Fiscal Year 2026 Medicare Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System Proposed Rule Summary
(CMS-1833-P)

On April 11, 2025, the Centers for Medicare & Medicaid Services (CMS) released its proposed rule describing federal fiscal year (FY) 2026 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 April 30, 2025. **The public comment period on the rule will end on June 10, 2025.**

The payment rates and policies described in the FY 2026 IPPS/LTCH PPS proposed rule 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. Unless otherwise specified, policies will be effective October 1, 2025.

The proposed rule also includes proposed changes to the TEAM Model that begins January 1, 2026, and requests public comment on requests for information (RFIs) to gather public input on the transition to digital quality measurement (dQM) in CMS quality reporting programs.

The proposed rule also references Executive Order (E.O.) 14192 "Unleashing Prosperity Through Deregulation," dated January 31, 2025. Consistent with EO 14192's focus on reducing regulatory compliance costs, the proposed rule requests public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. All comments should be made to: https://www.cms.gov/medicare-regulatory-relief-rfi.

CMS makes many data files available to support analysis of the proposed rule. These data files are generally available at: FY 2026 IPPS Proposed Rule Home Page | CMS. Numbered tables included in the IPPS/LTCH rule are only available on the CMS website at the above hyperlink.

TABLE OF CONTENTS

TABLE OF CONTENTS			
			Page
	C.	Worksheet S-3 Wage Data	106
	D.	Method for Computing the Unadjusted Wage Index	107
	E.	Occupational Mix Adjustment	107
	F.	Geographic Reclassifications	107
	G.	Wage Index Floors, Outmigration Adjustment and Other Wage Index Policies	110
	H.	Wage Index Tables	112
	I.	Labor-Related Share	112
IV.	**Rebasing and Revising the Hospital Market Baskets**		113
V.	**Disproportionate Share (DSH) and Uncompensated Care Payments (UCP)**		114
	A.	Background	114
	B.	Supplemental Payments: Indian Health Service (IHS), Tribal and Puerto Rico Hospitals	114
	C.	Uncompensated Care Payments	115
	D.	Payment Impacts	119
VI.	**Other Decisions and Changes to the IPPS**		121
	A.	Post-Acute Care Transfer Policy	121
	B.	Inpatient Hospital Update	122
	C.	Rural Referral Centers (RRCs)	123
	D.	Low-Volume Hospitals (LVH)	123
	E.	Medicare Dependent Small Rural Hospitals (MDH)	124
	F.	Indirect and Direct Graduate Medical Education Costs	124
	G.	Nursing and Allied Education	126
	H.	Payment Adjustment for Certain Immunotherapy Cases	127
	I.	Hospital Readmissions Reduction Program (HRRP)	128
	J.	Hospital Value-Based Purchasing (HVBP) Program	132
	K.	Hospital-Acquired Conditions (HAC) Reduction Program	139
	L.	Rural Community Hospital Demonstration Program	141
VII.	**Changes to the IPPS for Capital-Related Costs**		142
VIII.	**Changes for Hospitals Excluded from the IPPS**		145
	A.	Rate-of-Increase	145
	B.	Critical Access Hospitals (CAHs)	145
IX.	**Long-Term Care Hospital Prospective Payment System (LTCH PPS)**		146
	A.	Background	146
	B.	MS-LTC-DRGs and Relative Weights	147
	C.	Payment Rates and Other Changes	153
	D.	Impacts	159
X.	**Quality Data Reporting Requirements for Specific Providers**		160
	A.	Overview	160
	B.	Toward Digital Quality Measurement in CMS Quality Programs – RFI	161
	C.	Hospital Inpatient Quality Reporting (IQR) Program	163
	D.	PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program	173
	E.	Long-Term Care Hospital Quality Reporting Program (LTCH QRP)	177
	F.	Medicare Promoting Interoperability Program	182
XI.	**Transforming Episode Accountability Model (TEAM)**		192
	A.	Background	192
	B.	TEAM Provisions	194
	C.	Information Collection	204
XII.	Medicare Payment Advisory (MedPAC) Recommendations		204
APPENDIX: Impact Analysis for FY 2026			205

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

CMS estimates that the proposed rule will increase FY 2026 combined operating and capital payments to approximately 3,038 acute care hospitals paid under the IPPS by an estimated $4.0 billion. This net impact is primarily driven by the changes in FY 2026 operating payments, including uncompensated care payments (UCP), FY 2026 capital payments, and the expiration of the temporary changes in the low-volume hospital (LVH) and the Medicare Dependent (MDH) program in its entirety. These changes are relative to payments made in FY 2025.

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 2.4 percent for hospitals that successfully report quality measures and are meaningful users of electronic health records (EHR). The 2.4 percent rate increase is the net result of a market basket update of 3.2 percent less 0.8 percentage points for productivity. The payment rate update factors are summarized in the table below.

Hospitals that fail to participate successfully in the Hospital Inpatient Quality Reporting (IQR) Program or are not meaningful users of EHR do not receive the full payment rate increase. The table below 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
No IQR	25% of the MB	3.2	2.4	-0.8	1.6%
No EHR	75% of the MB	3.2	2.4	-2.4	0.0%
No IQR/EHR	100% of the MB	3.2	2.4	-3.2	-0.8%

In past years, CMS provided the number of hospitals that did not meet the requirement to receive the full update due to failing the IQR and/or are not meaningful users of EHR technology. On page 1335 of the display copy of the proposed rule, CMS indicates that approximately 100 hospitals on average fail the IQR program and that number for FY 2026 is expected to be the same as in past years. HPA did not find any similar information in the proposed rule about the number of hospitals failing the meaningful use of EHR program.

B. Payment Impacts

CMS' impact table for IPPS operating costs shows FY 2026 payments increasing 3.4 percent. Not all policy changes are reflected in this total. For example, the total does not include 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 2026 Payment Rate Increase	+2.3
FY 2026 Change to Outlier Payments	+0.2[1]
Expiration of the MDH Program and Changes to LVH Program	-0.1[2]
FY 2026 Change to Uncompensated Care Payments	1.3[3]
Wage Index Changes that are not Budget Neutral	-0.2[4]
Total	+3.4[5]

[1] CMS targets 5.1 percent of IPPS payments as outliers but estimates that it will pay "less than that target by approximately 0.3 percentage point" in FY 2025. As a result, CMS estimates total payments will increase by 0.2 percentage points due to targeting 5.1 percent of total IPPS payments as outliers for FY 2026 and the "interactive effects among various add-on factors."
[2] 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 hospitals to qualify than under regulations that were previously in effect.
[3] The past two years CMS estimates of the change in uncompensated care payment have increased in the proposed rule but declined in the final rule because of a re-estimate of the factors affecting uncompensated care between the proposed and final rule in the National Health Expenditures Accounts.
[4] Unlike in past years, CMS shows all wage index changes, including non-budget neutral changes in a single column that shows a -0.2 percentage point reduction in payments across all hospitals.
[5] If the percentage changes shown here are multiplied, the change is just over 3.5 percent or slightly higher than shown in the proposed rule. CMS typically explains any difference as due to rounding or the "interactive effects among various add-on factors."

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	3.4%
Urban	3.5%
Rural	2.5%
Major Teaching	3.3%

To the extent the impact on a given hospital category deviates from the national average of 3.4 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 lower impacts on rural hospitals appear to be driven by the expiration of the MDH program and the less permissive adjustments for low volume hospitals as well as the MS-DRG changes and recalibration of the relative weights. As noted above, the MDH and low volume hospital program statutory provisions have expired many times previously but have been extended by legislation.

CMS shows the combined impact of several wage index provisions in Column 6 of the wage index table. These impacts are described as the combination of several budget neutral changes

(changes to the wage data, changes to the labor-related share, geographic reclassification including urban to rural reclassifications as well as rural hospitals deemed urban under the "Lugar" provision explained below in section III. G. and the rural floor) and non-budget neutral changes such as the imputed floor applied in all urban states, the frontier wage index and the outmigration adjustment).

Other provisions having an impact include:

NTAP. NTAP payments are not subject to budget neutrality. CMS is proposing to continue NTAP payments for 25 technologies that remain eligible for add-on payments in FY 2026 and estimates Medicare will pay $598 million in FY 2026 for these technologies.

Generally, CMS will discuss new NTAP applications under the traditional pathway—those requiring a substantial clinical improvement determination—in the proposed rule and not make a final determination on substantial clinical improvement until the final rule.

For alternative pathway applications where the Food and Drug Administration (FDA) approval process is considered a proxy for substantial clinical improvement, CMS is proposing to approve 28 alternative pathway applications and estimates total expenditures of $405.5 million.

Uncompensated Care. Medicare payments to be distributed for uncompensated care costs are estimated to increase by $1.4 billion or by 25.1 percent.[1] The past two years CMS estimates of the change in uncompensated care payment have increased in the proposed rule but declined in the final rule because of a re-estimate of the factors affecting uncompensated care between the proposed and final rule in the National Health Expenditures Accounts.

Supplemental payments to Puerto Rico, Indian Health Service (IHS) and Tribal Hospitals are estimated to increase another $20.7 million in FY 2026. The supplemental payments to hospitals in Puerto Rico and for IHS and Tribal Hospitals are analogous to uncompensated care payments for other hospitals and account for unique issues with cost reporting that apply to these hospitals. More detail on these calculations is found in section IV.

Low Volume Hospitals (LVH). Section 1886(d)(12) of the Social Security Act (the Act) established the LVH program and provided authority to the Secretary to make an empirical determination of the payment for LVHs. Subsequent legislation changed the criteria to allow more hospitals to qualify. However, those qualifying criteria will expire on September 30, 2025, absent Congressional intervention. CMS estimates changes to the qualifying criteria will result in 580 fewer hospitals receiving the low volume hospital payment adjustment, resulting in lower spending of $375 million.

[1] CMS is reporting the increase as $1.505 billion and 26.0 percent in the impact section of the rule, but there appears to be a discrepancy with the preamble where the increase is reported as $1.435 billion. The preamble sections appear to track with other figures used to calculate uncompensated care payments and are assumed to be correct for this section of the summary to determine aggregate payment impact.

Hospital Readmissions Reduction Program (HRRP). CMS is proposing to modify the six readmission measures in the program to include Medicare Advantage (MA) beneficiaries into the patient cohorts and modify the applicable performance period from a 3-year period to a 2-year period beginning with the FY 2027 program year. As these changes will not begin until FY 2027, they will have no impact on FY 2026 payments.

The HRRP program is estimated to reduce FY 2026 payments to an estimated 2,828 hospitals or 82.8 percent of all hospitals eligible to receive a readmissions penalty. The proposed readmissions penalty is estimated to affect 0.42 percent of payments to the hospitals. The impact section of the rule includes table I.G.7.-01 that illustrates the average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural) in FY 2026.

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 or approximately $1.7 billion among 2,532 hospitals. Table 1.G.6.-01 in the impact section illustrates the proposed average net percentage payment adjustment by category of hospital (e.g., Large Urban, Other Urban, Rural) in FY 2026 and reflects CMS' proposal to remove the health equity adjustment.

Hospital Acquired Conditions (HAC) Reduction Program. The HAC reduction program reduces payment to 2,933 hospitals, which are among the lowest quartile for HACs. Table 1.G.7.01 shows the number of hospitals in the program and the number of hospitals that are in the lowest performing quartile by hospital category.

Rural Community Hospital Demonstration Program. CMS estimates costs for the Rural Community Hospital Demonstration Program at $47.5 million for FY 2026 using "as submitted" cost reports from FY 2020. CMS will use reconciled FY 2020 cost reports in the FY 2026 final rule when applying a final adjustment for budget neutrality to FY 2026 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 2026 (before adjustments):

	Update
Full Update	2.4%
No IQR	1.6%
No EHR	0.0%
No EHR/IQR	-0.8%

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

- MS-DRG recalibration, 0.998422 (a decrease of 0.16 percent).
- MS-DRG recalibration cap, 0.999938 (a decrease of 0.01 percent).
- Wage index, 1.001273 (an increase of 0.13 percent).
- Geographic reclassification, 0.97696 (a decrease of 2.30 percent).
- Transition for eliminating low-wage index policy 0.999741 or -0.03 percent.
- 5 percent cap on wage index reductions, 0.993116 or -0.69 percent.
- The outlier offset factor is 0.949 or -5.1 percent. and
- The rural community hospital demonstration program adjustment is 0.999548 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, budget neutrality for the 5 percent on reductions to the wage indexes, the outlier adjustment, and rural community hospital demonstration project are removed from the FY 2025 standardized amount before the FY 2026 adjustments are applied. The net increase in the standardized amount results as follows:

Factor	Net Change
Update	2.4%
DRG Recalibration	-0.16%
DRG Recalibration Cap	-0.01%
Wage Index	0.13%
Geographic Reclassification	1.47%
25th Percentile Transition Budget Neutrality	-0.03%
5% Cap on Wage Index Reductions	-0.61%
Outlier	0.00%
Rural Community Hospital	-0.03%
Net Change*	3.19%

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

The proposed increase in the capital rate is 3.28 percent from $512.14 to $528.95. The combined increase in the proposed operating standardized amount and the capital rate is 3.19 percent for FY 2026.

