system updates also would be incorporated into the MS-LTC-DRG system for FY 2025 since the two systems share an identical base. Proposed MS-DRG changes are described elsewhere in this summary and details can be found in section II.F. of the preamble of the proposed rule. Other proposed changes to the MS-DRGs that affect assignments under the proposed GROUPER Version 42 are discussed in section II.E of the proposed rule, including changes to the Medicare Code Editor (MCE) software and the ICD-10-CM/PCS coding system, which apply to the LTCH PPS.

3. Proposed 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 proposes to 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 proposes to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2025 MS-LTC-DRG relative weights.

a. Proposed Relative Weights Source Data

FY 2025 proposed relative weights are derived from the December 2023 update of the FY 2023 MedPAR file. These data are filtered to identify LTCH cases that met the established site neutral payment exclusion criteria or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. CMS notes that all LTCH PPS cases in FY 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 are 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 ratesetting calculations, including the calculation of the area wage level adjustment budget neutrality factor and the fixed-loss amount for LTCH PPS standard federal payment rate cases. Citing Department of Justice actions against this same provider for alleged false claims related to excessive cost outlier payments,[55] CMS proposes to remove the provider's claims from the FY 2025 MS-LTC-DRG relative weights and in all other FY 2025 ratesetting calculations.

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

b. Volume-related Adjustments

CMS proposes to continue to account for low-volume MS-LTC-DRG cases using its quintile methodology and to use it when calculating relative weights. Generally, if an MS-LTC-DRG has 1-24 cases, it is assigned to one of five quintiles based on average charges. CMS assigns the low-volume MS-LTC-DRGs to specific low-volume quintiles by sorting them in ascending order by average charge.

It finds that there are 236 such MS-LTC-DRGs in the claims, and the quintiles each contained at least 47 MS-LTC-DRGs (236/5 = 47 with a remainder of 1). CMS proposes to use its historical methodology of assigning each remainder low-volume MS-LTC-DRG to the low-volume quintile that contains an MS-LTC-DRG with an average charge closest to that of the remainder low-volume MS-LTC-DRG.

CMS then determines a proposed relative weight and (geometric) average length of stay for each quintile; each quintile's weight and length of stay are then assigned to each MS-LTC-DRG within that quintile. (See https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html for these low-volume MS-LTC-DRGs.)

c. Remove Statistical Outliers

Consistent with its current methodology, CMS proposes to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. It also proposes to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS-LTC-DRG. After removing statistical outlier cases and cases with a length of stay of 7 days or less in each set of claims, CMS has

[55] https://www.justice.gov/opa/pr/new-jersey-hospital-and-investors-pay-united-states-306-million-alleged-false-claims-related

applicable LTCH cases that have a length of stay greater than or equal to 8 days, which it refers to as "trimmed applicable LTCH cases."

d. Adjust Charges for Short Stay Outliers

The effect of short stay outlier (SSO) cases (i.e., those with a length of stay of five-sixths or less of the average for that MS-LTC-DRG) is adjusted for by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the SSO case to the average length of stay for the MS-LTC-DRG for non-SSO cases. CMS proposes to continue this policy for FY 2025.

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

CMS proposes to continue to use 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 proposes to continue for FY 2025 its approach of combining severity levels within the nonmonotonic MS-LTC-DRG for purposes of computing a relative weight to assure that monotonicity is maintained. Table 11 (listed in section VI. of the Addendum to the proposed rule) notes any adjustments made for nonmonotonicity.

g. Determination of Relative Weights for MS-LTC-DRGs with No Applicable LTCH Cases

If an MS-LTC-DRG has zero cases after data trims are applied (425 of these MS-LTC-DRGs are identified for the proposed rule), CMS proposes to continue to cross-walk that MS-LTC-DRG to another proposed MS-LTC-DRG based on clinical similarities in resource use intensity and relative costliness to assign an appropriate proposed relative weight. If the MS-LTC-DRG that is similar is a low-volume DRG that has been assigned to one of the five quintiles noted above, then the zero volume MS-LTC-DRG would be assigned to that same quintile.

CMS removes from this total the 11 transplant, 2 "error" and 15 psychiatric or rehabilitation MS-LTC-DRGs. Thus, there are 397 no-volume MS-LTC-DRGs for which CMS proposes to assign relative weights based on clinical similarity and relative costliness to 1 of the remaining 348 (773 – 425 = 348) MS-LTC-DRGs for which it calculated relative weights based on the trimmed applicable LTCH cases in the FY 2023 MedPAR file data. When necessary, adjustments are 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 proposed relative weights for the FY 2025 MS-LTC-DRGs with no applicable LTCH cases.

CMS proposes to assign a 0.0000 relative weight for each of the following:

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

h. Normalizing the Relative Weights

CMS proposes to normalize relative weights using its established methodology for FY 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 proposed MS-LTC-DRG relative weights for FY 2025, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by the proposed normalization factor in the first step of the budget neutrality methodology, which produces "normalized relative weights." CMS calculated a normalization factor of 1.27356.

i. Budget Neutrality

Annual updates to the MS-LTC-DRG classifications and relative weights are done in a budget neutral manner. CMS proposes to continue use its existing 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 would apply 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 proposed update of the MS-LTC-DRG classifications and relative weights before applying the 10-percent cap (or the uncapped relative weights), CMS proposes to continue to use its established two-step budget neutrality methodology.

First, it proposes to apply its normalization factor to the recalibrated relative weights. To do so, it 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 proposed 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 proposed MS-LTC-DRG relative weights for FY 2025, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by

the proposed normalization factor of 1.27356 in the first step of the budget neutrality methodology, which produces "normalized relative weights."

Next, CMS proposes to continue to determine the first budget neutrality adjustment factor (for uncapped relative weights) by calculating the ratio of estimated aggregate FY 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. CMS calculates a proposed budget neutrality factor of 0.988292, 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 proposes a capped FY 2025 MS-LTC-DRG relative weight equal to 90 percent of that MS-LTC-DRG's FY 2024 relative weight.

(3) Budget Neutralize Application of the 10-percent Cap Policy

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

- Simulate estimated total FY 2025 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2025 (determined in Step 10) and proposed GROUPER Version 42;
- Simulate estimated total FY 2025 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2025 (determined in Step 9) and proposed GROUPER Version 42; and
- Calculate the ratio of the estimated total payments.

The proposed budget neutrality adjustment factor for the 10-percent cap is 0.9946599. To determine the proposed FY 2025 MS-LTC-DRG relative weights, CMS would multiply each capped relative weight by the proposed budget neutrality factor to meet the proposed budget neutrality requirement.

Extensive discussion of the entire 13-step process to determine MS-LTC-DRG relative weights is provided in the proposed rule (pages 783 through 802 of the display copy).

C. Proposed Payment Rates and Other Changes

1. Overview LTCH PPS Standard Federal Payment Rates.

As noted earlier, only LTCH discharges meeting the site neutral payment rate exclusion criteria are paid based upon the LTCH PPS standard federal payment rate. The LTCH PPS uses a single payment rate to

cover both operating and capital-related costs, so the LTCH market basket includes both operating and capital cost categories.

2. Proposed FY 2025 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update.

CMS proposes 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 proposal to use a 2022 base year are described in section VIII.D. of the summary below.

The proposed update to the 2022-based LTCH market basket is 3.2 percent less 0.4 percentage points (PP) for multifactor productivity (renamed by BLS to be the total factor productivity (TFP)), which results in an update factor of 1.028 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 would be further reduced by 2.0 percentage points. CMS notes that the "other adjustment" under section 1886(m)(4)(F) of the Act does not apply for FY 2025. The proposed LTCH updates for FY 2025 are as follows:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	3.2%	3.2%
Multifactor Productivity	-0.4 PP	-0.4 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	2.8%	0.8%

3. Area Wage Levels and Wage-Index.

a. Proposed Labor Market Areas

CMS proposes to adopt the revised labor market area delineations announced in OMB Bulletin No. 23-01[56] (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 would be located in a rural area.
- 54 counties (and county equivalents) that were located in a rural area would be located in an urban CBSA.
- Some urban counties would shift from one urban CBSA to another urban CBSA.
    - Some of these shifts result only in a name change.
    - Some CBSAs would be split into multiple new CBSAs.

[56] https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.

    - An urban CBSA would 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 proposed FIPS county and county-equivalent codes and CBSA assignments:

CCN	Current FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Area (County Equivalent)	Proposed CBSA
072003	09009	New Haven	35300	09170	South Central Connecticut	35300
072004	09003	Hartford	25540	09110	Capitol	25540

The proposed FY 2025 LTCH PPS wage index values in Tables 12A and 12B listed in section VI. of the Addendum reflect the proposed 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 proposed 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. Proposed Labor-Related Share

CMS proposes an FY 2025 labor-related share of 72.8 percent based on IGI's fourth quarter 2023 forecast of the proposed 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. CMS will use more recent data for the final rule to determine the FY 2025 LTCH PPS labor-related share if the data are available before the publication of that final rule.

c. Proposed Wage Index for FY 2025 for the Standard Federal Rate

To determine the applicable area wage index values for the FY 2025 LTCH PPS standard federal payment rate, CMS proposes to use the same data it would use to compute the proposed 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 would be calculated consistent with the "urban" and "rural" geographic classifications, not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act. It also proposes to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy.

To determine area wage index values for areas where there are no IPPS wage data, CMS proposes to use its existing methodology, whereby the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all the urban areas within the state, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all the CBSAs that are contiguous to the rural counties

of the state. CMS notes there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980) or for rural North Dakota (CBSA 35).

d. Permanent Cap on Wage Index Decreases

The FY 2023 IPPS/LTCH PPS final rule established a permanent policy to apply 5-percent cap on any decrease in an LTCH's wage index from the LTCH's final wage index from the prior fiscal year by reason of large wage index decreases (87 FR 49440 through 49442). 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 proposed rule applies would not be subject to the cap (even when other LTCHs in the same geographic area are receiving a wage cap).

CMS calculates an "IPPS comparable amount" to determine payments for short-stay outliers and the site neutral payment rate. Additionally, an "IPPS equivalent amount" is calculated for LTCHs that do not meet the applicable discharge payment percentage. Calculation of these amounts includes adjustments to the IPPS operating and capital standardized amounts by the applicable IPPS wage index for non-reclassified hospitals in the same geographic area as the LTCH. CMS adopted, beginning with FY 2023, the application of a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Historically, CMS has not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for non-reclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner.

e. Proposed Budget Neutrality Adjustments or Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

CMS proposes to compute the wage index in a manner that is consistent with prior years; this includes ensuring that any changes to the area wage index values or labor-related share are implemented in a budget neutral manner. As noted above, the 5-percent cap on wage index decreases is included in the determination of the proposed area wage level budget neutrality factor. CMS determined a proposed FY 2025 LTCH PPS standard federal payment rate area wage level adjustment budget neutrality factor of 0.9959347.

4. Cost-of-Living (COLA) Adjustment.

CMS proposes to continue updating the COLA factors for Alaska and Hawaii as it has done since FY 2014. To account for higher living costs in Alaska and Hawaii, a COLA is provided to LTCHs in those states that is applied to the nonlabor-related portion of the standard federal payment rate.

The COLA is determined by comparing Consumer Price Index (CPI) growth in Anchorage, Alaska and Honolulu, Hawaii to that of the average U.S. city published by the Bureau of Labor Statistics (BLS). The COLA is capped at 25 percent and updated every 4 years.

CMS proposes to continue to use the COLA factors based on the 2009 OPM COLA factors updated through 2020 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2022 IPPS/LTCH PPS final rule. The table below shows the proposed COLAs for FY 2025 which are unchanged from the COLAs in effect for FY 2024.