The standardized amounts do not include the 2 percent Medicare sequester reduction that began in 2013 and will continue until at least 2032 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 2026

	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 (66.0%)	$4,511.41	$4,505.67	$4,476.16	$4,370.43
Non-Labor (34.0%)	$2,324.06	$2,269.59	$2,305.90	$2,251.43
WI<=1.0				
Labor (62%)	$4,237.99	$4,138.66	$4,204.88	$4,105.55
Non-Labor (38%)	$2,597.48	$2,536.60	$2,577.18	$2,516.31
National Capital Rate (All Hospitals)	$528.95			

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 $46,217 for FY 2025. 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 2026 outlier threshold. CMS proposes adopting an outlier threshold for FY 2026 of $44,305, an increase of 3.6 percent and $1,555 from the FY 2025 amount. CMS projects that the proposed outlier threshold for FY 2026 will result in outlier payments equal to 5.1 percent of operating DRG payments and 4.13 percent of capital payments. Accordingly, CMS is applying adjustments of 0.949 to the operating standardized amounts and 0.958716 to the capital federal rate to fund operating and capital outlier payments respectively.

FY 2026 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 2026, the latest year of claims data is the December 2024 update to the FY 2024 Medicare Provider Analysis and Review File (MedPAR). The latest cost report data is the December 2024 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 between FY 2023 and FY 2024, 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	$592,911,386,867	6,891,832	$86,031.03
FY 2024	$624,034,862,796	6,879,333	$90,711.54
Annual Rate of Increase			1.0544
Squared for 2 Years of Inflation			1.1118

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

These data are shown in the table below.

	December 2023 PSF	December 2024 PSF	% Change	Factor
Operating	0.252119	0.244584	-2.99%	0.97011
Capital	0.017659	0.016912	-4.23%	0.9577

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 2026 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 was effective October 1, 2024.

For the FY 2025 outlier threshold, CMS will use the historical outlier reconciliation amounts from the FY 2020 cost reports (cost reports with a beginning date on or after October 1, 2019, and on or before September 30, 2020). 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 2026 proposed rule, CMS is using the December 2024 extract of the Hospital Cost Report Information System (HCRIS) to determine the reconciliation amounts.

As the new methodology for reconciling outliers was not applicable during this cost reporting period, CMS is applying the new criteria to information on the FY 2020 cost reports to determine an estimate of reconciled outlier payments for FY 2026. CMS determined reconciled outlier payments as a percentage of total outlier payments for the year under analysis (FY 2020 for FY 2026). 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.

When determining reconciliation for FYs 2020 through 2025, reconciliation was always negative (hospitals were owed additional outlier funding) and the effect was a decrease to the outlier threshold. Using the FY 2020 cost report data and PSF values for the FY 2026 proposed rule, CMS reports that outlier reconciliation dollars is a positive value (hospitals owe Medicare additional outlier funding) and would have the effect of an increase to the outlier threshold. CMS believes these data are anomalous and proposes not to use these figures and instead hold the data constant and to use the same outlier reconciliation figure used for the FY 2025 IPPS final rule (-0.04 percent). Another possibility is that the application of the new outlier reconciliation criteria to a past year changes the result from Medicare owing hospitals to hospitals owing Medicare under the reconciliation process. CMS does not discuss this possibility. CMS will reconsider whether to adopt this proposal in the final rule if the updated data does not appear to be anomalous.

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. CMS found the same result for capital reconciliation as it did for operating reconciliation that it characterized as anomalous—the result was positive indicating that hospitals owed Medicare, and the effect would be to increase the outlier threshold. For this reason, CMS is also using the FY 2025 capital reconciliation amounts (-0.03 percent) for determining the FY 2026 proposed rule outlier threshold. CMS will also reconsider its capital reconciliation adjustment based on updated data available for the final rule.

FY 2024 Outlier Payments. CMS' current estimate, using available FY 2024 claims data, is that outlier payments for FY 2024 were approximately 5.13 percent of total MS-DRG payments or 0.12 percentage points more than the target of 5.1 percent—the amount the standardized amount was reduced to fund outliers. Following long-standing policy, the agency will not make

retroactive adjustments to ensure that total outlier payments for FY 2024 are equal to the projected 5.1 percent of total MS-DRG payments and the amount of the reduction in the standardized amounts.

FY 2025 Outlier Payments. CMS says that FY 2025 claims data are unavailable to estimate the percentage of total payments made as outliers in FY 2025. However, in the impact section of this proposed rule, CMS estimates that, using FY 2024 data, outlier payments will be 0.2 percentage points lower (4.9 percent) than the 5.1 percent targeted and removed from the standardized amounts to fund outlier payments.

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

A. Adoption of the MS-DRGs

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 DRG, relative to the average resources used to treat cases in all DRGs.

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

When CMS adopted the MS-DRGs, it also adopted a budget neutrality adjustment to offset increases in expenditures associated with improvements in documentation and coding that do not represent a change in patient severity of illness. Congress later enacted statutory provisions governing how these budget neutrality adjustments would be applied. For more information on these issues, CMS refers readers to past rulemakings between FY 2008 and FY 2023.

B. Changes to Specific MS-DRG Classifications

1. Discussion of Changes to Coding System and Basis for MS-DRG Updates[2]

Providers use the ICD-10 coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS-DRG system. The deadline for submitting MS-DRG classification change requests to CMS for FY 2026 was October 20, 2024. Change requests may include requests to create, modify, or delete MS-DRGs, change ICD-10-CM diagnosis code(s) severity level designations, change ICD-10-PCS procedures code(s), Operating Room (OR) designations, or to review the CC Exclusions List or the surgical hierarchy. MS-DRG change requests are only accepted through the Medicare Application Request Information System™ (MEARIS) at https://mearis.cms.gov.[3]

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 2027 by October 20, 2025 via MEARIS at https://mearis.cms.gov/public/home.

CMS received requests to modify the GROUPER logic in several MS-DRGs under major diagnostic categorie (MDC) 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and a request to modify GROUPER logic for the MS-DRG 794 (Neonate and Other Significant Problems) under MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period):

- Request 1: Modify the GROUPER logic of new MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device), new MS-DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and new MS-DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC); new MS- DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device) and new MS-DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC); and MS-DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with an ICD-10-PCS code that describes fusion of a sacroiliac joint using an internal fixation device with tulip connector or insertion of an internal fixation device with tulip connector into a pelvic bone with

[2] Throughout this section, reference is made to CC (complications and comorbidities) and MCC (major complications and comorbidities)

[3] The burden associated with this information collection requirement is subject to the Paperwork Reduction Act (PRA) of 1995 and was approved under OMB control number 0938-1431 which has an expiration date of 09/30/2025.

another spinal fusion procedure code that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG.

CMS Response to Request 1: **CMS is not proposing to modify the GROUPER logic of new MS-DRG 426, 427, 428, 447, 448.** As discussed separately in section II.C.5.c of the proposed rule, **CMS is proposing modifications related to the diagnostic code logic for MS-DRG 456, 457, and 458.**

- Request 2. Modify the GROUPER logic of MS-DRGs 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively); MS-DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively); and MS-DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with ICD-10-PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) that currently map to the lower severity level MS-DRG to the highest severity level (with MCC) MS-DRG.

  CMS Response to Request 2: **CMS is not proposing modifications to the GROUPER logic related to these MS-DRGs**. CMS believes additional time is needed to review and evaluate potential extensive modifications to the structure of these MS-DRGs due to claims data analyses suggesting that a key factor in some cases is the fact that patients have infection(s) which require additional resources. CMS indicates it must also consider if there are additional factors such as the severity of illness with other secondary conditions reported in any other O.R. procedures or services provided that may be contributing to resource consumption for these cases.

- Request 3. Modify the GROUPER logic of MS-DRG 794. The requestor recommended that ICD-10-CM diagnosis codes P09.6 (Abnormal findings on neonatal screening for neonatal hearing loss), Z13.0 (Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism), Z82.5 (Family history of asthma and other chronic lower respiratory diseases) and Z82.79 (Family history of other congenital malformations, deformations and chromosomal abnormalities) be added to the MS-DRG 795 (Normal Newborn) "only secondary diagnosis" list so that they would result in assignment to MS-DRG 795 when coded with a principal diagnosis code from ICD-10-CM category Z38 (Liveborn infants according to place of birth and type of delivery) instead of MS-DRG 794.

  CMS Response Request 3: CMS states that additional time is needed to fully and accurately evaluate cases currently grouping to the MS-DRGs in MDC 15 to consider if restructuring the current MS-DRGs would better recognize the clinical distinctions of these patient populations. **CMS is not proposing to change the MS-DRG assignment of individual ICD-10-CM diagnosis codes at this time,** however, CMS believes it is appropriate to consider the request to add ICD-10-CM diagnosis codes P09.6 (Abnormal

findings on neonatal screening for neonatal hearing loss), Z13.0 (Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism), Z82.5 (Family history of asthma and other chronic lower respiratory diseases) and Z82.79 (Family history of other congenital malformations, deformations and chromosomal abnormalities) to the MS-DRG 795 (Normal Newborn) "only secondary diagnosis" list in connection with its continued examination of the GROUPER logic that would determine the assignment of cases to the MS-DRGs in MDC 15 in future rulemaking.

CMS states it intends to continue to monitor the data as they continue to consider these issues. **CMS welcomes public comment and feedback on other factors it should consider in the potential restructuring of these MS-DRGs**. Feedback and other suggestions should be directed to MEARIS™ at: https://mearis.cms.gov/public/home

To allow the public to better analyze and understand the impacts of the proposals in this rule, CMS is again providing several resources, including the test version of the ICD-10 MS-DRG GROUPER Software, Version 43, the draft version of the ICD-10 MS-DRG Definitions Manual, Version 43, the draft version of the Definitions of Medicare Code Edits Manual, Version 43, and the supplemental mapping files in Tables 6P.1a and 6P.1b of the FY 2025 and FY 2026 ICD-10-CM diagnosis codes and ICD-10- PCS procedure codes which are all available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html and https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software

Note that as a result of changes in policy implemented in FY 2025, CMS no longer discusses the IPPS Medicare Code Editor (MCE) in rulemaking. Instead, it generally discusses future changes or updates to the MCE through instructions to the Medicare Administrative Contractors (MACs). Stakeholders are able to view a draft version of the Definitions of Medicare Code Edits (MCE) Manual to review any changes that will become effective October 1 for FY 2026. Any further changes that occur as a result of new and modified code updates approved after the annual spring ICD-10 Coordination and Maintenance Committee meeting are made available in association with the annual IPPS/LTCH PPS final rule. The draft FY 2026 ICD-10 MCE Version 43 Manual file on the CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software. Questions, comments, or recommendations regarding the MCE should be sent to CMS at MSDRGClassificationChange@cms.hhs.gov.

This section (section II.C) of the preamble discusses changes that CMS proposes to the MS-DRGs for FY 2026, and CMS is inviting public comments on each of them. For this proposed rule, CMS' MS-DRG analysis was based on ICD-10 claims data from the September 2024 update of the FY 2024 MedPAR file, which contains hospital bills received from October 1, 2023 through September 30, 2024 (referred to as the "September 2024 update of the FY 2024 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. CMS evaluates patient care costs using average costs and lengths of stay and relies on clinical factors to determine whether patients are clinically distinct or similar to other patients in the MS-DRG. To evaluate resource costs, CMS considers both the absolute and percentage differences in average costs between cases selected for review and the remainder of cases in the MS-DRG. In addition, CMS considers variation within these groups as well as 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.[4] CMS believes that this better reflects resource stratification and promotes stability in the relative weights by avoiding low volume counts for the NonCC level MS-DRGs. As discussed in the FY 2024 IPPS/LTCH PPS final rule,[5] CMS continues to apply the criteria to create subgroups, including application of the NonCC subgroup criteria, in its annual analysis of MS-DRG classification requests, consistent with its approach since FY 2021 when CMS finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. Accordingly, in CMS' analysis of the MS-DRG classification requests for FY 2026 received by October 20, 2024, as well as any additional analyses that were conducted in connection with those requests, the agency applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table, reproduced from the preamble of the proposed rule:

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

[4] 85 FR 58448
[5] 88 FR 58661

CMS notes that, in general, once the decision has been made to propose modifications to the MS-DRGs, or to split (or subdivide) an existing base MS-DRG into severity levels, all five criteria must be met for the base MS-DRG to be split (or subdivided) by a CC subgroup. When analyzing requests to create a new MS-DRG, CMS typically evaluates the most recent year of MedPAR claims data available. However, when evaluating requests to split an existing base MS-DRG into severity levels, CMS typically analyzes the most recent two years of data. This allows CMS to compare across years in order to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and to validate that the established severity levels within a base MS-DRG are supported.[6]

CMS explains that the first step in its process of evaluating if the creation of a new CC subgroup within a base MS-DRG is warranted is to determine if all criteria are satisfied for a three-way split. In applying criteria for a three-way split, a base MS-DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each subgroup is then analyzed in relation to the other two subgroups using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria fail, the next step is to determine if criteria are satisfied for a two-way split. In applying criteria for a two-way split, a base MS-DRG is initially subdivided into two subgroups: "with MCC" and "without MCC" (1_23) or "with CC/MCC" and "without CC/ MCC" (12_3). Each subgroup is then analyzed in relation to the other using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS-DRG. If the three-way split fails on any one of the five criteria and all five criteria for both two-way splits (1_23 and 12_3) are met, CMS applies the two-way split with the highest R2 value. CMS notes that if the request to split (or subdivide) an existing base MS-DRG into severity levels specifies the request is for either one of the two-way splits (1_23 or 12_3), in response to the specific request, CMS will evaluate the criteria for both of the two-way splits; however, CMS does 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

CMS received a request to review the recent MS-DRG assignments to Pre-MDC MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies) and to clarify how decisions for the assignment of cell and gene therapies will be made moving forward.[7] The request was made as a result of CMS' decision for FY 2025 to map prademagene zamikeracel (PZ) to Pre-MDC MS-DRG 018. CMS summarizes and responds to detailed questions posed by the requestor in the preamble of the proposed rule. **CMS is not proposing any revisions as a result of this request** and instead refers the reader to discussions in prior final rules[8] in which CMS has summarized and responded to similar comments, and to section II.C.11 of this

[6] As noted in prior rulemaking (80 FR 49368)
[7] CMS summarizes the requestor's feedback and suggestions in detail in the proposed rule preamble
[8] FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806), FY 2023 IPPS/LTCH PPS final rule (87 FR 48806 through 48807), FY 2025 IPPS/LTCH PPS final rule (89 FR 69008 through 69010)

proposed rule preamble for additional information regarding the ICD-10 Coordination and Maintenance Committee meeting process.

CMS also received a request to create a new neurosurgical gene therapy MS-DRG to more accurately reflect the clinical characteristics and resource intensity required for the administration of neurosurgical gene therapies, including eladocagene exuparvovec, for patients diagnosed with Aromatic L-amino acid decarboxylase (AADC) deficiency. The request is in connection with comments and questions about how products are grouped under the IPPS MS-DRGs, specifically with respect to cell and gene therapies under Pre-MDC MS-DRG 018. CMS refers the reader to previous final rules[9] for discussions regarding eladocagene exuparvovec. CMS summarizes details related to the request in the preamble of the proposed rule. In response, CMS expressed appreciation for the detailed clinical information provided by the requestor and acknowledged that cases involving neurosurgery are technically complex and that patients undergoing these procedures tend to be critically ill, many with rare diseases. However, CMS notes that their analysis of the September 2024 update of the FY 2024 MedPAR file yielded zero cases reporting the administration of eladocagene exuparvovec and concludes that it would be premature to consider the creation of a new neurosurgical gene therapy MS-DRG at this time. Therefore, **CMS is not proposing any revisions as a result of this request**. CMS also notes that it received a new procedure code request to identify and describe the Smartflow® Neuro Cannula as the delivery mechanism to administer eladocagene exuparvovec that was included as a topic in the Spring 2025 ICD-10 Coordination and Maintenance Committee Update materials. CMS refers the reader to: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials for additional detailed information regarding the request, and the related materials. **CMS continues to welcome additional feedback and comments on other options to consider on how to appropriately address low volume, high-cost treatments for rare diseases.**

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

a. Logic for MS-DRGs 023 through 027

CMS received three separate but related requests to review the MS-DRG assignments for a subset of procedures assigned to MS-DRGs 023 through 027. In response to these requests, CMS reviewed GROUPER logic for MS-DRGs 023 and 024 and examined claims data from the September 2024 update of the FY 2024 MedPAR file. The requests and actions CMS is taking include:

- Request to create a new MS-DRG for cases involving "chemotherapy implants" and cases involving "epilepsy with neurostimulator." CMS summarizes an analysis performed by the requestor. Based its own review of the claims data, as outlined in more detail in the preamble of the proposed rule, CMS does not believe the data support creating a new MS-DRG for these cases. Therefore, **CMS is not proposing** to create a new MS-DRG for cases reporting the insertion of a chemotherapy implant and cases describing a neurostimulator generator inserted into the skull with the insertion of a

[9] FY 2022 IPPS/LTCH PPS final rule (86 FR 44895) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 48853 through 48854)

neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy for FY 2026. However, as a result of this review, CMS determined that further analysis was needed, as outlined in more detail in the preamble of the proposed rule, resulting in proposals summarized below.

- Request to reassign cases reporting the implantation of a deep brain stimulation (DBS) system from the lower (without MCC) severity level MS-DRG 024 to the higher (MCC) severity level MS-DRG 023, even if there is no MCC reported. CMS summarizes the analysis provided by the requestor. Based on its own review of the claims data, as outlined in more detail in the preamble of the proposed rule, CMS does not believe the data support reassignment. Therefore, **CMS is not proposing** to reassign cases reporting the implantation of a DBS system from the lower (without MCC) severity level MS-DRG 024 to the higher (with MCC) severity level MS-DRG 023, even if there is no MCC reported. However, as a result of this analysis, CMS determined that further analysis was needed, as outlined in more detail in the preamble of the proposed rule, resulting in proposals summarized below.

- Request to have all cases reporting the concomitant insertion of a DBS generator and lead assigned to MS-DRGs 023 and 024. CMS summarizes the analysis performed by the requestor. Based on its own review of the claims data, as outlined in more detail in the preamble of the proposed rule, **CMS is not proposing** to reassign all cases reporting the procedure code combination describing a single array generator and insertion of neurostimulator lead into brain to MS-DRGs 023 and 024 because it does not believe reassignment would fully address the difference in resource utilization in these cases. However, as a result of this analysis, CMS determined that further analysis was needed, as outlined in more detail in the preamble of the proposed rule, resulting in proposals summarized below.

As a result of the analyses performed for the requests above, and in order to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped, based on additional analyses presented in more detail in the preamble of the proposed rule, **CMS is proposing the following:**

- **CMS is proposing to add 114 procedure code combinations to a new "Intracranial Neurostimulator Implant" logic list in MS-DRGs 020, 021, and 022** that describe (1) the insertion of multiple or single array neurostimulator generators with the insertion of a neurostimulator lead into the brain or the cerebral ventricle and (2) the insertion of neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain. CMS refers the reader to Table 6P.2e associated with this proposed rule (and available at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps) for the list of the 114 ICD-10-PCS procedure code combinations CMS proposes to add.
- **CMS is proposing to delete the "Major Device Implant," "Epilepsy Principal Diagnosis," "Neurostimulator" logic lists from MS-DRGs 023 and 024.**

- **CMS is proposing to change the titles of: MS-DRGs 020, 021, 022, 023 and 024 to better reflect the assigned procedures** effective October 1, 2025, for FY 2026.

Additionally, during its review of the GROUPER logic for MS-DRGs 023 and 024, CMS identified four ICD-10-PCS procedure codes that were inadvertently excluded from the "Chemotherapy Implant" logic list. Therefore, **CMS is proposing to add procedure codes 00H001Z, 00H005Z, 00H031Z, and 00H041Z to the "Chemotherapy Implant" logic list in MS-DRGs 023 and 024**, effective October 1, 2025, for FY 2026. Additionally, **CMS is proposing to change the description of the logic list in MS-DRGs 023 and 024** from "Chemotherapy Implant" to "Antineoplastic Implant" to better reflect the GROUPER logic that includes ICD-10-PCS procedure codes describing antineoplastic agents implanted in the brain.

b. Hypertensive Encephalopathy

CMS received a request to delete MS-DRGs 077, 078, and 079 (Hypertensive Encephalopathy with MCC, with CC, and without CC/MCC, respectively) as a result of the addition of an instructional note under diagnosis code I16.1 (Hypertensive emergency) in the ICD-10-CM Tabular List of Diseases and Injuries. CMS examined the ICE-10-CM Tabular List of Diseases and Injuries, as well as the GROUPER logic and claims data from the September 2024 update of the FY 2024 MedPAR file for all cases in MS-DRG 077, 078, and 079. As a result of these analyses:

- **CMS is proposing** to delete MS-DRGs 077, 078, and 079.
- **CMS is proposing** to reassign ICD-10-CM diagnosis code I67.4 (Hypertensive encephalopathy) from MDC 01 MS-DRGs 077, 078, and 079 to MS-DRGs 070, 071, and 072.
- **CMS is proposing** to change the titles of MS-DRGs 067, 068, and 069 from "Nonspecific CVA and Precerebral Occlusion without Infarction with MCC, with CC, and without CC/MCC, respectively" to "Precerebral Occlusion without Infarction with MCC, with CC, and without CC/MCC, respectively" and to change the titles of MS-DRGs 070, 071, and 072 from "Nonspecific Cerebrovascular Disorders, with MCC, with CC, and without CC/MCC, respectively" to "Other Cerebrovascular Disorders with MCC, with CC, and without CC/MCC, respectively" to better reflect the assigned diagnoses.

c. Encounter for Adjustment and Management of Implanted Devices of the Special Senses

CMS identified an inadvertent replication of codes in the transition from ICD-9 based MS-DRGs to ICD-10 based MS-DRGs. To correct this replication, **CMS is proposing to reassign ICD-10-CM diagnosis code Z45.31** from MS-DRGs 091, 092, and 093 to MDC 02 MS-DRG 123 (Neurological Eye Disorders). Additionally, **CMS is proposing to reassign ICD-10-CM diagnosis codes Z45.320, Z45.321, and Z45.328** from MS-DRGs 091, 092, and 093 to MDC 03 MS-DRGs 154, 155, and 156 (Other Ear, Nose, Mouth and Throat Diagnoses with MCC, with CC, and without CC/MCC, respectively)

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

a. Endovascular Aneurysm Repair (EVAR) with Iliac Branch Procedures

CMS received a request to create a new MS-DRG for cases reporting endovascular repair of abdominal aortic aneurysms that extend into at least one iliac artery to preserve blood flow to the external or internal iliac arteries. The request is summarized in detail in the preamble of the proposed rule. CMS performed its own analysis on claims data from the September 2024 update of the FY 2024 MedPAR file for MS-DRGs 268 and 269 and for cases reporting standard EVAR using an abdominal aortic aneurysm (AAA) endoprosthesis compared to cases reporting EVAR using an AAA endoprosthesis with an iliac branch endoprosthesis (IBE) that are used to treat aortoiliac and iliac artery aneurysms with the previously listed procedure codes. CMS' findings suggest that the cases reporting EVAR using an AAA endoprosthesis with an IBE utilize greater resources compared to the cases reporting standard EVAR using an AAA endoprosthesis. CMS therefore agreed that patients who have aortoiliac and iliac aneurysms are a more complex population to treat, contributing to increased resource utilization. Additionally, based on CMS' review and analysis of the cases reporting standard EVAR using an AAA endoprosthesis compared to the cases reporting EVAR using an AAA endoprosthesis with an IBE to treat aortoiliac and iliac artery aneurysms in MS-DRGs 268 and 269, CMS believes new MS-DRGs are warranted to differentiate the utilization of resources between standard EVAR to treat AAA and EVAR to treat AAA extending into the iliac artery. CMS applied its established process and criteria (discussed in section II.C.1.b of the proposed rule preamble) to create subgroups in a base MS-DRG.

Criteria for three-way and two-way splits failed. As a result, for FY 2026, **CMS is proposing to create new base MS-DRG 213 (Endovascular Abdominal Aorta and Iliac Branch Procedures) without a split.** The following table reflects a simulation of the proposed new base MS-DRG.

Proposed New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed MS-DRG-213	1,064	3.0	$51,784

b. Concomitant Single Valve Procedure with Open Surgical Ablation

CMS describes and summarizes a history of requests and revisions related to MS-DRG assignments for cases involving concomitant single valve procedures with open surgical ablation in MDC 05.[10] For this FY 2026 IPPS/LTCH PPS proposed rule, CMS again received a request to review the MS-DRG assignment of cases involving a single open surgical valve procedure with an open surgical ablation. The requestor recommended that CMS reassign cases involving a single open surgical valve procedure with an open surgical ablation from MS-DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 216,

[10] See: FY 2022 IPPS/LTCH PPS final rule (86 FR 44836 through 44848), FY 2023 IPPS/LTCH PPS final rule (87 FR 48845 through 48849), FY 2024 IPPS/LTCH PPS final rule (88 FR 58681 through 58690).

217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). The requestor asserted that reassigning cases involving a single open surgical valve procedure with an open surgical ablation, which are currently assigned in MS-DRGs 219, 220, and 221, to MS-DRGs 216, 217, and 218 would accommodate the clinical complexity of performing two or more open heart procedures, would enhance clinical coherence for patients undergoing multiple procedures within MDC 05, would more accurately reflect associated costs and resource utilization, and would help minimize the need for multiple patient admissions. The requestor also suggested that if finalized, the title for MS-DRGs 216, 217, and 218 should be revised to "Cardiac valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization or Open Ablation, with MCC, with CC or without CC/MCC, respectively." CMS summarizes the request in detail in the preamble of the proposed rule.