Area	**Proposed 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. Proposed Adjustment for High-Cost Outlier (HCO) Case Payments.

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

a. Determining LTCH CCRs

CMS calculates the estimated cost of an LTCH case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. Generally, an LTCH's overall CCR is computed based on the sum of LTCH operating and capital costs as compared to total Medicare charges, with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in some cases, an alternative CCR is used, such as the statewide average CCR, a CCR that is specified by CMS, or one that the hospital requests. The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling (which is 3 standard deviations from the national geometric average CCR). If the LTCH's CCR exceeds the LTCH total CCR ceiling, it is assigned the applicable statewide CCR.

CMS proposes to use its established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2023 update of the Provider Specific File (PSF). Thus, it proposes a LTCH total CCR ceiling of 1.371 under the LTCH PPS for FY 2025 for HCO cases under either payment rate and for the site neutral payment rate.

CMS also proposes to use its established methodology for determining the LTCH statewide average CCRs for urban and rural hospitals, based on the most recent complete IPPS total CCR data from the December 2023 update of the PSF. They would be 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.

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

As noted above, CMS establishes a fixed-loss amount so that total estimated outlier payments under the LTCH PPS for federal standard payments are projected to equal 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. The agency notes that the proposed fixed-loss amount for LTCH PPS standard federal payment rate cases for FY 2025 is significantly higher than the fixed-loss amount it finalized for FY 2024 (88 FR 59377).

(1) Proposed Charge Inflation Factor

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

- Identify standard federal payment rate cases for the two most recently available fiscal years, removing any Medicare Advantage or all-inclusive rate provider claims 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 proposed charge inflation factor using the December 2023 update of the FY 2023 MedPAR file and the December 2022 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 1.073863, and a 2-year charge inflation factor of 1.153182 (calculated by squaring the 1-year factor). It proposes to inflate the billed charges obtained from the FY 2023 MedPAR file by this 2-year charge inflation factor of 1.153182 when determining the proposed fixed-loss amount for LTCH PPS standard federal payment rate cases for FY 2025.

(2) Proposed 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 proposes to continue to use the following four-step methodology finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562-45566):

- Identify providers with standard federal payment rate cases from the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims) and identify for each of these providers the CCR from the most recently available PSF and from the prior year PSF.
- Trim providers with insufficient CCR data in the most recent PSF or the prior year PSF (i.e., providers whose CCR was missing; providers assigned the statewide average CCR for their state; and providers whose CCR was not updated between the most recent PSF and the prior year PSF).
- Remove statistical outliers. Calculate a provider's CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year PSF, and remove providers whose CCR growth factor is outside 3 standard deviations from the mean provider CCR factor.
- Using remaining providers, calculate a national CCR adjustment factor by determining the average case-weighted CCR from both the most recent PSF and the prior year PSF and dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

Under this methodology for FY 2025, CMS used the December 2023 PSF as the most recently available PSF and the December 2022 PSF as the PSF that was made available one year prior to the most recently available PSF. It also used claims from the December 2023 update of the FY 2023 MedPAR file in calculating the average case-weighted CCRs in the last step of the methodology. CMS calculated a December 2022 national average case-weighted CCR of 0.232841 and a December 2023 national average case-weighted CCR of 0.238141, which results in a proposed 1-year national CCR adjustment factor of 1.02276.

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

CMS does not propose any changes to its methodology to calculate the applicable fixed-loss amount for standard federal rate cases. The proposed fixed-loss amount must maintain estimated

HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard federal payment rate cases. Using LTCH claims data from the December 2023 update of the FY 2022 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2023 update of the PSF, CMS calculated a proposed fixed-loss amount for standard federal rate cases of $90,921 for FY 2025.

CMS notes that the proposed fixed-loss amount determined for FY 2025 is 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). The agency reports that actual high-cost outlier payments accounted for 11.6 percent of total LTCH PPS standard federal payment rate payments in FY 2023, which is significantly higher than the target 7.975 percent. It currently estimates that for actual high-cost outlier payments to have accounted for 7.975 percent of total LTCH PPS standard federal payment rate payments in FY 2023, the fixed-loss amount would have needed to be set at approximately $65,260, and applying this model to FY 2024, the FY 2024 fixed-loss amount would have needed to be set at approximately $72,275.

Alternative Considered. CMS considered, as an alternative to its established methodology, establishing the FY 2025 fixed-loss amount as an average of the FY 2024 fixed-amount ($59,873) and the modelled FY 2025 fixed-loss amount ($90,921), which would result in a proposed FY 2025 fixed-loss amount of $75,397. This alternative would provide 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 estimates the alternative fixed-loss amount would result 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 says 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).

CMS seeks comment on its proposed methodology and the assumptions underlying it as well as on the alternative approach it considered.

Consistent with historical practice, CMS would use the most recent available LTCH claims data and CCR data for the final rule.

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

CMS continues to believe that the most appropriate fixed-loss amount for site neutral payment rate cases is the IPPS fixed-loss amount. For FY 2025, CMS proposes a fixed-loss amount for site neutral payment rate cases of $49,237. CMS also proposes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2025. Consistent with the policy adopted in FY 2019, CMS proposes that the HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount. CMS estimates that HCO payments for site neutral payment rate cases would be 5.1 percent of the site neutral payment rate payments.

6. IPPS DSH and Uncompensated Care Payment Adjustment Methodology

CMS proposes to continue its policy that the calculations of the "IPPS comparable amount" (under the SSO policy at §412.529) and the "IPPS equivalent amount" (under the site neutral payment rate at §412.522) include an applicable operating Medicare DSH and uncompensated care payment amount. For FY 2025, the DSH/uncompensated care amount equals 71.61 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 proposes to rebase and revise the market basket applicable to the LTCH PPS. Currently, the LTCH PPS market basket uses 2017 data for the base year, and the agency proposes to move 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 it proposes to combine 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.

The below table shows the impact from changing to a 2022-based LTCH PPS market basket.

FY	Proposed 2022-Based LTCH Market Basket Index Percent Change	2017-Based LTCH Market Basket Index % 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 2024	3.9	3.7
FY 2025	3.2	3.1
FY 2026	2.8	2.8
FY 2027	2.8	2.8
Average FY 2024 – FY 2027	**3.2**	**3.1**

The below table shows the FY 2025 labor-related share using the proposed 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 would increase to 72.8 percent from 68.5 percent.

FY	FY 2025 Proposed Labor-Related Share based on Proposed 2022-based LTCH Market Basket	FY 2024 Final Labor-Related Share based on 2017-based LTCH Market Basket
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**

E. Impacts

CMS Impact Analysis for LTCHs

CMS projects that the overall impact of the proposed payment rates and factors for all LTCHs will result in an increase of 1.6 percent or approximately $41 million in aggregate payments. Based on the FY 2023 LTCH cases that were used for the analysis in this proposed 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 4.7 percent (or approximately $14 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the proposed updates to the IPPS rates and payments reflected in its estimate of the IPPS comparable per diem amount, as well as an estimated increase in costs for these cases determined using the proposed 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 1.2 percent (or approximately $26 million), which is primarily due to the projected 2.8 percent annual update to the LTCH PPS standard federal payment rate being partially offset by a projected 1.3 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 $2.624 billion, as compared to estimated aggregate proposed FY 2024 LTCH PPS payments of approximately $2.583 billion.

Table IV “Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments For LTCH PPS Standard federal Payment Rate Cases for FY 2025” in the proposed 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	**Estimated Percent Change in Payments per Discharge**
All LTCH providers	329	1.2%
By Location:		
Rural	18	2.3%
Urban	311	1.1%
By Ownership Type:		
Voluntary	52	0.2%
Proprietary	267	1.3%
Government	10	-0.3%
By Region		
New England	10	-0.2%
Middle Atlantic	19	1.1%
South Atlantic	59	1.4%
East North Central	47	0.8%
East South Central	31	1.6%
West North Central	21	0.8%
West South Central	92	1.5%
Mountain	27	2.2%
Pacific	23	0.5%
*More detail is available in Table IV "Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2025" on pages 1860-1861 of the display copy.		

IX. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. Overview

CMS seeks comment on and proposes changes under this section to the Hospital 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 Program Proposals and Requests for Comment

CMS proposes the following two crosscutting quality program policies:

- Adoption of the Patient Safety Structural Measure in the Hospital IQR Program for the 2025 reporting period/FY 2027 payment determination and in the PCHQR Program for the 2025 reporting period/FY 2027 program year; and
- Modification of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey in the Hospital IQR, Hospital VBP, and PCHQR Programs.

CMS also issues a Request for Information on Advancing Patient Safety and Outcomes Across the Hospital Quality Programs.

CMS invites public comment on the proposals in this section.

1. Proposed Adoption of Patient Safety Structural Measure

a. 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.

b. Measure Overview and Calculation

CMS proposes to adopt the attestation-based Patient Safety Structural measure in the Hospital IQR and PCHQR Programs. 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). Table IX.B.1-01 of the proposed rule shows the 5 attestation domains and corresponding attestation statements.

A hospital would 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 would need to attest affirmatively to each of the statements that correspond to that domain. A hospital would not be able to receive partial points for a domain, and therefore would 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 would need to satisfy these criteria for the hospital to affirmatively attest and receive points.

c. 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.

In addition, CMS notes that the measure aligns with patient safety guidelines and literature and that the majority of public comments it received on the measure during the PRMR process were supportive, with 94 percent either supporting adoption or supporting adoption with conditions.

CMS, therefore, proposes to adopt the measure, consistent with the exception for measures not endorsed by the consensus-based entity (non-CBE-endorsed measures),[57] having found no currently available, alternative measure that is comparable, CBE-endorsed, feasible, and practical.

d. Data Submission and Reporting

The measure would 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. Hospitals participating in either program would 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.

Hospitals would 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 would 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.

2. Proposal to Modify 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

[57] See sec. 1886(b)(3)(B)(viii)(IX)(bb) of the Act for the Hospital IQR Program; sec. 1866(k)(3)(B) of the Act for the PCHQR Program.

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.[58]

CMS discusses its literature review and focus group studies that contributed to the development of proposed updates to the HCAHPS Survey questions.

b. Proposal to Modify HCAHPS Survey Measure

Overview. CMS proposes modifications to the HCAHPS Survey measure. The proposed updates would 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 questions would make up 9 dimensions.

Hospital IQR and PHCQR Programs. Table IX.B.2-01 in the rule includes the updated sub-measures and survey questions.

Proposed Updated HCAHPS Survey Sub-Measures and Corresponding Survey Questions (Based on Table IX.B.2-01 in the Proposed 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?
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?

[58] The HCAHPS Survey can be found at https://hcahpsonline.org/en/survey-instruments/.

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 would include the following:

Addition of Care Coordination Sub-Measure. The new sub-measure would be composed of 3 new questions (shown above) that would 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 would not be 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 would be 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) would be 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.[59] CMS would replace this sub-measure with the proposed new Care Coordination sub-measure believing the new sub-measure would be more

[59] 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).

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 would include the following proposed 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.

Neither patient race nor ethnicity is used to adjust HCAHPS Survey results, but are instead questions included in the survey for congressionally-mandated reports. These modifications would not be included in public reporting of the survey nor would they affect scoring under the HVBP Program. The "Hospital Stay Planned in Advance" question would be used in the patient-mix adjustment of responses.

Implementation Timing for Hospital IQR and PCHQR Programs. The updated measure would 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 would 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 would 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. During that period, the agency proposes that publicly reported survey data for the Hospital IQR and PCHQR Programs would consist only of data from the 8 unchanged sub-measures (those that are in the current version and that would remain in the updated version). Once 4 quarters of the updated HCAHPS survey data have been submitted, then public reporting would reflect all of the modifications in the updated measure. Table IX.B.2-02 in the proposed rule includes the proposed timeline for public reporting of the HCAHPS Survey measure in the Hospital IQR and PCHQR Programs.

Burden Estimate. CMS believes that the proposed updated version of the survey measure would result in only a minimal change in burden, estimating that once the combination of removals and additions of survey questions are taken into account that there would be an additional 45 seconds to complete the survey. The proposed updates would 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 not extending the survey length and removal of overlapping items, 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 addresses the concern about the survey length by stating that 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. The agency notes that similar or overlapping questions were identified and considered for removal during the development and testing of the updated measure with patients' and caregivers' input, and that the agency believes the added questions provide unique, non-redundant information. CMS also explains that 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. Also, CMS explains that it would monitor trends in performance with the updated survey. Further, CMS states that 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.

c. Proposed 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 the updates would first have to be specified for the Hospital IQR and included on Care Compare for at least one year before the beginning of the performance period for which the updated measure could be included in the HVBP Program.

Therefore, CMS proposes to adopt the updated version of the measure into the HVBP Program beginning with the FY 2030 program year. So that hospitals would not have to use two different surveys in the Hospital IQR and HVBP Programs during the period between FY 2027 through 2029, the agency proposes that for the HVBP Program hospitals would be able to administer the updated version of the survey beginning with January 1, 2025 discharges and CMS would score only the 6 dimensions of the HCAHPS Survey that would 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 would 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 proposes to 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 would create the pre-normalized HCAHPS Base Score of 0-60 (rather than the current 0-80 for the current 8 dimensions). The agency would 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 would range from 0 to 80 points. HCAHPS consistency points would be calculated consistent with current rules and would continue to range from 0 to 20 points, but would only include scores across the 6 unchanged dimensions. Finally, as with the current methodology, the normalized score would be added with the consistency points score for a total score, ranging from 0-100 points.

d. Proposed Adoption of Updated HCAHPS Survey Measure and Scoring Modifications Beginning with the FY 2030 Program Year

CMS proposes to adopt 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 modifications proposed include the following:

- The current Care Transition dimension would be removed.
- The new Care Coordination, Restfulness of the Hospital Environment, and Cleanliness and Information about Symptoms dimensions would be added.
- The current Cleanliness and Quietness dimension would be modified. The dimension is renamed as the Cleanliness and Information About Symptoms dimension, and the Quietness question would be moved to the new Restfulness of Hospital Environment dimension, but the question would remain the same.
- The resulting 9 dimensions would be (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 would differ slightly from the proposed 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 would be combined into one dimension in the HVBP Program.
- Table IX.B.2-03 of the rule provides the timelines for the current and proposed HCAHPS Survey dimensions.

CMS also proposes the following new scoring methodology beginning with the FY 2030 program year. The agency would 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 would 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 would be multiplied by 8/9 and rounded to arrive at the normalized HCAHPS Base Score (ranging between 0-80 points). HCAHPS consistency points would be determined as they are now and would range from 0-20 points and would consider scores across all 9 dimensions.

Finally, the normalized HCAHPS Score would be added to the HCAHPS consistency points score to determine the total score (ranging from 0-100 points).

3. Request for Comment: Advancing Patient Safety and Outcomes Across the Hospital Quality Programs

CMS is seeking 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.

C. Hospital Inpatient Quality Reporting (IQR) Program

CMS proposes changes to the Hospital IQR program that would 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 proposes changes to the reporting and submission requirements for electronic clinical quality measures (eCQMs) and the validation process.

CMS estimates if the proposals are adopted there would be a total information collection burden increase for 3,050 IPPS hospitals of 40,019 hours at a cost of $1,274,980 annually from the 2025 reporting period/FY 2027 payment determination through the 2027 reporting period/FY 2029 payment determination, compared to the currently approved information collection burden estimates.

CMS further estimates that for FY 2025, 91 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 1.85 percent update; 87 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 26 hospitals will not receive the full update for failure to satisfy both requirements and will receive a -0.4 percent update.

CMS invites public comment on all of the proposed changes to the Hospital IQR Program under this section.

1. Background

The Hospital IQR Program is a pay-for-reporting program. Hospitals that do not submit specified quality data or fail to meet all program requirements are subject to a one-fourth reduction in their annual payment update. CMS provides a list of references for readers interested in details of the legislative and regulatory history of the IQR Program. Additional information on the Program is available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalRHQDAPU and https://qualitynet.cms.gov/inpatient/iqr.

CMS does not propose any changes to the previously finalized retention of adopted measures policy,[60] 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.[61] However, the agency describes the statutory and regulatory background for these policies.

2. Proposed New Measures for the Hospital IQR Program Measure Set

CMS proposes adoption of 7 new measures:

- 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.

a. Age Friendly Hospital Measure

Background. CMS describes the aging population in the United State 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

[60] 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).

[61] 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.

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 proposing 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).

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 proposes to adopt the measure, consistent with the exception for non-CBE-endorsed measures [62]

Measure Calculation. The measure consists of 5 domains and corresponding attestation statements. For each domain, to receive a point for the domain, hospitals would 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 would not be available. However, because the Hospital IQR Program is a pay-for-reporting program, hospitals would 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 proposes requiring reporting of the measure beginning with the 2025 reporting period/FY 2027 payment determination.

b. Proposed Adoption of Two Healthcare-Associated Infection (HAI) Measures Beginning with 2026 Reporting Period/2028 Payment Determination

[62] See sec. 1886(b)(3)(B)(viii)(IX)(bb) of the Act for the exception to the rule for CBE endorsement.

Background. CMS describes how the agency previously adopted the NHSN Catheter-Associated Urinary Tract Infection (CAUTI)[63] and NHSN Central Line-Associated Bloodstream Infection (CLABSI)[64] 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 proposes to adopt the CAUTI Standardized Infection Ratio Stratified for Oncology Locations and the CLABSI Standardized Infection Ratio Stratified for Oncology 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 proposed 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 would 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 reviewed the conditions but concluded 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

[63] The CAUTI measure is used in the HAC Reduction and Hospital VBP Programs.
[64] The CLABSI measure is used in the HAC Reduction and Hospital VBP Programs.

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 would be collected through the CDC's NHSN. For purposes of the Hospital IQR Program requirements, hospitals would report data for the CAUTI-onc measure quarterly. Hospitals would collect the numerator and denominator for the measure each month and submit data to the NHSN, and the data from all 12 months would 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 would 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 reviewed the conditions but concluded 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 would be collected through the CDC's NHSN. For purposes of the Hospital IQR Program requirements, hospitals would report data for the CLABSI-onc measure quarterly. Hospitals would collect the numerator and denominator for the measure each month and submit data to the NHSN, and the data from all 12 months would be calculated into quarterly reporting periods. Currently, CLABSI data is reported to the NHSN monthly and the SIR is calculated on a quarterly basis.

c. *Proposed 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 Measure. CMS proposes to adopt the Hospital Harm – Falls with Injury measure, a risk-adjusted outcome eCQM, beginning with the 2026 reporting period/FY 2028 payment determination.

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 product of 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 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 would be part of the eCQM measure set, from which hospitals may self-select measures to report to meet the eCQM reporting requirement.

d. Proposed 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 would 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 proposes adoption of the Hospital Harm – Postoperative Respiratory Failure measure, a risk-adjusted outcome eCQM, beginning with the 2026 reporting period/FY 2028 payment determination.

The measure would be calculated as the product of 1,000 multiplied by the ratio of the number of encounters in the numerator to the number of encounters in the denominator.

- 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 ASA categories 3-5) and lab values for oxygen, leukocytes, albumin, BUN, 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 would be part of the eCQM measure set, from which hospitals may self-select measures to report to meet the eCQM reporting requirement.

e. Proposed Adoption of the Thirty-Day Risk-Standardized Death Rate Among Surgical Inpatients with Complications (Failure-to-Rescue) Measure Beginning With 2027 Payment Determination

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 would replace that measure, which CMS is proposing for removal under section IX.C.6 of the rule contingent on adoption of the Failure-to-Rescue measure. 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 that the proposed measure has compared to the CMS PSI 04, including that the proposed 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.

Overview and Calculation of Measure. CMS proposes to adopt 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.

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.

Lower scores (i.e. hospitals performing in the lower percentiles) would 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 E&M Committee 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 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 would not be required to report additional data. The measure would 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 PSI 90 (the Patient Safety and Adverse Events Composite measure).

3. Proposed Measure Removals

CMS proposes to remove the following 5 measures:

- One claims-based measure beginning for FY 2027 payment determination.
- Four clinical episode-based payment measures beginning for FY 2026 payment determination.

a. Proposed Removal of the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI 04) Measure Beginning with FY 2027 Payment Determination

CMS proposes to remove 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 proposes removal of the measure contingent on adoption of the Failure-to-Rescue measure, proposed in section IX.C.5.e of the rule, which it believes would 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.

b. Proposed Removal of Four Clinical Episode-Based Payment Measures Beginning with FY 2026 Payment Determination

CMS proposes removal of the following 4 clinical episode-based payment measures beginning for the FY 2026 payment determination:[65]

- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI Payment) measure, beginning with the July 1, 2021 – June 30, 2024 reporting period.
- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Heart Failure (HF Payment) measure, beginning with the July 1, 2021 – June 30, 2024 reporting period.
- The Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Pneumonia (PN Payment) measure, beginning with the July 1, 2021 – June 30, 2024 reporting period.
- 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, beginning with the April 1, 2021 – March 31, 2024 reporting period.

All 4 measures are proposed for removal 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 proposed for removal but incorporates a larger set of conditions and procedures. It does not, however, provide the same level of granularity of data.

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

CMS proposes to make refinements to two measures:

- The Global Malnutrition Composite Score (GMCS) eCQM beginning with the 2026 reporting period/FY 2028 payment determination; and
- The HCAHPS Survey measure beginning with the 2025 reporting period/FY 2027 payment determination, which is proposed in section IX.B.2 of the rule and described in section IX.B.2 of this summary.

Background and Overview of Modification to GMCS eCQM. CMS adopted, in the FY 2023 IPPS/LTCH PPS final rule,[66] the 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

[65] The preamble describes the removal of these measures would be "beginning with the FY 2026 payment determination" and would be "beginning with" the respective reporting periods described. However, Table IX.C.3. of the proposed rule then shows the FY 2026 payment determination and the same dates indicated within the respective corresponding reporting periods as the "proposed final performance period and payment determination" for the measures.

[66] 87 FR 49239-49246.

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.

CMS, therefore, proposes to modify the measure to expand the applicable population to hospitalized adults 18 or older. This would be the only change to the measure specifications.[67]

Measure Calculation. The modified measure would continue 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.

- 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 composite 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 to 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 proposed, is scheduled for endorsement review in 2024.

Data Submission and Reporting. The modified GMCS eCQM would 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 would be used as with the current measure.

5. Summary of Previously Finalized and Proposed 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, if the policies as proposed are adopted. Selected information from those tables is consolidated into the table below.

[67] Measure specifications can be found at https://ecqi.healthit.gov/ecqm/eh/2024/cms0986v2.