Based on its own analysis, which is described in detail in the preamble of the proposed rule, CMS concluded that although cases that report an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization generally demonstrate slightly higher average costs in their respective MS-DRGs, CMS believes these cases are more suitably grouped to MS-DRGs 219, 220, and 221 where they are currently assigned, based on the closer similarities in resource utilization compared to all the cases in their respective MS-DRG. Moreover, CMS notes that the data do not indicate cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization utilize similar resources when compared to the cases assigned to MS-DRGs 216, 217, and 218. The cases are not clinically coherent with regard to resource utilization as reflected in the greater differences in average costs. Because CMS' analysis of the claims data continues to reflect that cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization are clinically coherent in their currently assigned MS-DRGs, **CMS is proposing to maintain the structure and title of MS-DRGs 216, 217, and 218 for FY 2026.**

c. Transcatheter Aortic Valve Replacement Procedures for Aortic Regurgitation

For this FY 2026 proposed rule, CMS received a request to reassign cases reporting TAVR procedures for aortic regurgitation (AR) from MS-DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with or without MCC, respectively) to what the requester described as a more clinically and cost cohesive MS-DRG such as MS-DRG 215 (Other Heart Assist System Implant) and to revise the title of MS-DRG 215 to "Other Heart Assist System Implant or Endovascular Cardiac Regurgitant Valve Replacement Procedures." The request is summarized in more detail in the preamble of the proposed rule.

CMS' own analysis indicates that the average costs and average length of stay for cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation appear to be generally more aligned with the average costs and average length of stay for all cases in MS-DRGs 266 and 267, where they are currently assigned. Additionally, based on CMS' review of the clinical considerations, CMS does not believe the procedure codes

describing a TAVR are clinically coherent with the procedure codes currently assigned to MS-DRG 215. For these reasons, **CMS is proposing to maintain the GROUPER logic for MS-DRGs 266 and 267 for FY 2026. Additionally, CMS is proposing to maintain the title of MS-DRGs 215 as "Other Heart Assist System Implant" for FY 2026.**

d. Percutaneous Coronary Atherectomy

CMS describes and summarizes a history of requests and revisions related to MS-DRG assignments and GROUPER logic for cases involving percutaneous coronary intervention (PCI) procedures, including percutaneous coronary lithotripsy (IVL) which is utilized in a subset of PCIs.[11] For FY 2026, CMS received a request to reassign percutaneous coronary atherectomy procedures from MS-DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Intraluminal Device with MCC and without MCC, respectively) and MS-DRGs 321 and 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices and without MCC, respectively) to MS-DRGs 323, 324, and 325 where cases reporting percutaneous coronary IVL are assigned. According to the requestor, removing percutaneous coronary atherectomy procedures from their current MS-DRG assignments and assigning them to MS-DRGs 323, 324, and 325 would reduce cost variance and improve clinical coherence across all PCI MS-DRGs. The requestor endorsed creating a new MS-DRG for all cases involving percutaneous coronary atherectomy procedures as a reasonable alternative option if CMS did not agree with the reassignment of these cases to MS-DRGs 323, 324, and 325.

Upon review of the request and its own analysis of the claims data, as outlined in more detail in the preamble of the proposed rule, CMS does not agree with reassigning cases reporting percutaneous or percutaneous endoscopic coronary atherectomy from MS-DRGs 250, 251, 321, and 322 to MS-DRGs 323, 324, and 325. CMS states that it agrees that the performance of percutaneous or percutaneous endoscopic coronary atherectomy contributes to increased resource consumption for these PCI procedures, as it previously noted, the data do not support that cases reporting percutaneous or percutaneous endoscopic coronary atherectomy, with or without involving the insertion of an intraluminal device, utilize similar resources when compared to coronary IVL procedures currently assigned to MS-DRGs 323, 324, and 325. Additionally, CMS continues to believe that the root operation Extirpation is not the same as the root operation Fragmentation and do not warrant similar MS-DRG assignment.[12]

As requested, CMS explored alternative options. As discussed in prior rulemaking,[13] CMS continues to agree that clinically, the presence of severe calcification can increase the treatment difficulty and complexity of service. The data analysis clearly shows that cases reporting percutaneous or percutaneous endoscopic coronary atherectomy, with or without involving the insertion of an intraluminal device, have higher average costs and longer lengths of stay compared to all the cases in their assigned MS-DRG. For these reasons, **CMS is proposing to**

[11] See: FY 2024 IPPS/LTCH PPS final rule (88 FR 58704 through 58712), FY 2025 IPPS/LTCH PPS final rule (89 FR 69000 through 69002),
[12] 85 FR 58572 through 58573
[13] 88 FR 58706

create two new MS-DRGs with a two-way severity level split for cases describing percutaneous or percutaneous endoscopic coronary atherectomy involving the insertion of an intraluminal device in MDC 05, specifically: MS-DRG 359 (Percutaneous Coronary Atherectomy with Intraluminal Device with MCC) and MS-DRG 360 (Percutaneous Coronary Atherectomy with Intraluminal Device without MCC). Additionally, **CMS is proposing to create a new base MS-DRG for cases describing percutaneous or percutaneous endoscopic coronary atherectomy without an intraluminal device,** specifically: MS-DRG 318 (Percutaneous Coronary Atherectomy without Intraluminal Device).

A list of procedure codes CMS is proposing to define in the logic for each of the proposed new MS-DRGs can be found in Table 6P.4a and Table 6P.4b associated with this FY 2026 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index). A discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.10 of the preamble of the proposed rule.

e. Complex Aortic Arch Procedures

For this FY 2026 proposed rule, CMS received two separate but related requests to review and reconsider the MS-DRG assignments for a subset of codes describing aortic arch procedures assigned to MS DRGs 216, 217, 218, 219, 220, and 221 (Cardiac Valve & Other Major Cardiothoracic Procedure with and without Cardiac Catheterization, with MCC, with CC, without CC/MCC, respectively).

- The first request was to reassign cases reporting a procedure code describing endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device from MS-DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS-DRG 216 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC). Alternatively, the requestor stated CMS could consider reassigning other similar complex aortic arch branch procedures to MS-DRG 216. The requestor suggested that if finalized, the title for MS-DRG 216 should be revised to reflect "Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC or with Aortic Arch Branch Intraluminal Device." The request is summarized in detail in the preamble of the proposed rule.

  CMS' own analysis of the claims data for cases reporting procedure codes 02VX3EZ and 02VW3DZ and cases reporting procedure codes describing other complex arch procedures demonstrated a relatively low volume of cases in comparison to all the cases in their respective MS-DRGs (that is, in MS-DRGs 216, 217, 218, 219, 220, and 221). CMS notes that the data analysis indicates that most of these cases have average costs that are considerably higher than the average costs of all cases in MS-DRG 216. However, **CMS is not proposing to reassign the cases reporting procedure codes 02VX3EZ and 02VW3DZ** and the cases reporting procedure codes describing other

complex arch procedures to MS-DRG 216, even if there is no cardiac catheterization procedure reported and no secondary diagnosis designated as an MCC reported, because CMS does not believe that reassignment would fully address the difference in resource utilization in these cases. Instead, CMS decided to further explore alternative options and to make proposals as summarized below.

- The second request CMS received was from the manufacturer of the Thoraflex™ Hybrid device (also known as the Terumo Aortic Hybrid device) who requested that CMS reassign cases reporting thoracic aortic arch replacement combined with restriction of the descending thoracic aorta from MS-DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). CMS summarizes the request in the preamble of the proposed rule. To explore mechanisms to address this request and to understand the resource use for the subset of cases reporting procedure codes X2RX0N7 (Replacement of thoracic aorta, arch using branched synthetic substitute with intraluminal device, open approach, new technology group 7) and X2VW0N7 (Restriction of thoracic aorta, descending using branched synthetic substitute with intraluminal device, open approach, new technology group 7), CMS examined claims data from the September 2024 update of the FY 2024 MedPAR file for cases reporting the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta assigned to MS-DRGs 216, 217, 218, 219, 220, and 221. This analysis is described in detail in the preamble of the proposed rule. Based on CMS' review and analysis, **the agency is not proposing the reassignment as requested**. CMS does not believe that the data adequately support a potential reassignment of these cases to MS-DRGs 216, 217, and 218. CMS also does not believe that the small subset cases that report the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta warrants the creation of a new MS-DRG at this time. The agency reiterated concerns expressed in prior rulemaking[14] regarding making proposed MS-DRG changes based on a specific, single technology (such as the Thoraflex™ Hybrid device) identified by only one unique procedure code combination versus considering proposed changes based on a group of related procedure codes that can be reported to describe the same type or class of technology, which is more consistent with the intent of the MS-DRGs. However, CMS explored other mechanisms to address this request and made proposals as summarized below.

CMS explored other mechanisms that might address these two separate but related requests. Specifically, the agency explored an option to create a new MS-DRG to better differentiate these complex aortic arch procedures from other cases in their respective MS-DRGs, based on treatment difficulty, clinical similarity, and resource use. As a result of its further analysis, **CMS is proposing to create new base MS-DRG 209 (Complex Aortic Arch Procedures) for cases**

[14] 85 FR 58472

reporting complex aortic arch procedures in MDC 05. A list of procedure codes CMS is proposing to define in the logic for the proposed new MS-DRG can be found in Table 6P.5a, available on the CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software. The discussion of the surgical hierarchy for the proposed modification is discussed in the preamble of the proposed rule in section II.C.10.

f. Deep Vein Thrombophlebitis

Consistent with its annual review of the MS-DRGs, CMS considers changes in resource consumption, treatment patterns, technology, and any other factors that may change the relative use of hospital resources. In CMS' review of the claims data from the September 2024 update of the FY 2024 MedPAR file, CMS identified a low volume of cases for MS-DRGs 294 and 295 (146 cases for Deep Vein Thrombophlebitis with CC/MCC and zero cases for Deep Vein Thrombophlebitis without CC/MCC, respectively). In light of this and in accordance with CMS general MS-DRG principles, CMS indicated its belief that it would be appropriate to further analyze how to potentially reclassify these cases.

To investigate further, CMS identified 35 ICD-10-CM diagnosis codes describing deep vein thrombophlebitis that are currently assigned to MS-DRGs 294 and 295 and evaluated the number of cases over the past 5 fiscal years. The data indicate that the number of cases grouping to MS-DRGs 294 and 295 has declined in each year. Additionally, CMS identified MS-DRGs 299, 300, and 301 (Peripheral Vascular Disorders with MCC, with CC, and without CC/MCC, respectively) which also include diagnoses describing other types of phlebitis and thrombophlebitis in the logic for case assignment, consistent with the diagnosis codes in the logic for case assignment to MS-DRGs 294 and 295. CMS determined that the average length of stay and costs of cases for MS-DRG 294 are comparable to the cases in MS-DRG 300. Therefore, **CMS is proposing to delete MS-DRGs 294 and 295 and reassign their 35 diagnosis codes[15] to MS-DRGs 299, 300, and 301.** For complete documentation of the GROUPER logic for MS-DRGs 299, 300, and 301, CMS refers the reader to the ICD-10 MS-DRG Version 42.1 Definitions Manual (which is available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software).

5. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)

a. Hip or Knee Procedures with Periprosthetic Joint Infection

CMS received a request to reassign cases reporting a hip or knee procedure with a principal diagnosis of periprosthetic joint infection (PJI) from the lower severity level "without CC/MCC" MS-DRG (MS-DRG 465, 468, 476, 482, and 487) to the higher severity level "with CC" MS-DRG (MS-DRG 464, 467, 475, 481, and 486, respectively) when there is no major complication

[15] The 35 diagnosis codes describing deep venous thrombophlebitis (DVT) in MS-DRGs 294-295 are presented in a table in the preamble of the proposed rule.

or comorbidity (MCC) or complication or comorbidity (CC) reported. The request is summarized in the preamble of the proposed rule.

CMS reviewed claims data from the September 2024 update of the FY 2024 MedPAR file for MS-DRGs 463, 464, 465, 466, 467, 468, 474, 475, 476, 480, 481, 482, 485, 486, and 487 and for cases reporting a principal diagnosis of PJI with a hip or knee procedure. CMS refers readers to Table 6P.6a for the list of diagnosis codes CMS analyzed to identify PJI and for the list of procedure codes it analyzed from the previously listed MS-DRGs to identify a him or knee procedure. Based on the findings from this analysis, CMS disagreed with the request to reassign PJI cases from the lower severity "without CC/MCC" level MS-DRG to the higher severity "with CC" level MS-DRG suggested by the requestor as the average costs of the PJI cases in the "without CC/MCC" level are not comparable and do not align with the average costs of all the cases at the "with CC" level. CMS notes, however, that the findings show that other than for MS-DRGs 466, 467, and 468, the cases reporting a PJI with a hip or knee procedure at the higher "with CC" level and the highest "with MCC" level have higher average costs compared to all the cases in their respective MS-DRG. Therefore, CMS believes the data support proposing a new base MS-DRG for the cases reporting a PJI with a hip or knee procedure in MS-DRGs 463, 464, 465, 474, 475, 476, 480, 481, and 482 to better reflect the complexity of services, resource utilization, and severity of illness of these patients. CMS applied its process and criteria for creating subgroups for the base MS-DRG. Criteria were met for a two-way split. **CMS is proposing to create new MS-DRGs 403 and 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC and without MCC, respectively).** The following table reflects a simulation of the proposed new MS-DRGs.

Proposed New MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed MS-DRG-403	1,052	13.6	$48,305
Proposed MS-DRG-404	2,051	7.1	$29,006

b. Arthroscopy

Consistent with its annual review of the MS-DRGs, CMS considers changes in resource consumption, treatment patterns, technology, and any other factors that may change the relative use of hospital resources. In CMS' review of the claims data from the September 2024 update of the FY 2024 MedPAR file, CMS identified an extremely low volume of cases for MS-DRG 509 (16 cases for Arthroscopy).