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) 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)*	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 HH-HYPO HH-HYPER HH-ORAE GMCS	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications AND 3 of the following eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-HYPO HH-HYPER HH-ORAE GMCS HH-PI HH-AKI IP-ExRad	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications [*AND, AS PROPOSED#, HH-HYPO, HH-HYPER, and HH-ORAE*] AND 3 of the following eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 *HH-HYPO#* *HH-HYPER#* *HH-ORAE#* *GMCS** HH-PI HH-AKI IP-ExRad *HH-FI** *HH-RF** *# as proposed, these eCQMs would be mandatory rather than among the list for self-selection*	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications [*AND, AS PROPOSED#, HH-HYPO, HH-HYPER, HH-ORAE, HH-PI, and HH-AKI*] AND 3 of the following eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-HYPO# HH-HYPER# HH-ORAE# *GMCS** HH-PI# HH-AKI# IP-ExRad *HH-FI** *HH-RF** *# as proposed, these eCQMs would be mandatory rather than among the list for self-selection*
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)			Proposed Inclusion	Proposed Inclusion

Summary Table IQR Program Measures by Payment Determination Year				
	2026	**2027**	**2028**	**2029**
CLABSI -onc (CBE #0139)			Proposed Inclusion	Proposed Inclusion
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
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	Proposed Removal		
FTR 30-day Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (CBE #4125)		Proposed Inclusion	Proposed Inclusion	Proposed Inclusion
Claims-Based Efficiency/Payment				
AMI payment per 30-day episode of care (CBE #2431)	Proposed Removal			
Heart Failure payment per 30-day episode of care (CBE # 2436)	Proposed Removal			
Pneumonia payment per 30-day episode of care (CBE #2579)	Proposed Removal			
THA/TKA payment per 30-day episode of care (CBE#3474) Refined	Proposed Removal			
MSPB-Hospital (CBE#2158)	X	X		
Patient Experience of Care				
HCAHPS survey (CBE #0166) (0228)	X	X Proposed 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

Summary Table IQR Program Measures by Payment Determination Year				
	2026	**2027**	**2028**	**2029**
Hospital Commitment to Health Equity HCHE	X	X	X	X
Age Friendly Hospital		Proposed Inclusion	Proposed Inclusion	Proposed Inclusion
Patient Safety		Proposed Inclusion	Proposed Inclusion	Proposed Inclusion
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
* Proposed in this rule for inclusion beginning with FY 2028 payment determination. Plus, in this rule GMCS proposed refinements beginning with FY 2028 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 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 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 2023 IPPS/LTCH PPS final rule, CMS finalized the adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure with voluntary data collection for the CY 2023 reporting period, and then mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and subsequent years (87 FR 49201 through 49220).				

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.

CMS proposes changes to reporting and submission requirements for eCQMs. Specifically, the agency proposes a progressive increase in the number of mandatory eCQMs a hospital must report beginning with the 2026 reporting period/FY 2028 payment determination. Specifically, the agency proposes to include the 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. 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. 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.

If a hospital does not have patients that meet the denominator criteria for an eCQM that would be required, the hospital would submit a zero denominator declaration for the measure, which allows the hospital to meet the reporting requirements for that eCQM.

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).

b. Proposed Modification of eCQM Validation Scoring

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 proposes 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 proposes to remove the requirement that hospitals submit 100 percent of the requested eCQM medical records to pass the validation requirement and that missing eCQM medical records be treated as mismatches (consistent with the practice for chart-abstracted measure validation). Also, eCQM validation scores would 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 proposes to have 2 separate validation scores – one for chart-abstracted measures and one for eCQMs – rather than the existing combined validation score. Hospitals would 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 proposal, to be eligible for the full update (if all other Hospital IQR Program requirements are met) a hospital would 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 proposed validation scoring policies.

8. Reconsideration and Appeal Procedures

As part of the reconsideration process, hospitals can request reconsideration of a CMS determination that the hospital did not meet validation requirements.[68] 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.[69]

[68] Reconsideration and appeals procedures can be found at 42 CFR 412.140(e).
[69] Electronic submission was established in the FY 2021 IPPS/LTCH final rule (85 FR 58949-58950).

CMS, therefore, proposes, 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.

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

1. Background; Overview of 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.

CMS proposes the following policies:

- To adopt the Patient Safety Structural measure beginning with the 2025 reporting period/FY 2027 program year. This cross-Program proposal is described in section IX.B.1 of the summary.
- To modify the HCAHPS Survey measure beginning with the 2025 reporting period/FY 2027 program year. This cross-Program proposal is described in section IX.B.2 of the summary.
- To move up the start date for publicly displaying hospital performance on the Hospital Commitment to Health Equity measure.

If the proposals are adopted, CMS estimates a total information collection burden increase for the 11 PCHs of 166 hours at a cost of $4,047 annually beginning with the FY 2027 program year compared to the currently approved information collection burden estimates.

CMS invites public comment on all of the proposed changes to the PCHQR Program under this section.

2. Summary of Previously Adopted and Newly Proposed 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 adopted measures as well as proposed measures, with corresponding public display start date.

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

PCHQR Program Measures for FY 2027 and Subsequent Years	
Measure	**Public Display Start Date**
NHSN COVID-19 vaccination coverage among health care personnel	October 2022
NHSN CLABSI (CBE #0139)	October 2022
NHSN CAUTI (CBE #0138)	October 2022
*Proposed 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	
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	*Proposed July 2026 or as soon as feasible thereafter*
Claims-Based Outcomes	
Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	April 2020
30-Day Unplanned Readmissions for Cancer Patients (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	July *(proposed 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 new measures proposed in the proposed rule. * Proposed new start date of January 2026 for publicly displaying.	

3. Proposal to Move Up 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.[70]

[70] FY 2024 IPPS/LTCH PPS final rule (88 FR 59204-59210; 59228).

CMS proposes 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 proposes 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 on the MCDS, and extension of the admission assessment window for the LCDS. The agency also seeks information on future measure concepts and on a future LTCH Star Rating system.

If the proposals are adopted, CMS estimates a total information collection burden increase for the eligible LTCHs of 2,117 hours for a total cost increase of $138,232 annually (attributable to the additional SPADEs items and modified item) compared to the currently approved information collection burden estimates.

CMS invites public comment on all of the proposals.

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.[71] 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.[72]

The 18 quality measures currently adopted for the FY 2024 LTCH QRP are shown in Table IX.E.-01 of the proposed rule. No new measures are being 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

[71] Post-acute care providers required to report SPADEs are long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.
[72] 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
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
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. Proposal to Collect 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,[73] 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,

[73] 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.

such as incontinence and an impaired ability to hear, see, or swallow; and (6) other categories deemed necessary and appropriate by the Secretary.[74]

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.[75] 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.

c. Proposal to Collect Four New Items as SPADEs

CMS proposes 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 Proposed. 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 therefore proposes to adopt the Living Situation item, which would ask "What is your living situation today?" The proposed response options would 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 proposes two new food items:

- The first would state: "Within the past 12 months, you worried that your food would run out before you got money to buy more."
- The second would state: "Within the past 12 months, the food you bought just didn't last and you didn't have money to get more."
- The proposed response options for each would be: Often true; Sometimes true; Never true; Patient declines to respond; and Patient unable to respond.

[74] These six categories are specified under section 1899B(b)(1)(B) of the Act.
[75] See 84 FR 42578-42581.

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, therefore, proposes to adopt the Utilities item, which would ask "In the past 12 months has the electric gas, oil, or water company threatened to shut off services in your home?" The proposed response options would be: Yes; No; Already shut off; Patient declines to respond; and Patient unable to respond.

d. Proposal to Modify the Transportation Item

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.[76] 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 proposed modifications would 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 proposes to modify the Transportation item. The modified item would ask: "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 proposed response options would be: Yes; No; Patient declines to respond; and Patient unable to respond.

3. RFI: LTCH QRP Quality Measure Concepts Under Consideration for Future Years

CMS seeks input on the following three concepts for the LTCH QRP:

- A composite measure of vaccinations, which could represent overall immunization status of LTCH patients.[77]
- The concept of depression, which may be similar to the Clinical Screening for Depression and Follow-up measure in the Universal Foundation.[78]

[76] Adopted in the FY 2020 LTCH PPS final rule (84 FR 42587).
[77] 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).
[78] See Centers for Medicare and Medicaid Services Measures Inventory Tool (cms.gov).

- The concept of pain management.

CMS will not respond to specific comments in the final rule, but intends to use input in response to this RFI for future measure development.

4. RFI: Future LTCH Star Rating System

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.

The agency seeks feedback on the development of a 5-star methodology for LTCHs that would help consumers quickly identify differences in quality and that would encourage continuous quality improvement. CMS also seeks feedback on measures to use in a star rating system. Specifically, CMS asks if there are specific criteria the agency should use to select measures for the system and how the agency should present the star ratings information in a way that is most useful to consumers. It will consider how a rating system would determine the star rating, the methods used for such calculations, and a timeline for implementation.

CMS will not respond to specific comments in the final rule, but intends to use input in response to this RFI for future measure development.

5. Form, Manner, and Timing of Data Submission under the LTCH QRP[79]

a. Proposed Reporting Schedule for the Proposed New SPADEs and Modified Transportation Data Element

- For the FY 2028 LTCH QRP, LTCHs would submit data on the 4 proposed 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 would (starting in CY 2027) submit data for the entire calendar year.
- LTCHs would be required to submit the new items (Living Situation, Food, and Utilities) with respect to admission only (and not also at discharge) because it is unlikely the status for those items would change between admission and discharge.
- Beginning with October 1, 2026 LTCH admissions, LTCHs would be required to submit the proposed modified Transportation item at admission only (as opposed to the current submissions at admission and discharge).

b. Proposed 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

[79] The current policies for reporting LTCH QRP data can be found at 42 CFR §412.560(b).

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 proposes to extend the admission assessment period to 4 days, beginning with LTCH admissions on October 1, 2026.

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.[80] 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.[81] In the following provisions of this section, the term hospital includes a critical access hospital unless otherwise noted.

2. Proposed 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).[82] 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 proposes 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 would need to 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 would be required to report AU data or AR data, respectively to CDC's NHSN for the selected EHR reporting period and would 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:

[80] Sections 1886(b)(3)(B)(ix) of the Act.
[81] Section 1814(l)(4) of the Act.
[82] 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.

- 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 proposes to add an exclusion for hospitals when they do not have a data source containing the minimal discrete data elements that are required for reporting. If the proposal for two separate measures is finalized, this exclusion would be applied to both measures, as would exclusion #1 described above. Exclusion #2 described above would be applied to the AU measure and exclusion #3 described above would be applied to the AR measure to align the appropriate exclusion to the data on which each separate measure would rely.

If the proposal for two separate measures is finalized, CMS further proposes to treat those measures as independent of any prior level of active engagement for the AUR surveillance measure in the reporting period in 2024. This means that for each measure hospitals could spend only one reporting period at the Option 1: Pre-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 would not be an expansion on reporting requirements. Therefore, CMS would maintain 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 would increase from five measures to six measures.

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 proposals made in the proposed 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.[83] 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).[84]

[83] See 88 FR 79307-79312.

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 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[85] 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. Proposed Change 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 proposes, 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.

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
	-AND-		

Objective	Measures	Maximum Points	Required/Optional
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	must choose one of the three reporting options)
	-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. *As proposed, the current single AUR Surveillance Reporting measure would be split into two separate measures (AU Surveillance and AR Surveillance).			

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 are 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 proposed 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. Proposed Update to Clinical Quality Measures

a. *Proposed Update 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.[86] Tables IX.F.-05 and IX.F.-06 of the proposed rule summarize the previously finalized eCQMs available for hospitals to report under the Medicare PIP for the 2024 and 2025 reporting periods.

Proposed eCQM Adoptions. CMS intends to continue to align the Medicare PIP eCQM reporting requirements with similar requirements under the Hospital IQR Program. To that end, the agency proposes the following changes for the Medicare PIP eCQM measure set (consistent with what CMS proposes in the rule for the Hospital IQR Program) beginning with the 2026 reporting period:

- To 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).
- To 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.

CMS refers readers to the discussion of the two new proposed measures and the proposed modification to the Global Malnutrition Composite measure for purposes of the Hospital IQR Program in section IX.C. (described above). Tables IX.F.-07 and IX.F.-08 show the proposed and previously finalized eCQMs for the 2026 and 2027 reporting periods and subsequent years.

b. Proposed 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).

In alignment with the Hospital IQR Program proposals in the rule, CMS proposes the following:

- 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).

[86] See sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act for these requirements applied to CAHs and hospitals, respectively.

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.

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.

8. Proposal to Update the Definition of Meaningful EHR User for Healthcare Providers That Have Committed Information Blocking

CMS reviews some of the proposals within the Disincentives proposed rule issued on November 1, 2023,[87] 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[88] must be referred to the appropriate agency to be subject to disincentives established through rulemaking. CMS specifically reviews one of its proposals within that rule. Under that policy, 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 would not be considered a meaningful EHR user in that reporting period or payment adjustment year – meaning the hospital would 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).[89]

9. Future Goals of Medicare PIP

Fast Healthcare Interoperability Resources (FHIR) Application Programming Interfaces (APIs) for Patient Access. 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

[87] 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (hereafter referred to as the Disincentives proposed rule) (88 FR 74947).
[88] Information blocking is defined in 45 CFR 171.103.
[89] 88 FR 74957.

certification criterion,[90] the adoption of the HL7 FHIR US Core Implementation Guide (IG) Standard for Trial Use version 6.1.0,[91] and the creation of the Insights Condition and Maintenance of Certification requirements (Insights Condition) within the ONC HIT Certification Program.[92] 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 reviews resources regarding appropriate cybersecurity practices, including the National Institute of Standards and Technology (NIST) updated guidance[93] 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.[94]

10. RFI Regarding Public Health Reporting and Data Exchange

CMS is working with the CDC and ONC on ways that the Medicare PIP could advance the public health infrastructure through health IT and data exchange standards. The agency describes that current public health-related certification criteria and standards support single patient, evidence-based submission of data from health care providers to public health agencies (PHAs), but may not adequately support complex data exchange use cases, such as bulk exchange data for patients who received a specific vaccine. CMS believes that increased use of FHIR-based APIs could enable PHAs to use health IT to securely query data directly when needed. ONC is evaluating standards development around the use of FHIR for public health data exchange that could be incorporated into certification criteria. CMS describes the benefits of establishing minimum functional capabilities and exchange standards to send and receive public health data as part of health IT certification criteria, including helping PHAs to align with health care provider data sources.

CMS believes that the following goals should drive future changes to the Public Health and Clinical Data Exchange objective of the Medicare PIP:

- Goal #1: The meaningful use of CEHRT enables continuous improvement in the quality, timeliness, and completeness of public health data reported.

[90] See 45 CFR 170.315(g)(10).
[91] See 45 CFR 170.215(b)(1)(ii).
[92] 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.
[93] NIST SP 800-66r2. The guidance is for health care entities on implementing requirements of the HIPAA Security Rule.
[94] 89 FR 8909-8927.

- Goal #2: The meaningful use of CEHRT allows for flexibility to respond to new public health threats and meet new data needs without requiring new and substantial regulatory and technical development.
- Goal #3: The meaningful use of CEHRT supports mutual data sharing between public health and healthcare providers.
- Goal #4: The reporting burden on hospitals is significantly reduced.

CMS invites comment on these four goals and on the following specific questions associated with each of these goals.

Questions for Goal #1: Quality, Timeliness, and Completeness of Public Health Reporting. Currently, under the Medicare PIP, hospitals must report their level of active engagement between the hospital and a PHA. However, that requirement does not allows assessment of the comprehensiveness, quality, or timeliness of the data provided to the PHAs. CMS is considering alternatives approaches, including to leverage FHIR-based data exchange for public health needs and to further automate reporting and minimize administrative burden for hospitals. Specifically, CMS asks:

- Instead of focusing on active engagement, should there be a shift to numerator/denominator reporting requirements for measures?
- How could performance be measured under approaches such as the use of FHIR APIs to support information exchange with PHAs?
- Should CMS continue to add measures under the Public Health and Clinical Data Exchange (PHCDE) objective to include additional system-specific requirements (for example, vital records)? If so, which ones and why?
- Should CMS create a new measure for each new type of data or use case added to the PHCDE objective? Are there risks of including too many measures? Or, should CMS group data types and use cases under a more limited set of PHCDE objective measures?
- How can CMS incentivize more complete electronic case reporting to PHAs?
- What are the benefits versus burdens CMS should consider? How should varying levels of public health readiness and capacity for electronic reporting (such as in rural areas) be taken into account?
- Are there other means other than the Medicare PIP that should be used to improve the completeness of reporting to PHAs?

Questions for Goal #2: Flexibility and Adaptability of Public Health Reporting Enterprise.

- How can the Medicare PIP support or incentivize ready reporting capabilities for healthcare providers? Are there any challenges around sharing data with PHAs?
- How can CMS and ONC work with vendors to ensure that provider systems are updated to meet new data needs, such as those in rural areas?

Questions for Goal #3: Increasing Bi-Directional Exchange with PHAs.

- How, if at all, could the Medicare PIP support or incentivize PHA adoption of certified systems and technologies?
- How can the PHCDE objective be used to incentivize early adoption of FHIR-based APIs for public health data exchange?

- Should CMS adopt a measure similar to the Enabling Exchange under TEFCA measure to allow providers to receive credit for the HIE objective by exchanging public health data through participation in TEFCA?

Questions for Goal #4: Eliminating Provider Reporting Burden.

- Which measures or other requirements under the current PHCDE objective result in the most administrative burden for hospitals?
- How can the PHCDE objective requirements be balanced with the goal of reducing burden on hospitals?
- How can technical approaches to data exchange with PHAs, such as FHIR APIs, reduce burden for health care providers? What are potential barriers to the goal of reducing burden as the new technical approaches are implemented?

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 Social Security Act (hereafter referred to as "the Act"). 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), and remedial actions CMS may take in the event model participants fail to comply with applicable requirements (§512.592) (CMS specifically seeks comment on these remedial provisions).

CMS also proposes rules for model participants' obligation to report bankruptcies, change in ownership, and other conditions (§512.595). The agency seeks comments on these proposed notifications.

2. Proposed Transforming Episode Accountability Model (TEAM) – Introduction

Under its 1115A waiver authority, CMS is proposing 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 proposes this model within the CMMI strategic refresh framework,[95] 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

[95] Innovation Center Strategy Refresh: https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper

2023.[96] 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 discusses 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).[97]

3. Provisions of Proposed Transforming Episode Accountability Model

As noted previously, the model performance period will be January 1, 2026 – December 31, 2030, with CMS having considered other alternatives. CMS seeks comment on the performance period.

Model participants would be limited to acute care hospitals paid under the IPPS, as defined in section 1886(d)(1)(B) of the Act, and would be the only entities to initiate episodes under TEAM. Participation will be mandatory for hospitals selected to participate in order to avoid selection issues that arise in voluntary models. CMS seeks comment on these aspects of the model.[98] CMS also asks for comment on whether or not to permit hospitals in states participating in CMS' Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model to participate in TEAM as well.

While CMS is proposing that participation in TEAM be mandatory for selected hospitals, the agency is considering, and seeks comment on, whether to create a voluntary opt-in participation arm of the model, and describes the terms that would govern the eligibility and selection of voluntary participants.

CMS proposes 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 seeks comment on this proposal.

As proposed, there would be three tracks in TEAM, defined by varying levels of potential risk and reward. Track 1 would be available only in 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.

[96] https://www.federalregister.gov/documents/2023/07/18/2023-15169/request-for-information-episode-based-payment-model

[97] Most of these models produced no net savings to the Medicare program, after accounting for provider reconciliation payments.

[98] Maryland hospitals under the Total Cost of Care (TCOC) model would be excluded from participating in the TEAM.

CMS is proposing 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 proposes 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, which would allow TEAM participants to have higher levels of reward and risk. The agency proposes to only allow TEAM participants to participate in Track 1 for one performance year, specifically PY 1.

Because some participants are less able to take on substantial financial risk, CMS is proposing to allow certain TEAM participants[99] 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 PROPOSED 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)
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 (10% 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 seeks comment on the proposals for the TEAM Participation Tracks at §512.520, and on the proposal that TEAM participants who meet the eligibility criteria for Track 2 may self-select into Track 2 and change their track selection annually.

a. Proposed Approach to Select TEAM Participants and Statistical Power

[99] 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.

CMS proposes 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 proposed rule lists the 803 CBSAs eligible for selection in TEAM in Table X.A.-02.)

CMS proposes 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 proposes 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 in 16 unique combinations, but would 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.

CMS specifically seeks comment on the proposed participant selection method.

b. Proposed Episodes

CMS proposes 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 is not proposing to include medical episodes in TEAM, but because CJR and BPCI Advanced showed that medical episodes reflect a higher proportion of dually eligible beneficiaries than surgical episodes, CMS is soliciting comment on whether the agency should include medical episodes in the TEAM.

CMS also wants to ensure that the episodes in the model include post-acute care services. Given these criteria, CMS proposes 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 are described in detail at proposed §512.525(d). 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.

CMS is soliciting comments on including medical episodes in TEAM, on the five surgical episode categories it has proposed and how each of the surgical episodes is defined (and the use of MS-DRG and HCPCS codes to identify them), and any other additional episode categories that should be considered. (The selected episode categories and billing codes are summarized in Table X.A.-04, reproduced below.)

TABLE X.A.-04: PROPOSED 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 453, 454, 455, 459, 460, 471, 472, 473. HCPCS 22551, 22554, 22612, 22630, 22633
Major bowel procedure: MS-DRG 329, 330, 331

CMS proposes 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 seeks comment on the proposed episode duration.

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);[100] 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. CMS seeks comment on the proposed excluded services, and the process for updating the lists of excluded services for TEAM included in §512.525(f), §512.525(g), and §512.525(h). CMS also seeks comment on its proposed criteria for canceling a TEAM episode (beneficiary no longer meets criteria for inclusion, beneficiary dies during the admission or procedure, or the participating hospital is subject to the extreme and uncontrollable circumstances (EUC) policy).

c. Quality Measures and Reporting

CMS proposes 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. Where possible, CMS would align TEAM quality measures with those used in ongoing models and programs to minimize participant burden.

CMS proposes 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). Reconciliation payments to TEAM participants would be adjusted based on their

[100] MDC 02 (Diseases and Disorders of the Eye), MDC 14 (Pregnancy, Childbirth, and Puerperium), MDC 15 (Newborns), and MDC 25 (Human Immunodeficiency Virus).

performance on these measures throughout the duration of the model. CMS includes an extensive discussion of the background of and rationale for using these measures, and their specifications, in the proposed rule. CMS seeks comment on these three measures.

In addition, CMS is considering the future use of three measures on the 2023 Measures Under Consideration (MUC) list:[101] 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 is seeking comment on the potential for these three measures to replace the CMS PSI 90 measure beginning in 2027.

CMS proposes 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.

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.

At proposed §512.540, CMS proposes 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 proposes to roll the three-year baseline forward for each year of the model and lays out the specific data used for each performance year at proposed §512.540(b)(2). Within each three-year baseline period, CMS proposes 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 (see next paragraph). CMS seeks comment on the data it proposes to use and the weighting methodology for calculating episode target prices.