CMS analyzed the ICD-10-PCS codes describing arthroscopy and currently assigned to MS-DRG 509 and their utilization over 5 fiscal years which ranged from 31 to 16. CMS indicates its belief that this low inpatient utilization suggests that arthroscopy procedures have shifted to the outpatient setting over the years. Based on additional analysis and review of the cases grouping to MS-DRG 509, as outlined in more detail in the preamble of the proposed rule, **CMS believes it is appropriate and is proposing to delete MS-DRG 509 and reassign the 47 procedure**

codes[16] describing arthroscopy of various anatomic sites to clinically appropriate MS-DRGs that also align with the resource utilization for these cases.

Specifically, for FY 2026, **CMS is proposing to:**

- **Reassign the 8 procedure codes describing arthroscopy of the shoulder or elbow joint to MS-DRGs 510, 511, and 512** (Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC, with CC, and without CC/MCC, respectively)
- **Reassign the 10 procedure codes describing arthroscopy of the hand or wrist joint to MS-DRGs 513 and 514** (Hand or Wrist Procedures, Except Major Thumb or Joint Procedures with CC/MCC and without CC/MCC, respectively)
- **Reassign the 29 procedure codes describing arthroscopy of various vertebral joints and other musculoskeletal joints to MS-DRGs 515, 516, and 517** (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively)

For a detailed list of procedure codes with the proposed MS-DRG reassignments, CMS refers the reader to Table 6P.7a. available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html

c. MS-DRG Logic for MS-DRGs 456, 457, and 458

CMS identified an inconsistency in the GROUPER logic for MS-DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) related to the ICD-10-CM diagnosis codes describing a principal diagnosis of infection (specifically, the second of four logic lists which is entitled "Spinal Curvature/Malignancy Infection").[17] CMS identified 47 diagnoses that it believes are clinically appropriate to add to the list describing spinal infections in MS-DRGs 456, 457, and 458. For clinical consistency, **CMS is proposing to add 47 diagnoses[18] to the existing diagnosis codes describing spinal infections in MS-DRGs 456, 457, and 458.** Additionally, CMS identified eight diagnoses that it believes are not clinically appropriate to maintain in the second logic list describing spinal infections in MS-DRGs 456, 457, and 458. **CMS is proposing to remove the eight diagnosis codes[19] from the logic list entitled "Spinal Curvature/Malignancy/Infection" in MS-DRGs 456, 457, and 458**, effective October 1, 2025, for FY 2026.

[16] In the preamble of the proposed rule, CMS provides a table of the 47 ICD-10-PCS procedure codes describing arthroscopy in MS-DRG 509.
[17] The logic for case assignment to MS-DRGs 456, 457, and 458 as displayed in the ICD-10 MS-DRG Definitions Manual Version 42.1 is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software and is comprised of four logic lists.
[18] The 47 ICD-10-CM diagnosis codes identified by CMS are listed in a table in the preamble of the proposed rule.
[19] These ICD-10-CM diagnosis codes are M4850XA, M4854XA-M4858XA, M8008XA and M8088XA and are listed in a table in the preamble of the proposed rule.

6. Review of Procedure Codes in MS-DRGs 981 Through 983 and 987 Through 989

CMS annually conducts a review of procedures producing assignment to MS-DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS-DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS-DRGs into one of the surgical MS-DRGs for the MDC into which the principal diagnosis falls. CMS looks at a frequency count of each major operative procedure code and also compares procedures across MDCs by volume of procedure codes within each MDC. CMS uses this information to determine which procedure codes and diagnosis codes to examine. CMS identifies those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS-DRGs for the MDC in which the diagnosis falls. CMS also considers whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

Based on the results of CMS' review of the claims data from the September 2024 update of the FY 2024 MedPAR file of cases found to group to MS-DRGs 981 through 983 or MS-DRGs 987 through 989, **CMS is proposing to move the cases reporting the procedures and/or principal diagnosis codes described in more detail below from MS-DRGs 981 through 983 or MS-DRGs 987 through 989 into one of the surgical MS-DRGs for the MDC into which the principal diagnosis or procedure is assigned.**

a. Control of Bleeding in the Genitourinary Tract

During the review of the cases that group to MS-DRGs 981 through 983, CMS noted that when ICD-10-PCS procedure codes describing the control of bleeding in the genitourinary tract (specifically, 0W3R0ZZ, 0W3R3ZZ, 0W3R4ZZ, 0W3R7ZZ, and 0W3R8ZZ) are reported in conjunction with ICD-10-CM diagnosis codes in MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, and Immunologic Disorders), the cases group to MS-DRGs 981 through 983. The principal diagnosis most frequently reported with the five procedure codes is ICD-10-CM code D68.32. Following an examination of the claims data from the September 2024 update of the FY 2024 MedPAR file (as outlined in more detail in the preamble of the proposed rule) CMS concluded that because a procedure code describing the control of bleeding in the genitourinary tract would be expected to be related to a principal diagnosis describing a hemorrhagic disorder due to extrinsic circulating anticoagulants, it is clinically appropriate for the procedures to group to the same MS-DRGs as the principal diagnoses. Therefore, **CMS is proposing to add five procedure codes (specifically, 0W3R0ZZ, 0W3R3ZZ, 0W3R4ZZ, 0W3R7ZZ, and 0W3R8ZZ) to MDC 16.** Under this proposal, cases reporting a procedure code describing the control of bleeding in the genitourinary tract with a principal diagnosis of a hemorrhagic disorder due to extrinsic circulating anticoagulants (diagnosis code D68.32) in MDC 16 would group to MS-DRGs 802, 803, and 804.

b. Removal of Infusion Device from Peritoneal Cavity

During the review of the cases that group to MS-DRGs 981 through 983, CMS noted that when ICD-10-PCS procedure codes describing the removal of an infusion device from the peritoneal cavity (specifically, 0WPG03Z, 0WPG33Z, and 0WPG43Z) are reported in conjunction with ICD-10-CM diagnosis codes in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs), the cases group to MS-DRGs 981 through 983.

As a result of its examination of claims data from the September 2024 update of the FY 2024 MedPAR file (as outlined in more detail in the preamble of the proposed rule) **CMS is proposing to add the three procedure codes listed previously to MDC 21.** CMS notes that under this proposal, cases reporting a procedure code describing the removal of an infusion device from the peritoneal cavity with a principal diagnosis of an infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter (diagnosis code T85.71XA) in MDC 21 would group to MS-DRGs 907, 908, and 909.

CMS notes it did not receive any requests suggesting reassignment in these MS-DRGs, and CMS' analysis did not identify any cases for reassignment. Therefore, for FY 2026 **CMS is not proposing to move any cases reporting procedure codes from MS-DRGs 981 through 983 to MS-DRGs 987 through 989 or vice versa**.

7. Operating Room (O.R.) and Non-O.R. Procedures

a. Background

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. Currently, each ICD-10-PCS procedure code has designations that determine whether and in what way the presence of that procedure 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 recommends the MS-DRG assignment, makes them public in association with the proposed rule[20] and subjects them to public comment. CMS notes these proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes.

[20] Table 6B. – New Procedure Codes – FY 2026 is available on the CMS website for public inspection at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.html. CMS also refers readers to the ICD-10 MS-DRG Version 42.1 Definitions Manual at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.html for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS- DRG) in Appendix E--Operating Room Procedures and Procedure Code/MS-DRG Index.

In prior rules,[21] CMS discusses its plans to conduct a multi-year comprehensive, systematic review of the O.R. and non-O.R. ICD-10-PCS procedure codes. CMS continues to believe additional time is necessary to develop the process and methodology. CMS notes that in prior rules, it has signaled that the designation of an O.R. procedure encompasses more than the physical location of the hospital room in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor CMS will consider as it examines the designation of a procedure in the ICD-10-PCS classification system. The agency is exploring alternatives on how it may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD-10 claims data. CMS is considering the feedback received on what factors and/or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD-10-PCS classification system, and intends to provide more detail on this analysis and the methodology for conducting this comprehensive review in future rulemaking. **CMS encourages the public to continue to submit feedback and comments on any other factors in consideration of its refinement efforts to recognize and differentiate consumption of resources under the ICD-10 MS-DRGs.**

For this FY 2026 proposed rule, CMS received requests regarding changing the designation of specific ICD-10-PCS procedure codes from non-O.R. to O.R. procedures, which are discussed in this section of preamble. Additionally, CMS discusses the proposal it is making based on its internal review and analysis and the process that was utilized for evaluating each procedure code. For each procedure, CMS considered the following: whether the procedure would typically require the resources of an operating room; whether it is an extensive or a non-extensive procedure; and to which MS-DRGs the procedure should be assigned. Cases with a principal diagnosis associated with a particular MS-DRG would, by default, be grouped to that MS-DRG. Therefore, CMS only discusses MS-DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS-DRG assignment as intended. For procedures that would not typically require the resources of an operating room, CMS determined if the procedure should affect the MS-DRG assignment. In cases where CMS is proposing to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, it is also proposing one or more MS-DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS-DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS-DRGs 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS-DRGs 981 through 989 in order for this to occur. Therefore, CMS did not specifically address that aspect in summarizing the request and its response to that request or the proposal CMS is making based on its internal review and analysis in this section.

[21] See: FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19230), FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), 2024 IPPS/LTCH PPS final rule (88 FR 58749).

b. Non-O.R. Procedures to O.R. Procedures

(1) Open Drainage of the Mandible

In a prior rule,[22] CMS discussed a request it received to change the designation of procedure codes 0N9R0ZZ (Drainage of maxilla, open approach), 0N9T0ZZ (Drainage of right mandible, open approach), and 0N9V0ZZ (Drainage of left mandible, open approach) from non-O.R. to O.R. procedures. At that time, CMS disagreed that the procedures describing the open drainage of the maxilla or mandible typically require the resources of an operating room. After consideration of the public comments received, CMS finalized its proposal to maintain the non-O.R. designation of ICD-10-PCS procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ, without modification, for FY 2022.

For this FY 2026 proposed rule, CMS again received a request to change the designation of ICD-10-PCS codes 0N9T0ZZ (Drainage of right mandible, open approach), and 0N9V0ZZ (Drainage of left mandible, open approach), from non-O.R. to O.R. CMS reviewed the requestor's rationale (outlined in more detail in the preamble of the proposed rule) and continues to disagree that the procedures describing the open drainage of the mandible are typically performed in the operating room under general anesthesia. Therefore, **CMS is proposing to maintain the current non-O.R. designation of ICD-10-PCS procedure codes 0N9T0ZZ and 0N9V0ZZ.**

CMS agrees with the requestor that in the ICD-10 MS-DRGs Definitions Manual Version 42.1, procedure code 0W950ZZ (Drainage of lower jaw, open approach) is currently designated as an O.R. procedure for purposes of MS-DRG assignment. CMS agrees that procedures that describe the open drainage of mandible consume resources comparable to the related ICD-10-PCS procedure code that describes the open drainage of the jaw. These procedures do not typically require the resources of an operating room and are not surgical in nature. Therefore, for clinical consistency, **CMS is proposing to remove procedure code 0W950ZZ (Drainage of lower jaw, open approach) from the FY 2026 ICD-10 MS-DRGs Version 43 Definitions Manual in Appendix E--Operating Room Procedures and Procedure Code/MS-DRG Index as an O.R. procedure.** Under this proposal, this procedure would no longer impact MS-DRG assignment.

(2) Introduction of Paclitaxel-Coated Balloon Catheter Technology

In the FY 2025 final rule, CMS summarized and responded to comments received regarding the O.R. designation and MS-DRG assignment of 16 ICD-10-PCS procedure codes that describe introduction of the AGENT™ Paclitaxel-Coated Balloon Catheter technology that is indicated to treat coronary in-stent restenosis (ISR) in patients with coronary artery disease. Sixteen procedure codes describing the use of the technology were finalized following the March 19, 2024 ICD-10 Coordination and Maintenance Committee meeting and made available on the CMS website at: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-

[22] See: FY 2022 IPPS/LTCH PPS final rule (86 FR 44895 through 44896)

2026-ipps-proposed-rule-home-page. CMS lists the 16 ICD-10-PCS codes in a table in the preamble of the proposed rule.

CMS received a request from the manufacturer to reconsider the designation and MS-DRG assignment of the previously finalized 16 procedure codes. Specifically, the requestor requested that the procedure codes be designated as O.R. procedures and assigned to the following surgical MS-DRGs: MS-DRG 250-251 (Percutaneous Cardiovascular Procedures without Intraluminal Device with and without MCC), MS-DRG 321-322 (Percutaneous Cardiovascular Procedures with Intraluminal Device with and without MCC), MS-DRG 323-324 (Coronary Intravascular Lithotripsy with Intraluminal Device with and without MCC), and MS-DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device). The requestor stated that the surgical procedure during which paclitaxel is delivered (as described in the instructions for use) is more appropriate as an O.R. procedure than a non-O.R. procedure.

CMS summarizes its discussion from the FY 2025 IPPS final rule[23] in which it noted that because the procedure codes describing the use of an AGENT™ Paclitaxel-Coated Balloon Catheter are describing delivery of the paclitaxel to the coronary vessel(s), the predecessor code is 3E073GC, is designated as a non-O.R. procedure and does not affect MS-DRG assignment. CMS further noted that use of the AGENT™ Paclitaxel-Coated Balloon Catheter to deliver the paclitaxel to the coronary vessel(s) cannot occur in the absence of a surgical vessel preparation and, therefore, it is the vessel preparation procedure that will determine the surgical MS-DRG assignment to one of the previously listed surgical MS-DRGs. Moreover, per FDA guidance, the drug component is considered a permanent implant because it remains in the body for greater than 30 days.

As such, CMS continues to disagree with designating the procedure to deliver paclitaxel to a coronary vessel as identified by any one of the previously listed 16 procedure codes as O.R. procedures. Therefore, **CMS is maintaining the designation of the 16 procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology as non-O.R. for FY 2026.**

(3) Endoscopic Drainage of the Ureter with Drainage Device

During its internal review, CMS noted that procedure codes that describe drainage of the ureter with a drainage device, via a natural or artificial opening endoscopic approach, are not recognized as O.R. procedures for purposes of MS-DRG assignment. CMS identified the following three related codes (0T9680Z, 0T9780Z, and 0T9880Z) that describe the drainage of the ureter with a drainage device via a natural or artificial opening endoscopic approach that warrant designation as O.R. procedures. These procedures are typically performed in an operating room under anesthesia, can take about 30 minutes or more, including preparation time, and require that a patient's vital signs be monitored by the health care team for the duration of the procedure.

Therefore, **CMS is proposing to add procedure codes 0T9680Z, 0T9780Z, and 0T9880Z to the FY 2026 ICD-10 MS-DRG Version 43 Definitions Manual in Appendix E--Operating Room Procedures and Procedure Code/MS-DRG Index** as O.R. procedures assigned to MS-DRG 264 in MDC 05; MS-DRGs 656, 657, and 658 and MS-DRGs 659, 660, and 661 in MDC 11; MS-DRGs 907, 908, and 909 in MDC 21; and MS-DRGs 957, 958, and 959 in MDC 24.

8. Proposed Changes to the MS-DRG Diagnosis Codes for FY 2026

a. Background of the CC List and CC Exclusions List

Under the IPPS MS-DRG classification system, CMS developed a standard list of diagnoses that are considered CCs. In the FY 2008 IPPS final rule,[24] CMS evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment.

b. Overview of Comprehensive CC/MCC Analysis.

The FY 2008 IPPS final rule describes CMS' process for establishing three different levels of CC severity into which CMS subdivides the diagnosis codes. The categorization of diagnoses as MCC, a CC, or a non-CC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. More recently, as a result of the transition to ICD-10-CM, CMS conducted a comprehensive analysis once again and proposed changes to the severity level designations for 1,492 ICD-10-CM diagnosis codes.[25] As a result of careful consideration of public comments received, however, 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.[26] CMS summarizes the interval steps it has taken since then, including: finalizing a new Medicare Code Editor (MCE) code edit for "unspecified" codes, effective with discharges on and after April 1, 2022;[27] finalizing an increase in the severity levels for diagnosis codes related to homelessness;[28] and the finalization of nine guiding principles it believes are meaningful indicators of expected resource use by secondary diagnosis.[29] The guiding principles include:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- 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.

[24] 72 FR 47152 through 47171
[25] FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) for a detailed discussion and proposals.
[26] FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152)
[27] FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943)
[28] FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759)

- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation and/or management of care.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

CMS plans to continue a comprehensive CC/MCC analysis using a combination of the prior mathematical analysis of claims data in combination with the guiding principles. **CMS is not proposing any severity designation changes for FY 2026.** CMS has updated the Impact on Resource Use Files on the CMS website so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2024 MedPAR files: https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.

c. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2026

For FY 2026, CMS is proposing additions and deletions to the diagnosis code MCC severity levels list and to the diagnosis code CC severity levels. The proposed additions and deletions can be found in Tables 6I.1&2 and Tables 6J.1&2, respectively, on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.

d. Proposed CC Exclusions List for FY 2026

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 CCs; and to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.[30] CMS also established excluded secondary diagnoses using the five following principles: (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 42.1 CC Exclusion List is included as Appendix C in the ICD-10 MS-DRG Definitions Manual at https://www.cms.gov/Medicare/Medicare-Fee-For-Service-Payment/AcuteInpatientPPS/index.html and includes three lists identified as Part 1, Part 2, and Part 3. 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

[30] 52 FR 33143

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. Part 3 is the list of diagnosis codes that are designated as a CC or MCC and included in the definition of the logic for the listed MS-DRGs. When 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 (that is, suppression logic).

As a result of commenter concerns raised in the FY 2025 IPPS final rule related to Part 1 of Appendix C, CMS reviewed the list of principal diagnosis codes listed in Principal Diagnosis Collection List numbers 1330 and 1331 that exclude diagnosis codes N18.5 and N18.6 from acting as a CC or MCC to assess clinical appropriateness. The findings from CMS' review indicate several of the listed conditions, when reported as a principal diagnosis, are not applicable to exclude the designated N18.5 or N18.6 secondary CC/MCC diagnosis code under application of the five established principles previously discussed. Under proposed Version 43, **CMS is proposing to:**

- **Add diagnosis code I12.9 to Principal Diagnosis Collection List number 1335 to exclude diagnosis code N18.5 from acting as a CC;**
- **Remove the diagnosis codes listed in Table 6P.8a associated with this FY 2026 IPPS/LTCH PPS proposed rule and available via the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps from Principal Diagnosis Collection List number 1335; and**
- **Add diagnosis codes I13.0 and I13.10 to Principal Diagnosis Collection List number 1335 to exclude diagnosis codes N18.5 and N18.6 from acting as a CC/MCC.**

CMS states it intends to continue this type of internal review to ensure all the other Principal Diagnosis Collection lists reflect the appropriate codes in connection with the CC/MCC secondary diagnosis code that is excluded from acting as a CC/MCC. Any proposed changes to the lists will be discussed in future rulemaking. To inform future rulemaking, feedback and other suggestions may be submitted by October 20, 2025, and directed to MEARIS™ at: https://mearis.cms.gov/public/home.

CMS also performed an internal review of the diagnoses listed in "Appendix C-Part 2 Codes That are Major CC Only if Patient Discharged Alive." CMS describes its analyses and findings in detail in the preamble of this proposed rule. Based on its findings, In proposed Version 43, **CMS is proposing to:**

- **Remove code R57.1 from the list found in Appendix C – Part 2: Codes That are Major CC Only if Patient Discharged Alive.** Under this proposal, when reported as a secondary diagnosis, R57.1 (Hypovolemic shock) will be assigned as an MCC when the patient is discharged alive or if the patient expires.
- **Add code T79.4XXA to the list found in Appendix C – Part 2: Codes That are Major CC Only if Patient Discharged Alive.** Under this proposal, when reported as a

secondary diagnosis, T79.4XXA (Traumatic shock, initial encounter) would be assigned as an MCC only when the patient is discharged alive.

As a result of these proposals, CMS has developed several Tables (6G.1., 6G.2., 6H.1., and 6H.2.) associated with this FY 2026 IPPS/LTCH PPS proposed rule that are available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html

For Table 6G.1 – Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2026, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk, and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2026, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk, and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2026, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2026, each of the principal diagnosis codes is shown with an asterisk, and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis.

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

To identify new, revised, and deleted diagnosis and procedure codes, CMS has developed the following tables for the FY 2026 IPPS proposed rule which are available at https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page

Table 6A	New Diagnosis Codes
Table 6B	New Procedure Codes
Table 6C	Invalid Diagnosis Codes
Table 6D	Invalid Procedure Codes
Table 6E	Revised Diagnosis Code Titles
Table 6F	Revised Procedure Code Titles

The code titles are adopted as part of the ICD-10 Coordination and Maintenance Committee meeting process and are not subject to comment in the proposed or final rules. As part of this proposed rule, **CMS is proposing the MDC and MS-DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.–New Diagnosis Codes and Table 6B.–New Procedure Codes**. The proposed severity level designations for the new diagnosis codes are set forth in Table 6A and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with its established process, CMS reviews the predecessor code and MS-DRG assignment most closely associated with the new diagnosis or procedure code, and in

the absence of claims data, CMS considers other factors that may be relevant to the MS-DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition.

Tables 6A-F, 6G.1 to 6G.2, 6H.1 to 6H.2, 6I.1 and 6I.2, 6J.1 and 6J.2 that are associated with this proposed rule are available on the CMS website at https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page

10. Proposed Changes to the 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. CMS provides examples of instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost, such as "other O.R. procedures" and when differences between the average costs for two surgical classes is very small.

CMS intends to consider if the development of evaluation criteria would be useful for future proposed modifications and continues to examine what factors should be taken into account for future proposals. **CMS welcomes feedback and other suggestions** to be submitted via (MEARIS™) at https://mearis.cms.gov/public/home by October 20, 2025.

Based on the proposed changes for FY 2026, **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).** CMS notes that the tables are subject to revision based on policies that are finalized for FY 2026. The proposed Version 43 surgical hierarchy rankings for newly proposed MS-DRGs for FY2026 are presented in the tables below. Complete tables of ranking revisions based on the proposals of this proposed rule can be found in the preamble.

Proposed Version 43 Surgical Hierarchy for Proposed New MS-DRGs in MDC 05		Proposed Rank
Proposed New MS- DRG 209	Complex Aortic Arch Procedures	1
Proposed New MS-DRG 213	Endovascular Abdominal Aorta with Iliac Branch Procedures	10
Proposed New MS-DRGs 359-360	Percutaneous Coronary Atherectomy with Intraluminal Device	27
Proposed New MS-DRG 318	Percutaneous Coronary Atherectomy without Intraluminal Device	30
Proposed New MS-DRGs 403 - 404	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection	6

For issues pertaining to the surgical hierarchy, as with other MS-DRG related requests, CMS encourages interested parties to submit comments no later than October 20, 2025, via

MEARIS™ at https://mearis.cms.gov/public/home, so that they can be considered for possible inclusion in the annual proposed rule.

11. 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. In this co-chaired committee, the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) has lead responsibility for the ICD-10-CM diagnosis codes while CMS has lead responsibility for the ICD-10-PCS procedure codes. 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.

The Committee encourages public participation. CMS provides the following contact information for members to submit comments on the proposed procedure code topics: ICDProcedureCodeRequest@cms.hhs.gov. Members of the public may submit comments on the proposed diagnosis code topics to nchsicd10cm@cdc.gov.

CMS summarizes Committee activity and timeline related to coding changes for implementation in FY 2026. Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 10-11, 2024, meeting and the materials for the Spring 2025 ICD-10-PCS procedure code topics can be obtained from the CMS website at: https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials

Effective with discharges on and after April 1, 2025, CMS implemented 50 new ICE-10-PCS procedure codes including cardiac stereotactic body radiotherapy (SBRT), transplantation of the larynx, repositioning of long bones using a ring external fixation device with automated strut adjustment, supplementing the right atrium with heterotopic bioprosthetic valve(s), the administration of emapalumab-Izsg anti-IFNy monoclonal antibody, and the administration of tarlatamab-dlle antineoplastic. These codes, including their O.R. status, MDC and MS-DRG assignment are listed in a table in the proposed rule preamble. The 50 procedure codes are also reflected in Table 6B.- New Procedure Codes, which is available on the CMS website at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS. **CMS is soliciting public comments on the most appropriate MDC, MS-DRG, and operating room status assignments for these codes for FY 2026, as well as any other options for the GROUPER logic.**

Additionally, CMS describes the mechanism and process it has developed for approving and updating diagnosis and procedure codes on April 1 and October 1 of each year.[31] Beginning April 1, 2022, CMS adopted a new April 1 implementation date, in addition to the annual October 1 update.[32] CMS is continuing to use several aspects of its existing established process to implement new codes through the April 1 code update, which includes presenting proposals for April 1 consideration at the September ICD-10 Coordination and Maintenance Committee

[31] As required by section 503(a) of the Medicare Modernization Act (Pub. L. 108-173)
[32] FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956)

meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. CMS notes that there were code proposals presented for an April 1, 2025, implementation at the September 10–11, 2024, Committee meetings. Following the receipt of public comments, the code proposals were approved and finalized; therefore, there were new codes implemented April 1, 2025. CMS announced the new codes in November 2024 and provided the updated code files in December 2024. The NCHS provided the ICD-10-CM Official Guidelines for Coding and Reporting in January 2025. By February 27, 2025, CMS made available the updated Version 42.1 ICD-10 MS-DRG GROUPER software and related materials on the CMS web page at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.

CMS notes that for FY 2025, there are 74,044 diagnosis codes and 78,986 procedure codes. At this time, there are 487 new diagnosis codes and 14 new procedure codes finalized for FY 2026 at the time of development of this proposed rule and 50 new procedure codes that were effective with discharges on or after April 1, 2025.