The agency would 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 are combined for purposes of target pricing with the applicable MS-DRG representing an inpatient hospitalization without

[101] 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

Major Complications and Comorbidities, as CMS expects those beneficiaries to have similar clinical characteristics and costs. CMS proposes 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 proposes to define as the 9 U.S. census divisions), and seeks comments on this approach to high-cost outliers.

CMS proposes 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 proposes that TEAM participants would be provided the regional prices as episode targets, rather than hospital-specific or a blend of regional/hospital-specific prices. However, CMS notes that the health services research literature found that safety-net hospitals were disproportionately disadvantaged by the 100 percent regional price targets under CJR, and considered ways to protect such hospitals under TEAM. CMS therefore solicits comment on the 100 percent regional episode price targets, and alternative ways of setting or adjusting price targets for safety-net hospitals, or hospitals in TEAM Tracks 1 and 2.

The agency proposes 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. CMS is soliciting comment on the proposed calculation of the trend factor, and alternatives that it considered but is not proposing. Similarly, CMS solicits comment on the proposed 3 percent discount factor, as well as other alternatives considered, but not proposed.[102]

CMS proposes to risk adjust episode-level target prices at reconciliation by beneficiary age, the beneficiary's Hierarchical Condition Count, and social risk. CMS proposes 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 proposes 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 proposes 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 proposes 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

[102] Such as varying the discount factor based on episode category, or using a lower or no discount factor.

threshold of at least 31 total episodes in the baseline period for PY1, CMS would still reconcile their episodes, but the TEAM participant would be subject to the Track 1 stop-loss and stop-gain limits for PY1. 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 PY 2-5. CMS seeks comment on its proposal for setting and applying the low volume threshold at reconciliation.

Risk Adjustment and Normalization. For TEAM, CMS proposes 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. For beneficiary age, CMS proposes to use the same age brackets used in CJR: less than 65 years, 65-75 years, 75-85 years, and 85 years or more, based on the beneficiary's age on the first day of the episode. CMS also proposes 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 proposes to use a variable to account for social risk composed of three elements: (1) fully dually eligible for Medicare/Medicaid, (2) position on the distribution 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). As part of the risk adjustment methodology, CMS proposes to provide TEAM participants with a prospective normalization factor along with preliminary target prices. CMS seeks comment on its risk adjustment proposals.

Proposed Process for Reconciliation. At proposed §512.550, CMS proposes 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 seeks comment on this approach.

Composite Quality Score. CMS proposes, as part of the annual reconciliation process, to adjust the difference between the TEAM participant's performance year spending and their reconciliation price (the reconciliation amount) by its Composite Quality Score, an approach similar to that used in CJR and BPCI Advanced.

As noted above, the three quality measures used in TEAM would be collected through the CMS Hospital IQR program and the Hospital-Acquired Conditions (HAC) reduction program. Similar to BPCI Advanced, for TEAM CMS proposes 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 proposes 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 proposes 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 asserts 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 proposes 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.

Calculating the Reconciliation Payment Amount or Repayment Amount. CMS proposes 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 as described in section X.A.3.d.(3)(e) of the preamble of this proposed 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).[103] CMS seeks comment on this calculation methodology.

CMS proposes 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.-08 of the proposed rule, reproduced below.

TABLE X.A.-08 – TEAM PROPOSED 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 seeks comment on TEAM's proposed methodology at proposed §512.550(d) to calculate and apply the CQS, and also on its proposed definition of quality-adjusted reconciliation amount at §512.505.

Limitations on NPRA. CMS proposes 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 proposes 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-

[103] This amount would be adjusted by a post-episode spending calculation, discussed later in the proposed rule.

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 proposes 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. CMS considered, but is not proposing, higher and lower stop-loss limits for Track 3. The agency seeks comments on its proposed stop-loss and stop-gain limits, and the alternatives considered.

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 proposes to calculate total Part A and Part B spending in the 30-day period following the completion of each episode, whether or not the spending is related to the defined episode. CMS proposes that starting in PY1 for Track 3 TEAM participants, and PY2 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 seeks comment on its proposal to make TEAM participants responsible for making repayments to Medicare based on high spending in the 30 days after the end of the episode, and on its proposed methodology to calculate the threshold for high post-episode spend.

Reconciliation Payments and Repayments. For the performance year 1 reconciliation process for Track 1 TEAM participants, CMS proposes 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.

CMS is not proposing that model participants post financial guarantees in the event of negative performance in the model that results in a repayment obligation. CMS discusses, but does not specifically propose, the manner in which repayments may be collected (*e.g.*, a dollar amount or percentage reduction applied to future Medicare payments, limiting the reductions to the same kinds of episodes under which the model operates). CMS also discusses an alternative approach such as those used in current Medicare value-based purchasing programs, whereby which payments or repayments would be executed at the claim level, rather than on a lump sum basis. CMS seeks stakeholder input on these alternatives.

Proposed Appeals Process. At proposed §512.560, CMS proposes 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 proposes 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.

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 mis-aligned. 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 proposes 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. This proposal would allow any savings generated on an episode in TEAM and any contribution to savings in the total cost of care model be retained by each respective participant. The episode spending in TEAM would be accounted for the in the total cost of care model's total expenditures, but TEAM's reconciliation payment amount or repayment amount would not be included in the total cost of care model's total expenditures.

This proposal is in contrast to the policies governing providers who previously participated simultaneously in BPCI and an ACO, which involved disbursing reconciliation payments to BPCI participants and then submitting a recoupment demand for any savings generated on overlap. Overwhelming feedback from participants indicated that this recoupment process was perceived negatively and postured participants in BPCI and the total cost of care model into an adversarial relationship. 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.

CMS acknowledges that some ACOs may prefer that their aligned beneficiaries not be included in TEAM, given that this would amount to ceding control over spending for these beneficiaries to an entity outside the ACO. CMS seeks comment on an alternative proposal whereby ACO-aligned beneficiaries would be prohibited from being in a TEAM episode. CMS also seeks 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.

f. Health Equity

CMS for purposes of TEAM defines safety net hospitals and rural hospitals, and flexibilities that would be afforded to these providers.

CMS considered several definitions of safety net providers, including the CMMI Strategy Refresh definition (acute care and critical access hospitals whose patient mix of beneficiaries with dual eligibility or Part D LIS exceeds the 75th percentile threshold for all congruent facilities who bill Medicare),[104] MedPAC's Medicare Safety Net Index (MSNI, calculated as the sum of (1) the share of the hospital's Medicare volume associated with low-income beneficiaries; (2) the share of its revenue spent on uncompensated care; and (3) an indicator of how dependent the hospital is on Medicare),[105] and using the Area Deprivation Index[106] to identify hospitals in geographic areas with socioeconomic challenges. Having considered these options, CMS proposes to use the CMMI Strategy Refresh definition of safety net hospitals within TEAM, and seeks comment on this proposal.

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 proposes 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. CMS seeks comment on this definition.

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 proposes 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 seeks comment on this proposal.

Health Equity Plans and Reporting. To further align with other CMS Innovation Center models and promote health equity, CMS proposes 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 proposes that these plans would be mandatory for TEAM participants beginning in PY2.

CMS similarly proposes that TEAM participants voluntarily submit demographic data (including data on race, ethnicity, language, disability, sexual orientation, gender identity, sex

[104] https://www.cms.gov/priorities/innovation/data-and-reports/2022/cmmi-strategy-refresh-imp-tech-report
[105] https://www.medpac.gov/document/chapter-3-hospital-inpatient-and-outpatient-services-march-2023-report/
[106] https://www.neighborhoodatlas.medicine.wisc.edu/

characteristics, and other demographics) to CMS in PY1, and that this would become mandatory in PY2 and subsequent years.

Beginning in PY1, CMS proposes 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 proposes 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 PY1 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.

CMS solicits comments on all of these health equity reporting proposals. In addition, the agency also seeks 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.[107]

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. If the proposed arrangements are finalized, CMS expects to make 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 proposed 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 proposes 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:

[107] Somewhat cryptically, CMS suggests that these funds would not come out of the Medicare Parts A and B Trust Funds.

- 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.
- 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 seeks comment on the proposed definition of TEAM collaborators and any additional Medicare-enrolled providers or suppliers that should be included in this definition.

Sharing Arrangements. CMS proposes 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 proposes 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 proposes 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 proposes that a sharing arrangement must comply with the provisions of section X.A.3.g.(b) of this proposed rule[108] and all other applicable laws and regulations, including the applicable fraud and abuse laws and all applicable payment and coverage requirements. CMS proposes that the TEAM participant and TEAM

[108] 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.

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.
- 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 proposes 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 proposes 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 proposes 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 seeks 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 are met.

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 proposes 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 must 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 proposes to establish similar requirements for PGPs, NPPGPs and TGPs that vary because these entities do not themselves directly furnish billable services.

CMS proposes 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 seeks comment on this proposal, and also seeks comment on whether the methodology must be based *solely* on these two elements, or if, alternately, the methodology must be based *substantially* on these two elements. Lastly, CMS seeks comment on this proposal, where the methodology could take into account the amount of TEAM activities provided by a TEAM collaborator relative to other TEAM collaborators.

CMS proposes that for each performance year, 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.[109] The agency also proposes 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 seeks comment on its proposed aggregate and individual TEAM collaborator limitations on alignment payments.

Documentation Requirements. CMS proposes detailed documentation requirements for financial arrangements, proposes mandatory records that the TEAM participant must keep, and proposes 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 seeks seek 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.

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[109] For example, CMS proposes 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 must 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.

Distribution Arrangements. CMS proposes 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 proposes 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 proposes 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 proposes 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 seeks comment on these proposals, and specifically 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 proposes 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 proposes 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 proposes 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 or entity's same contribution toward model goals and provision of TEAM activities in the methodologies for both gainsharing and distribution payments, leading 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 seeks comment on all of these provisions. In addition, CMS seeks comments from stakeholders on how the regulation of these financial arrangements may interact with similar regulations under the Medicare Shared Savings Program (MSSP).

Distribution Arrangements. CMS proposes and seeks 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 for the sole purpose of sharing a distribution payment received by the PGP, NPPGP, or TGP.[110] 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.

Beneficiary Incentives. CMS proposes 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. In the event this proposal is finalized, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model patient incentives (42 CFR 1001.952(ii)) 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 proposes 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 seeks comment on this proposal.

With respect to technology, CMS proposes specific safeguards to prevent abuse. The agency proposes that no item or service involving technology can exceed $1000 for any TEAM beneficiary in any episode. CMS also proposes 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 seeks comment on its proposals related to technology in TEAM episodes.[111]

CMS proposes 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 proposes 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.

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[110] 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.

[111] 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.

CMS proposes documentation requirements for all beneficiary incentives.

CMS seeks comment on its proposals related to beneficiary incentives.

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 previously, if the proposals herein are finalized, CMS expects 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 proposes 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.

CMS seeks comment on this proposal.

h. Proposed Waivers of Medicare Program Requirements

Given the potential of TEAM to reduce Medicare spending and improve quality of care, CMS proposes 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 considered, but is not proposing, to waive the current law requirement that a beneficiary be "homebound" in order to receive home health services. Nor is CMS proposing to waive the "incident to" rules at §410.26(b)(5), which allow physicians or a non-physician practitioner to bill for services furnished in the beneficiary's home, when the beneficiary does not meet the eligibility criteria for the home health benefit. (This waiver was available under BPCI Advanced and CJR, but CMS is not proposing it for TEAMs given very low uptake under those models.)

CMS also discusses 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 proposes to waive the same two provisions. CMS is proposing 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. Like under BPCI Advanced and CJR, CMS proposes 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. With respect to beneficiaries

receiving telehealth services in their home or place of residence, CMS emphasizes the current law requirement that such visits cannot substitute for in-person home health visits per section 1895(e)(1)(A) of the Act. In this proposed rule, CMS describes other current law requirements that would still be in effect for TEAM beneficiaries receiving telehealth services.

CMS seeks comments on the proposed waivers with respect to telehealth services, and the proposed creation of the home visit telehealth codes.

Lastly in this section, CMS discusses waiving the current law requirement that a beneficiary have a 3-day hospital stay in order to qualify for a coverage of subsequent skilled nursing facility care (the "SNF 3-day rule"). CMS proposes 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.[112] 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 proposes to monitor use of this waiver to ensure that TEAM beneficiaries are not being inappropriately prematurely discharged from the hospital.

CMS seeks comment on its proposal to waive the SNF 3-day rule for TEAM participants and beneficiaries.

CMS also notes 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 believes there are situations where it would be appropriate to require additional beneficiary financial protections under the SNF 3-day waiver for TEAM, given that the waiver of the SNF 3-day rule could result in unintended beneficiary financial liability in some situations. CMS proposes 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 planning notice outlining their potential financial liability; however, CMS would 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.

CMS seeks comment on these proposals, as well as any other issues the agency should consider under the auspices of beneficiary protections.

i. Monitoring and Beneficiary Protection

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[112] https://www.medicare.gov/care-compare/?redirect=true&providerType=NursingHome

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 proposes 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 proposed 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 must 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.

Additionally, CMS proposes to require that TEAM participants must 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 proposes 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 proposes 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).[113]

j. Access to Records and Record Retention

CMS notes that MSSP and other CMMI models contain audit and record retention requirements that CMS proposes to replicate in TEAM. CMS proposes 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, without limitation, documents and other evidence regarding

[113] As discussed earlier, this monitoring is intrinsic to the TEAM reconciliation process, given that this proposed rule would require that TEAM participants be financially accountable for certain post-episode payments occurring in the 30 days after conclusion of the episode.

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 solicits comments on its monitoring and beneficiary protection policies.

k. Data Sharing

Based on its experience with BPCI Advanced and CJR, CMS is proposing under its existing authority[114] 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.[115] 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 proposes 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 proposes 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 requests comments on all aspects of its proposal to share beneficiary-identifiable claims data with TEAM participants. CMS also seeks comments on the minimum data necessary beneficiary-identifiable information for TEAM participants to request beneficiary-identifiable

[114] Under the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 45 CFR 164.501, under the auspices of "health care operations."

[115] CMS proposes 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.

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.

l. Evaluation Approach

CMS proposes 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 historic patterns of care among the TEAM participants to any changes made in these patterns in response to the TEAM. In addition, the overall design would include a comparison of TEAM participants with hospitals not participating in TEAM to help us discern simultaneous and competing provider and market level forces that could influence our findings. CMS discusses analytic parameters of the TEAM evaluation, including analytic techniques, statistical methods, data to be collected and analyzed, and evaluation questions.

CMS proposes 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.

CMS seeks comments on its approach to evaluating TEAM.

m. Decarbonization and Resilience Initiative

CMS discusses a proposal for a voluntary Decarbonization and Resilience Initiative within TEAM to assist hospitals in addressing the threats to the nation's health and its health care system presented by climate change and 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 Scope 1 and Scope 2 emissions as defined by the Greenhouse Gas Protocol (GHGP) framework,[116] with the potential to add Scope 3 in future years. CMS asserts that the surgical episodes under TEAM represent opportunities for hospitals to become more energy efficient, pointing to studies showing that although operating rooms represent a relatively small proportion of hospitals' physical footprint, they typically consume 3-6 times more energy per square foot as the hospital as a whole, account for 40-60 percent of the hospital's supply costs, and produce 30 percent of the hospital's waste.[117,118]

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[116] 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

[117] Andrea J. MacNeill, Robert Lillywhite, & Carl J. Brown. The Impact of Surgery on Global Climate: A Carbon Footprinting Study of Operating Theatres in Three Health Systems. *Lancet Planetary Health*, vol. 1, no. 9, pp. E381-E388. December 2017. https://www.thelancet.com/journals/lanplh/article/PIIS2542-5196(17)30162-6/fulltext

[118] Maya A Babu, Angela K Dalenberg, Glen Goodsell, Amanda B Holloway, Marcia M Belau, & Michael J Link. Greening the Operating Room: Results of a Scalable Initiative to Reduce Waste and Recover Supply Costs. Neurosurgery, vol. 85, no. 3, pp. 432-437. September 1, 2019. https://pubmed.ncbi.nlm.nih.gov/30060055/

In this proposed rule, CMS provides a literature review of 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.

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 states that given the established impact GHG emissions have on Medicare, Medicaid, and CHIP beneficiary health, the agency proposes to collect data on GHG emissions, through voluntary reporting, as part of its monitoring and evaluation of TEAM. CMS proposes to assist TEAM participants in measuring their GHG emissions, reporting these metrics, and sharing benchmark data on GHG emissions through Individualized Feedback Reports. In doing so, CMS hypothesizes that the proposed Decarbonization and Resilience Initiative could directly support TEAM participants in building greater energy resilience to disasters and ensuring greater continuity of care. CMS expects the Decarbonization and Resilience Initiative to increase the energy efficiency of participating TEAM participants, and increase the degree to which they have sustainable, more localized sources of energy that are resilient to disasters and other climate change related hazards. Further, CMS contends that reductions in operating costs and spending due to energy efficiency and more efficient provision of care (in the case of anesthetic gases) directly contribute to savings for CMS, citing cost-based reimbursement for critical access hospitals as a direct example, and improvements in beneficiaries' health as an indirect example.

Under the first element of the Initiative (technical assistance) CMS indicates 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 proposes 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 proposes four areas for reporting: (1) Organizational Questions; (2) Building Energy Metrics; (3) Anesthetic Gas Metrics; and (4) Transportation Metrics. CMS proposes specific metrics under each of these four areas. CMS also proposes a set of questions that TEAM participants opting into the Initiative would be required to answer.

Looking into the future, in this proposed rule CMS also includes a request for information (RFI) on Scope 3 metrics and Metered-dose Inhalers (MDI).

CMS proposes 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 proposes 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 contends that TEAM participants may receive additional indirect benefits from engaging in the voluntary reporting portion of the Decarbonization and Resiliency Initiative.

CMS solicits comments on all elements of its proposed voluntary Decarbonization and Resilience Initiative. In addition, CMS includes 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.

n. Termination of the TEAM

CMS states that the general provisions relating to termination of models by CMS in 42 CFR 512.596 would apply to the TEAM. CMS indicates that the agency would provide written notice to TEAM participants specifying the grounds for termination and 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.

4. Information Collection 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 (Paperwork Reduction Act), shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule for TEAM need not be reviewed by the Office of Management and Budget.

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 $27 million, contending that most participants will begin participation in Track 1, which carries no downside risk (see Table I.G.12.-01 of the proposed 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 on net, TEAM participants would pay CMS $403 million, and that TEAM would save the Medicare program approximately $705 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.[119]

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	$5,729	$5,842	$5,958	$6,073	$6,179
(+) Reconciliation payment amounts (positive) and Repayment amounts (negative)	$85	-$98	-$133	-$136	-$121
- Baseline episode spending	$5,787	$5,902	$6,018	$6,134	$6,241
Impact	$27	-$157	-$194	-$197	-$184
Impact as % of Baseline	**0.5%**	**-2.7%**	**-3.2%**	**-3.2%**	**-2.9%**

[119] https://www.cms.gov/oact/tr/2023

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, 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.

CMS is proposing 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 will 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 cites other reasons 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 notes 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 is proposing that Board Members serve a maximum of three consecutive terms, it is also considering a policy that would allow Board Members to serve four consecutive terms (12 years in total). Under the alternative proposal, CMS is also considering 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.

C. Maternity Care Request for Information (RFI)

CMS is seeking information 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 wishes to gather 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).

D. RFI on Obstetrical Services Standards

1. Background

CMS establishes health and safety requirements that hospitals, Rural Emergency Hospitals (REHs) and CAHs must meet to participate in Medicare and Medicaid. These requirements are known as Conditions of Participation (CoPs) for Medicare-certified providers and suppliers and selected Medicaid provider types.

There are no baseline care requirements for hospitals, CAHs, and REHs that are specific to labor and delivery, prenatal and post-partum care, and care for newborn infants. Given the ongoing concerns about the delivery of maternity care in Medicare and Medicaid certified hospitals, CAHs, and REHs, CMS plans to propose baseline health and safety standards for obstetrical services in the 2025 Outpatient Prospective Payment System (OPPS) proposed rule.[120]

[120] CMS is requesting public comment in the IPPS rule on the types of requirements that should be included in the CoPs for obstetrical care. The public comment period on this rule ends on June 10, 2024 or about 1-month before the OPPS rule is typically available to the public. At the time the IPPS proposed rule comment period end, the OPPS proposed rule will be well into development.

In the FY 2023 IPPS proposed rule (87 FR 28549), CMS solicited feedback on a wide range of maternal health issues and opportunities for CMS to improve maternal health care. In response, some commenters were concerned that failure to comply with a new CoP specifically for obstetrical care would result in the loss of Medicare certification and could negatively impact access to obstetrical care. Other commenters, including the American College of Obstetrics and Gynecology and the American Medical Association supported the creation of a CoP specifically for labor and delivery.

2. Obstetrical Services CoP.

CMS is soliciting comment on what should be the overarching requirement, scope, and structure for an obstetrical services CoP. Potential options that CMS is exploring include:

- Creating an optional services CoP specific to obstetrical services, similar to the current Optional Services CoPs for Surgical services (42 CFR 482.51), Anesthesia services (42 CFR 482.52).
- Modeling an OB services CoP after infection prevention and control stewardship program CoPs (42 CFR 482.42). This could include requirements relating to service organization and policies, leadership responsibilities, and application to multi-hospital systems.
- Requiring hospitals to develop standard processes for managing pregnant, birthing, and postpartum patients with or at risk for:
    - Obstetric hemorrhage (a leading cause of maternal mortality); and
    - Severe hypertension (a common pregnancy complication).

3. Staff Training.

Existing hospital CoPs for emergency services (42 CFR 482.55) already require hospitals to:

> Provide a medical screening examination (MSE) [...] for an emergency medical condition (EMC), including active labor, regardless of an individual's ability to pay. Applicable facilities are then required to provide stabilizing treatment for patients with EMCs."

Furthermore, existing Joint Commission standards on the provision of care, treatment, and services standards for maternal safety require the education of all staff and providers who treat pregnant/postpartum patients on the hospital's evidence-based severe hypertension/preeclampsia and hemorrhage procedures.

Despite these existing regulations and standards, several organizations have cited that obstetrical readiness for hospitals with and without obstetrical services is suboptimal. CMS is interested in feedback on requiring additional training, protocols, or equipment for hospital non-OB unit, emergency department, CAH, and REH staff that treat pregnant and postpartum patients as a stop-gap measure to ensure individuals living without access to maternal health care can safely and effectively receive necessary services.

The proposed rule further notes that hospitals are neither required to provide obstetrical services nor emergency services. CMS is interested in ways to mitigate potential impacts and costs to hospitals in implementing a possible CoP requirement. In addition, CMS is interested in understanding if and how requiring hospitals to submit data related to maternal morbidity and mortality could be incorporated into any maternal services CoP.