12. Replaced Devices Offered without Cost or with a Credit

a. Background

In the FY 2008 final rule with comment period,[33] 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,[34] 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.

b. Proposed Changes for FY 2026

As discussed in section II.C.4 of the preamble of this proposed rule, CMS is making several proposals related to adding and reassigning certain MS-DRGs under MDC 01 and MDC 05. CMS reprises these proposals in this section. 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. Further, CMS notes that several of the proposed MS-DRGs are on the list of MS-DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as shown in the following table. Therefore, **CMS is proposing that if the applicable proposed MS-DRG changes are finalized, CMS also would add MS-DRGs 020, 021, and 022 and proposed new MS-DRGs 209 and 213 to the list of MS-DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit and make conforming changes to the titles of MS-DRGs 023 and 024 in the list of MS-DRGs subject to the policy** as reflected in the following table, reproduced from the

[33] 72 FR 47246 through 47251
[34] 76 *FR* 51556 and 51557

proposed rule. **CMS is also proposing to continue to include the existing MS-DRGs currently subject to the policy as displayed in the following table.**

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG DRG**	**MS-DRG Title**
PreMDC	001	Heart Transplant or Implant of Heart Assist System with MCC
PreMDC	002	Heart Transplant or Implant of Heart Assist System without MCC
MDC 01	020	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with MCC
MDC 01	021	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with CC
MDC 01	022	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant without CC/MCC
MDC 01	023	Craniotomy with Acute Complex CNS Principal Diagnosis with MCC or Antineoplastic Implant
MDC 01	024	Craniotomy with Acute Complex CNS Principal Diagnosis without MCC
MDC 01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
MDC 01	026	Craniotomy and Endovascular Intracranial Procedures with CC
MDC 01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
MDC 01	040	Peripheral/Cranial Nerve and Other Nervous System Procedures with MCC
MDC 01	041	Peripheral/Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulation
MDC 01	042	Peripheral/Cranial Nerve and 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	209	Complex Aortic Arch Procedures
MDC 05	213	Endovascular Abdominal Aorta with Iliac Branch Procedures
MDC 05	215	Other Heart Assist System Implant
MDC 05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
MDC 05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
MDC 05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
MDC 05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
MDC 05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
MDC 05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
MDC 05	242	Permanent Cardiac Pacemaker Implant with MCC
MDC 05	243	Permanent Cardiac Pacemaker Implant with CC
MDC 05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
MDC 05	245	AICD Generator Procedures
MDC 05	258	Cardiac Pacemaker Device Replacement with MCC

List of MS-DRGs Subject to the IPPS Policy for Replaced Devices Offered without Cost or with a Credit		
MDC	**MS-DRG DRG**	**MS-DRG Title**
MDC 05	259	Cardiac Pacemaker Device Replacement without MCC
MDC 05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
MDC 05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
MDC 05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
MDC 05	265	AICD Lead Procedures
MDC 05	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
MDC 05	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
MDC 05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
MDC 05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
MDC 05	270	Other Major Cardiovascular Procedures with MCC
MDC 05	271	Other Major Cardiovascular Procedures with CC
MDC 05	272	Other Major Cardiovascular Procedures without CC/MCC
MDC 05	275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
MDC 05	276	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator
MDC 05	277	Cardiac Defibrillator Implant without MCC
MDC 05	319	Other Endovascular Cardiac Valve Procedures with MCC
MDC 05	320	Other Endovascular Cardiac Valve Procedures without MCC
MDC 08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
MDC 08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
MDC 08	466	Revision of Hip or Knee Replacement with MCC
MDC 08	467	Revision of Hip or Knee Replacement with CC
MDC 08	468	Revision of Hip or Knee Replacement without CC/MCC
MDC 08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
MDC 08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
MDC 08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
MDC 08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

C. Recalibration of the MS-DRG Relative Weights

The Secretary is required by statute to revise the MS-DRG groups and weights annually to reflect changes in technology, medical practice, and other factors. CMS uses the MedPAR file (fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year) from the 2nd year preceding the ratesetting year (e.g., FY 2024 for FY 2026). It also uses Medicare cost report data from the 3rd year preceding the ratesetting year (e.g., FY 2023 for FY 2026).

In developing relative weights for FY 2026, CMS proposes to use:

FY 2024 MedPAR data: Bills received through December 31, 2024, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS). Medicare Advantage (MA) claims and claims from facilities currently classified as CAHs are excluded. CMS used data from approximately 6,860,436 million Medicare discharges regrouped using the FY 2026 proposed MS-DRG classifications.
FY 2023 Medicare Cost Reports: Medicare cost report data files from HCRIS, principally for FY 2023 cost reporting periods, using the December 31, 2024 update of the FY 2023 HCRIS.

For FY 2026, 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 the HCRIS cost report data file it used to calculate the 19 CCRs for FY 2026, available at: FY 2026 IPPS Proposed Rule Home Page | CMS. (Select file #4 under FY 2026 Proposed Rule Data files, "FY 2026 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 2026, 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 2026 proposed CCRs in comparison to the final FY 2025 CCRs are shown in the following table:

Group	Final FY 2025 CCR	Proposed FY 2026 CCR
Routine Days	0.418	0.395
Intensive Days	0.360	0.341
Drugs	0.178	0.179
Supplies & Equipment	0.297	0.304
Implantable Devices	0.259	0.265
Inhalation Therapy	0.162	0.149
Therapy Services	0.265	0.260
Anesthesia	0.071	0.074
Labor & Delivery	0.381	0.367
Operating Room	0.160	0.156
Cardiology	0.088	0.087
Cardiac Catheterization	0.104	0.100
Laboratory	0.102	0.099
Radiology	0.127	0.124
MRIs	0.067	0.066
CT Scans	0.033	0.032
Emergency Room	0.153	0.141
Blood and Blood Products	0.246	0.238
Other Services	0.336	0.330

Relative Weight Calculation for CAR-T cell Therapy (MS-DRG 018). Beginning with FY 2021, CMS adopted differential payment for clinical trial and expanded access use cases (also known as compassionate use) where the hospital does not incur the costs of the CAR-T product. For FY 2026, 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" or contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS-DRG 018.

CMS notes that MS-DRG 018 appears to include some claims identified as clinical trial cases or involving expanded access use that have drug charges like other cases where the full cost of the drug is incurred by the hospital. These charges are generally in revenue center 0891, Cell Therapy Drug Charges. CMS seeks comments on why a hospital would have charges in revenue center 0891, Cell Therapy Drug Charges when they receive the drug at no cost.

CMS estimates that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($88,484) were 23 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($385,147). Accordingly, CMS proposes a payment adjustor of 0.23 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 2026 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 this policy for FY 2026.

Other Issues. CMS proposes normalizing the relative weights by an adjustment factor of 1.92111 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 but may include other types of cases), 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 10 MS-DRGs (7 for newborns and 3 for other rare conditions in the Medicare population).

D. Add-on Payments for New Services and Technologies

1. Background

The statute[35] requires the Secretary to establish a mechanism for recognizing new medical services and technologies under the IPPS. The Secretary is required to establish criteria used to

[35] Sections 1886(d)(K) and (L) of the Social Security Act

determine if a medical service of technology is new, meaning that the DRG payment rate that would otherwise apply is inadequate.[36] The implementing regulations[37] 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;[38] 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.[39] 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.[40]

a. New Technology Add-on Payment Criteria

Newness Criterion. CMS notes that a technology is no longer "new" after CMS has recalibrated the MS-DRGs based on available data to reflect the cost of the technology. Further, 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 another 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:[41]

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, will not consider the medical service or technology "new".[42] CMS first determines whether a medical service or technology is new; if CMS determines the medical service or technology is considered new, then

[36] Section 1886(d)(5)(K)(vi) of the Act
[37] 42 CFR 412.87
[38] 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).
[39] 84 FR 42292 through 42297; regulations at §412.87(c) and (d)
[40] 85 FR 58736
[41] 74 FR 43813 and 43814
[42] For detailed discussion of the criteria for substantial similarity, see FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

it makes a determination as to whether the cost threshold and substantial clinical improvement criteria are met.

Cost Criterion. The statute requires CMS to assess the new technology for payment adequacy. CMS therefore evaluates whether the charges of the cases involving a new technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized for all cases in the MS-DRG to which the new technology is assigned. If the new technology is assigned to several MS-DRGs, CMS uses the case-weighted average of all the relevant MS-DRGs. The MS-DRG threshold amounts that are generally used for evaluating applications for the FY 2026 new tech add-on payments are presented in a data file found at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index

Additionally, applicants should submit a significant sample of data to demonstrate that the new technology meets the high-cost threshold which will allow CMS to undertake an initial validation and analysis of the data.

Substantial Clinical Improvement Criterion. Under the third criterion, a new technology must represent an advance that substantially improves, relative to available technologies, the diagnosis or treatment of Medicare beneficiaries. CMS reiterates[43] that it does not rely upon FDA criteria in its evaluation of substantial clinical improvement, and this criterion does not depend on the standard of safety and effectiveness used by the FDA. Rather, the CMS standard relies on a demonstration of substantial clinical improvement in the Medicare population. The following aspects[44] are used by CMS in its evaluation:

- The totality of circumstances is considered when making a determination of substantial clinical improvement.
- A determination of substantial clinical improvement means:
    - The new tech offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;
    - The new tech offers the ability to diagnose a medical condition that is currently undetectable or diagnoses the condition earlier than allowed by currently available methods. There must also be evidence that the detection or early detection affects the management of the patient.
    - The new tech significantly improves clinical outcomes relative to services or technologies previously available. This can be demonstrated by at least 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;

[43] Initially discussed in the FY 2003 IPPS final rule (67 FR 50015)
[44] Established in the FY 2020 IPPS final rule and codified at §412.87(b)

        - 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, including from following sources: clinical trials, peer reviewed journal articles, study results, meta-analyses, consensus statements, white papers, patient surveys, case studies, reports, systematic literature reviews, letters from major healthcare associations, editorials and letters to the editor, and public comments. Other appropriate information sources may be considered.
- The medical condition diagnosed or treated may have a low prevalence among Medicare beneficiaries.
- The new tech may represent an advance that substantially improves, relative to available options, the diagnosis or treatment of a subpopulation of patients with the medical condition.

b. Alternative Inpatient New Technology Add-on Payment Pathway

CMS has established alternative pathways through which some devices and drugs may apply and qualify for new tech add-on payments. Specifically, CMS has established pathways for considering a medical device that is part of the FDA's Breakthrough Devices Program and for certain microbial products that are designated by the FDA as a Qualified Infectious Disease Product (QIDP) and for a drug approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD). CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of application submission. To receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other eligibility requirements in the regulations in §412.87(c) and (d), as applicable.

Alternative Pathway for Certain Transformative New Devices. A medical device qualifies for this alternative pathway if the device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation. Such devices will be considered "new" by CMS until CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology. Devices in this alternative pathway must meet the cost criterion previously discussed and established by CMS for new tech applications; however, devices in this alternative pathway are

not required to meet the previously discussed substantial clinical improvement criteria that otherwise would apply to new tech applications.[45]

Alternative Pathway for Certain Antimicrobial Products. A medical product may qualify for consideration under this alternative pathway if the product is designated by FDA as a QIDP and received FDA marketing authorization, or it is a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway. Such products will be considered "new" by CMS until CMS has recalibrated the DRGs, based on available data, to reflect the costs of an otherwise new medical technology. Products in this alternative pathway must meet the cost criterion previously discussed and established by CMS for new tech applications; however, products in this alternative pathway are not required to meet the previously discussed substantial clinical improvement criteria that otherwise would apply to new tech applications.[46]

c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. CMS does not include or make capital-related costs in these payments. Payments are made if the costs of a discharge involving a new technology exceed the full DRG payment (including payments for IME and DSH but excluding outlier payments).

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.[47] Additionally, CMS finalizes payment amounts in each fiscal year final rule and does not make mid-year changes to those amounts. Updated cost information may be submitted and included in rulemaking to be considered for the following fiscal year.

For new technologies, other than a medical product designated as a QIDP or a product approved under FDA's LPAD, for discharges on or after October 1, 2019: Medicare's add-on payment is equal to the lesser of: (1) 65 percent of the costs of the new technology; or (2) 65 percent of the difference between the standard DRG payment and the cost of the case.

For medical products designated as a QIDP, for discharges on or after October 1, 2019: Medicare's add-on payment is equal to the lesser of: (1) 75 percent of the costs of the new technology; or (2) 75 percent of the difference between the standard DRG payment and the hospital's cost for the case.

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[45] See governing regulatory eligibility criteria at § 412.87(c)
[46] See governing regulatory eligibility criteria at § 412.87(d)
[47] 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.

For a medical product approved under FDA's LPAD pathway, for discharges on or after October 1, 2020: Medicare's add-on payment is equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment.

For certain gene therapies approved for add-on payments that are indicated and used specifically for the treatment of sickle cell disease (SCD), for discharges on or after October 1, 2024: Medicare's add-on payment is equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. CMS notes these payment amounts only apply to Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD.

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

When evaluating a new services or technology application, CMS first determines whether the medical service or technology meets the newness criterion, and only if so, does CMS then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement. 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 and must provide CMS with documentation of FDA acceptance (for a 510k application or De Novo Classification request) or filing (for a PMA, NDA, or BLA)[48] at the time of application submission. CMS considers the application to be complete when the full application has been submitted to FDA and FDA has provided documentation to the applicant indicating that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA.

CMS notes that the FDA does not conduct a new filing review for NDA or BLA applications that were the subject of a Complete Response Letter (CRL) and were subsequently resubmitted to FDA. To address this situation, for applications submitted for FY 2027, CMS will require these new technology add-on payment applicants provide to CMS a copy of the resubmission acknowledgement letter from FDA that indicates that FDA considers the resubmission to be sufficient to restart the review clock and provides the new goal date for FDA review of the application. CMS states that if other situations arise that are not addressed in the preamble, or if the FDA changes its review processes, then applicants must provide to CMS the most up-to-date documentation that indicates FDA has determined that the application is sufficiently complete to allow for substantive review by FDA.