E. 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 is proposing to remove the prior exclusion of Puerto Rico from the PERM program now that it has developed measures to comply with PERM requirements.

F. CoP Requirements for Hospitals and CAHs to Report Acute Respiratory Illnesses

1. Background.

As noted above, 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. Proposal to Continue Requiring 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 and seasonal influenza virus, influenza-like illness, and severe acute respiratory infection in a standardized format.

In this proposed rule, effective October 1, 2024, CMS proposes 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 proposes 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 encourages hospitals and CAH to voluntarily continue reporting this information.

3. Soliciting Input on Collecting Data by Race and Ethnicity

The proposed rule indicates 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 seeks 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.

4. Proposal to Collect Additional Elements During a PHE

CMS' proposal to require acute respiratory illness reporting is not 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 proposes 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.

5. Collaboration.

If CMS finalizes its proposal, 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, local, jurisdictional 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 National Syndromic Surveillance Program (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 is requesting public comment 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.

XI. Medicare Payment Advisory (MedPAC) Recommendations

In its March 2024 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law plus 1.5 percent. CMS responded that consistent with the statute, it is proposing an applicable percentage increase for FY 2025 of 2.6 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 recommends redistributing disproportionate share hospital (DSH) and uncompensated care payments using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommends 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 a 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]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2025 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2025 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2025 MGC RB Reclassifications (4)[5]	Proposed 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 Proposed FY 2025 Changes (8)[9]
All Hospitals	3,090	2.6	0.0	0.0	0.0	0.0	0.4	-0.2	2.4
By Geographic Location:									
Urban hospitals	2,390	2.6	0.0	0.0	-0.2	0.0	0.4	-0.1	2.4
Rural hospitals	700	2.6	-0.4	0.6	2.4	-0.4	0.1	-1.0	1.9
Bed Size (Urban):									
0-99 beds	643	2.6	-0.2	0.4	-1.2	0.5	0.5	-2.0	0.4
100-199 beds	683	2.6	-0.2	0.0	-0.6	0.6	0.4	-0.4	1.9
200-299 beds	418	2.6	-0.1	-0.1	0.0	0.4	0.4	0.0	2.3
300-499 beds	397	2.6	0.0	0.1	0.3	0.2	0.3	-0.1	2.4
500 or more beds	247	2.5	0.2	-0.2	-0.3	-0.5	0.4	-0.4	3.0
Bed Size (Rural):								0.0	0.0
0-49 beds	350	2.5	-0.5	0.4	1.7	-0.4	0.2	-0.2	0.7
50-99 beds	183	2.6	-0.5	0.3	2.0	-0.4	0.3	-0.1	0.0
100-149 beds	92	2.6	-0.4	0.4	2.4	-0.4	0.1	-0.1	2.2
150-199 beds	44	2.6	-0.2	0.6	2.6	-0.5	0.0	0.0	3.4
200 or more beds	31	2.6	-0.2	1.4	3.1	-0.6	0.2	0.0	4.1
Urban by Region:									
New England	106	2.6	0.0	-1.4	-0.1	-0.4	1.4	-1.9	0.1
Middle Atlantic	280	2.6	-0.1	-1.5	0.6	-0.3	0.9	-0.1	1.6
East North Central	367	2.6	0.1	0.4	-0.9	-0.7	0.1	-0.4	2.9
West North Central	156	2.6	0.0	0.3	-0.7	-0.6	0.5	0.0	3.7
South Atlantic	396	2.6	0.0	1.2	-0.7	-0.5	0.3	-0.2	2.9
East South Central	141	2.6	0.0	2.0	-1.2	-0.6	0.1	-0.1	4.8
West South Central	357	2.6	0.1	1.2	-0.8	-0.6	0.1	-0.1	4.5
Mountain	178	2.6	0.0	1.3	-0.5	0.0	0.3	0.0	1.6
Pacific	358	2.5	0.1	-1.6	1.3	2.6	0.1	0.0	1.2
Rural by Region:									
New England	21	2.6	-0.2	0.3	2.1	-0.6	0.4	-1.9	2.0
Middle Atlantic	53	2.6	-0.3	2.1	5.6	-0.6	0.0	-0.3	3.7
East North Central	111	2.6	-0.3	0.1	2.5	-0.4	0.1	-2.4	0.1
West North Central	79	2.6	-0.5	0.0	0.6	-0.2	0.4	-0.4	1.8
South Atlantic	112	2.6	-0.5	0.1	1.5	-0.4	0.1	-1.2	0.8
East South Central	134	2.5	-0.3	1.5	2.7	-0.6	0.0	-0.6	3.6
West South Central	124	2.5	-0.4	0.6	2.6	-0.5	0.0	-0.4	2.9
Mountain	42	2.4	-0.3	0.7	-0.3	-0.2	0.6	0.0	2.4
Pacific	24	2.6	-0.4	0.0	3.0	-0.3	0.0	0.0	1.5
Puerto Rico									
Puerto Rico Hospitals	51	2.6	-0.5	-2.0	-2.1	-0.5	0.5	0.0	2.5
By Payment Classification:									
Urban hospitals	1,705	2.6	-0.1	0.0	-1.3	0.9	0.6	0.0	2.4
Rural areas	1,385	2.6	0.0	0.0	1.0	-0.7	0.2	-0.3	2.4
Teaching Status:									

	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2025 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2025 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2025 MGCRB Reclassifications (4)[5]	Proposed 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 Proposed FY 2025 Changes (8)[9]
Nonteaching	1,843	2.6	-0.2	0.1	-0.1	0.7	0.3	-0.5	1.8
Fewer than 100 residents	959	2.6	-0.1	0.2	0.2	0.0	0.4	-0.2	2.5
100 or more residents	288	2.5	0.2	-0.3	-0.2	-0.5	0.4	0.0	2.8
Non-DSH	325	2.6	-0.1	-0.1	-1.0	-0.3	0.6	-0.2	2.6
100 or more beds	1,009	2.6	0.0	0.0	-1.3	1.1	0.6	0.0	2.5
Less than 100 beds	371	2.6	-0.2	0.1	-1.4	1.0	0.4	-0.5	1.6
Rural DSH:									
Non-DSH	96	2.6	0.0	0.3	0.7	-0.8	0.2	-2.5	-0.6
SCH	248	2.6	-0.4	0.1	0.2	-0.1	0.0	0.0	2.3
RRC	791	2.6	0.1	0.0	1.1	-0.7	0.2	-0.1	2.6
100 or more beds	41	2.6	0.2	0.1	-1.4	-0.8	0.1	-0.6	3.5
Less than 100 beds	209	2.5	-0.4	0.5	3.6	-0.8	0.3	-6.8	-4.1
Urban teaching and DSH:									
Both teaching and DSH	579	2.6	0.0	0.0	-1.3	0.7	0.7	0.0	2.6
Teaching and no DSH	54	2.6	-0.1	-0.3	-0.8	-0.6	0.8	-0.4	2.3
No teaching and DSH	801	2.6	-0.1	0.0	-1.3	1.8	0.3	0.0	2.2
No teaching and no DSH	271	2.6	-0.1	0.1	-1.2	0.0	0.5	0.0	2.8
Special Hospital Types:									
RRC	142	2.6	-0.1	1.3	2.4	-0.3	0.3	-0.9	2.7
RRC with Section 401 Reclassification	586	2.6	0.1	-0.1	1.0	-0.8	0.2	-0.1	2.5
SCH	249	2.5	-0.6	0.1	0.2	-0.1	0.1	0.0	2.1
SCH with Section 401 Reclassification	38	2.6	-0.1	0.0	0.1	0.0	0.0	0.0	2.5
SCH and RRC	120	2.6	-0.4	0.3	1.1	-0.2	0.1	0.0	2.7
SCH and RRC with Section 401 Reclassification	43	2.6	-0.3	0.2	0.2	-0.1	0.0	0.0	2.5
Type of Ownership:									
Voluntary	1,911	2.6	0.0	-0.1	0.1	-0.1	0.4	-0.2	2.3
Proprietary	753	2.6	-0.1	0.8	-0.3	0.7	0.2	-0.1	2.6
Government	425	2.5	0.1	-0.4	-0.2	-0.1	0.1	-0.1	2.7
Medicare Utilization as a Percent of Inpatient Days:									
0-25	1,362	2.6	0.1	0.1	-0.3	0.1	0.3	0.0	2.9
25-50	1,623	2.6	-0.1	-0.1	0.2	-0.1	0.5	-0.3	2.0
50-65	65	2.6	-0.3	-1.5	-0.1	1.6	0.5	-0.3	1.3
Over 65	17	2.2	-2.5	0.6	-0.2	-0.4	2.3	-1.2	-0.5
Medicaid Utilization as a Percent of Inpatient Days:									
0-25	1,955	2.6	-0.1	0.2	0.0	-0.3	0.4	-0.3	2.3
25-50	1,009	2.6	0.1	-0.2	0.0	0.2	0.4	0.0	2.6
50-65	97	2.5	0.0	-1.3	-0.2	2.2	0.1	0.0	1.4
Over 65	29	2.4	0.0	-1.1	-1.4	5.6	0.1	0.0	1.3
FY 2025 Reclassifications:									
All Reclassified Hospitals	1,141	2.6	0.0	0.0	1.1	-0.5	0.2	-0.2	2.4
Non-Reclassified Hospitals	1,949	2.6	-0.1	0.0	-1.5	0.7	0.6	-0.1	2.4
Urban Hospitals Reclassified	965	2.6	0.1	0.0	0.9	-0.5	0.2	-0.2	2.4
Urban Non-reclassified Hospitals	1,438	2.6	-0.1	0.0	-1.8	0.9	0.7	0.0	2.5
Rural Hospitals Reclassified Full Year	294	2.6	-0.4	0.7	2.8	-0.5	0.0	-0.6	2.5
Rural Non-reclassified Hospitals Full Year	393	2.5	-0.4	0.4	1.5	-0.4	0.3	-1.3	1.4

	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2025 Weights and DRG Changes with Application of Recalibration Budget Neutrality (2)[3]	Proposed FY 2025 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2025 MGCRB Reclassifications (4)[5]	Proposed 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 Proposed FY 2025 Changes (8)[9]
All Section 401 Reclassified Hospitals:	741	2.6	0.1	-0.1	0.8	-0.8	0.2	-0.2	2.4
Other Reclassified Hospitals (Section 1886(d)(8)(B))	56	2.6	-0.3	0.9	5.2	-0.8	0.4	-3.4	-0.8

[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 proposed hospital rate update, including the proposed 2.6 percent update to the national standardized amount and the hospital-specific rate (the proposed 3.0 percent market basket rate-of-increase reduced by 0.4 percentage point for the proposed productivity adjustment).

[3] This column displays the proposed payment impact of the changes to the Version 42 GROUPER, the proposed 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 proposed recalibration budget neutrality factors of 0.997301 and 0.999873.

[4] This column displays the payment impact of the proposed update to wage index data using FY 2021 cost report data. This column displays the payment impact of the application of the proposed wage budget neutrality factor. The proposed wage budget neutrality factor is 1.000014.

[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 proposed geographic budget neutrality factor of 0.972192.

[6] This column displays the effects of the proposed rural floor. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The proposed rural floor budget neutrality factor applied to the wage index 0.981486.

[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 for FY 2025, a non-budget neutral payment provision. As previously noted, this analysis does not reflect the 3-month extension of the MDH program through December 31, 2024 under section 307 of the CAA, 2024 (Pub. L. 118-42).

[9] This column shows the estimated change in proposed payments from FY 2024 to FY 2025.