Finally, CMS specifies that all applicants for a new technology add-on payment (except for an application that is submitted under the alternative pathway for certain antimicrobial products)

[48] FDA marketing authorization can include pre-market approval (PMA), 510(k) clearance, the granting of a De Novo classification request, or approval of a New Drug Application (NDA) or Biologics License Application (BLA)

must have FDA approval or clearance[49] by May 1[50] of the year prior to the beginning of the fiscal year for which the application is being considered.

For applications submitted under the alternative pathway for certain antimicrobial products, CMS provides conditional approval for new technology add-on payment, provided that the technology otherwise meets applicable add-on payment criteria. CMS explains that under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

e. Pharmaceutical & Technology Ombudsman (PTO)

CMS uses the Pharmaceutical & Technology Ombudsman (PTO) (PharmTechOmbud@cms.hhs.gov) 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 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech and https://www.cms.gov/medicare/coding-billing/guide-medical-technology-companies-other-interested-parties.

f. Application Information for New Medical Services or Technologies

For FY 2027, 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 post a list of the FY 2027 applications submitted, along with a brief description of each technology as provided by the applicant. At the time the proposed rule is published, CMS also posts 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. **Beginning with new technology add-on applications submitted for FY 2027, CMS intends to include certain cost criterion information in the public posting.** Specifically, beginning with the FY 2027 applications, the public posting will include the applicant's explanation of the cost analysis methodology, including the step-by-step explanation of the columns used in the cost analysis spreadsheet attachment, any optional comments provided by the applicant, and information about the case weighted threshold and final inflated case weighted standardized charge per case, as is currently subject to discussion in the cost criterion analysis for

[49] CMS considers FDA marketing authorization as representing that a product has FDA approval or clearance, as well as products that have been granted a De Novo classification request.
[50] CMS finalized a change from July 1 to May 1 in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958) which applies to FY 2025 applications.

each eligible application in the proposed rule. The cost analysis spreadsheet attachment and other charge values provided in the applicant's responses would not be included in the public posting.[51]

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

The law requires the Secretary to undertake certain actions in order to obtain public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement.[52] As a result, on December 11, 2024, CMS held a virtual town hall meeting for the express purpose of discussing the "substantial clinical improvement criterion" for pending new technology applications.[53] Applicant presentations as well as written comments received by the December 16, 2024 deadline were considered by CMS in the development of this proposed rule. 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.

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. Proposals to create, delete, or revise Section "X" codes under the ICD-10-PCS structure will be referred to the ICD-10 Coordination and Maintenance Committee. CMS encourages providers to review the guidelines for ICD-10-PCS Section "X" codes which can be found on the CMS website at: https://www.cms.gov/medicare/coding-billing/icd-10-codes

4. Proposed FY 2026 Status of Technologies Receiving New Technology Add-On Payments for FY 2025

In this section of the proposed rule, CMS discusses the proposed FY 2026 status of 42 technologies approved for 39 new technology add-on payments for FY 2025, as set forth in the tables below that are reproduced from the proposed rule. CMS reminds the reader that a medical service or technology may be considered new within 2 or 3 years after the point at 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, generally following 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 the FY 2025 IPPS final rule,[54] CMS finalized a new policy to extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. This

[51] This burden is subject to the PRA and approved under OMB control number 0938–1347 and has an expiration date of December 31, 2026.
[52] Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Pub. L. 108-73.
[53] The recording of the virtual town hall is available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.
[54] FY 2025 IPPS/LTCH PPS final rule (89 FR 69238 through 69242)

change is effective beginning with those technologies that are initially approved for new technology add-on payments in FY 2025 or a subsequent year. For technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies CMS determines to be substantially similar to those technologies, the agency continues to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered "new" for purposes of new technology add-on payments.

CMS is inviting public comments on its proposals to continue new technology add-on payments for FY 2026 for the technologies listed in Tables II.E.-01.A and 01.B

TABLE II.E.-01.A: PROPOSED CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2025 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2026 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER APRIL 1, 2026

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2026	Coding Used to Identify Cases Eligible for NTAP
1	*CYTALUX® (pafolacianine) (lung indication)*	*06/05/2023*	*10/01/2023*	*06/05/2026*	88 FR 58810 through 58818 89 FR 69120 through 69126	$2,762.50	8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN, or 8E0W8EN
2	*EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm)*	*05/19/2023*	*10/01/2023*	*05/19/2026*	88 FR 58818 through 58835 89 FR 69120 through 69126	$6,504.07	XW013S9, XW033P9, or XW043P9
3	*Aveir™ AR Leadless Pacemaker*	*06/29/2023*	*10/01/2023*	*06/29/2026*	88 FR 58919 through 58923 89 FR 69120 through 69126	$10,725.00	X2H63V9
4	*Aveir™ Dual-Chamber Leadless Pacemaker*	*06/29/2023*	*10/01/2023*	*06/29/2026*	88 FR 58923 through 58925 89 FR 69120 through 69126	$15,600.00	X2H63V9 in combination with X2HK3V9
5	*Ceribell Status Epilepticus Monitor*	*05/23/2023*	*10/01/2023*	*05/23/2026*	88 FR 58927 through 58930 89 FR 69120 through 69126	$913.90	XX20X89
6	*DETOUR System*	*06/07/2023*	*10/01/2023*	*06/07/2026*	88 FR 58930 through 58932 89 FR 69120 through 69126	$16,250.00	X2KH3D9, X2KH3E9, X2KJ3D9, or X2KJ3E9
7	*DefenCath® (taurolidine/heparin)*	*11/15/2023*	*01/01/2024*	*11/15/2026*	88 FR 58942 through 58944 89 FR 69120 through 69126	$3,656.10	XY0YX28
8	*Phagenyx® System*	*04/12/2023*	*10/01/2023*	*04/12/2026*	88 FR 58935 through 58937 89 FR 69120 through 69126	$3,250.00	XWHD7Q7
9	*REZZAYO™ (rezafungin for injection)*	*07/19/2023*	*10/01/2023*	*07/19/2026*	88 FR 58944 through 58946 89 FR 69120 through 69126	$4,387.50	XW033R9 or XW043R9

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2026	Coding Used to Identify Cases Eligible for NTAP
10	*TOPS™ System*	*06/15/2023*	*10/01/2023*	*06/15/2026*	88 FR 58940 through 58942 89 FR 69120 through 69126	$11,375.00	XRHB018 in combination with M48.062
11	*XACDURO® (sulbactam/durlobactam)*	*05/23/2023*	*10/01/2023*	*05/23/2026*	88 FR 58946 through 58948 89 FR 69120 through 69126	$13,680.00	XW033K9 or XW043K9 in combination with one of the following: Y95 and J15.61; OR J95.851 and B96.83

Table II.E-01.B (below) lists the technologies that were first approved for new technology add-on payments in FY 2025, for which CMS is proposing to continue making new technology add-on payments for FY 2026 because they are still considered "new" for purposes of new technology add-on payments because the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1, 2025.

TABLE II.E.-01.B: PROPOSED CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2025 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2026 BECAUSE THE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER OCTOBER 1, 2025

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2026	Coding Used to Identify Cases Eligible for NTAP
1	*Annalise Enterprise CTB Triage—OH*	*10/10/2023*	*10/01/2024*	*10/10/2026*	89 FR 69205 through 69208	$241.39	XXE0X1A
2	*ASTar® System*	*04/26/2024*	*10/01/2024*	*04/26/2027*	89 FR 69208 through 69210	$97.50	XXE5X2A
3	*Edwards EVOQUE™ Tricuspid Valve Replacement System ("EVOQUE™ System")*	*02/01/2024*	*10/01/2024*	*02/01/2027*	89 FR 69210 through 69213	$31,850.00	X2RJ3RA
4	*GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)*	*01/12/2024*	*10/01/2024*	*01/12/2027*	89 FR 69213 through 69215	$47,238.75	X2VE3SA
5	*LimFlow™ System*	*11/01/2023*	*10/01/2024*	*11/01/2026*	89 FR 69215 through 69218	$16,250.00	041M3JS, 041N3JS, 041P3JS, 041Q3JS, 041R3JS, 041S3JS, 041T3JS, or 041U3JS
6	*Paradise™ Ultrasound Renal Denervation System*	*11/7/2023*	*10/01/2024*	*11/07/2026*	89 FR 69218 through 69221	$14,950.00	X051329
7	*PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter*	*12/13/2023*	*10/01/2024*	*12/13/2026*	89 FR 69221 through 69225	$6,337.50	02583ZF
8	*Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter*	*11/17/2023*	*10/01/2024*	*11/17/2026*	89 FR 69225 through 69228	$10,400.00	X05133A
9	*TriClip™ G4*	*04/01/2024*	*10/01/2024*	*04/01/2027*	89 FR 69228 through 69230	$26,000.00	02UJ3JZ

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2026	Coding Used to Identify Cases Eligible for NTAP
10	*VADER® Pedicle System*	*02/26/2024*	*10/01/2024*	*02/26/2027*	89 FR 69230 through 69236	$28,242.50	XRH60FA, XRH63FA, XRH64FA, XRH70FA, XRH73FA, XRH74FA, XRH80FA, XRH83FA, XRH84FA, XRHA0FA, XRHA3FA, XRHA4FA, XRHB0FA, XRHB3FA, XRHB4FA, XRHC0FA, XRHC3FA, XRHC4FA, XRHD0FA, XRHD3FA, or XRHD4FA **in combination with** one of the following: M46.20, M46.22, M46.23, M46.24, M46.25, M46.26, M46.27, M46.30, M46.32, M46.33, M46.34, M46.35, M46.36, M46.37, M46.39, M46.40, M46.42, M46.43, M46.44, M46.45, M46.46, M46.47, M46.49, M46.50, M46.51, M46.52, M46.53, M46.54, M46.55, M46.56, M46.57, M46.59, M46.80, M46.82, M46.83, M46.84, M46.85, M46.86, M46.87, M46.89, M46.90, M46.92, M46.93, M46.94, M46.95, M46.96, M46.97, or M46.99
11	*ZEVTERA™ (ceftobiprole medocaril); ABSSSI and CABP indications*	*04/03/2024*	*10/01/2024*	*04/03/2027*	89 FR 69236 through 69238	$2,812.50	XW0335A or XW0435A
12	*ZEVTERA™ (ceftobiprole medocaril); SAB indication*	*04/03/2024*	*10/01/2024*	*04/03/2027*	89 FR 69236 through 69238	$8,625.00	XW0335A or XW0435A **in combination with** R78.81 (**in combination with** B95.61 or B95.62)
13	*CASGEVY™ (exagamglogene autotemcel); Sickle Cell Disease indication*	*12/08/2023*	*10/01/2024*	*12/08/2026*	89 FR 69128 through 69135	$1,650,000.00	XW133J8 or XW143J8 **in combination with** one

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2026	Coding Used to Identify Cases Eligible for NTAP
							of the following: D57.1, D57.20, D57.40, D57.42, D57.44, or D57.80
14	*HEPZATO™ KIT (melphalan for injection/hepatic delivery system)*	*01/08/2024*	*10/01/2024*	*01/08/2027*	89 FR 69158 through 69170	$118,625.00	XW053T9 **in combination with** 5A1C00Z
15	*LYFGENIA™ (lovotibeglogene autotemcel)*	*12/08/2023*	*10/01/2024*	*12/08/2026*	89 FR 69188 through 69196	$2,325,000.00	XW133H9 or XW143H9

CMS is proposing to discontinue new technology add-on payments for FY 2026 for the technologies listed in Table II.E.-02 (reproduced below from the preamble of the FY 2026 IPPS proposed rule preamble). CMS invites public comment on this proposal.

TABLE II.E.-02: PROPOSED DISCONTINUATION OF TECHNOLOGIES

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market
1	*Thoraflex™ Hybrid Device*	*04/19/2022*	*10/01/2022*	*04/19/2025*
2	*ViviStim® Paired VNS System*	*04/29/2022*	*10/01/2022*	*04/29/2025*
3	*GORE® TAG® Thoracic Branch Endoprosthesis*	*05/13/2022*	*10/01/2022*	*05/13/2025*
4	*CERAMENT® G (bone infection indication)*	*05/17/2022*	*10/01/2022*	*05/17/2025*
5	*iFuse Bedrock Granite Implant System*	*05/26/2022*	*10/01/2022*	*05/26/2025*
6	*CYTALUX® (pafolacianine) (ovarian indication)*	*04/15/2022*	*10/01/2023*	*04/15/2025*
7	*Lunsumio™ (mosunetuzumab)*	*12/22/2022*	*10/01/2023*	*12/22/2025*
8	*REBYOTA™ (fecal microbiota, live-jslm) and VOWST™ (fecal microbiota spores, live-brpk)*	*01/23/2023*	*10/01/2023*	*01/23/2026*
9	*SPEVIGO® (spesolimab)*	*09/01/2022*	*10/01/2023*	*09/01/2025*
10	*TECVAYLI™ (teclistamab-cqyv) ELREXFIO™ (elranatamab-bcmm) and TALVEY™ (talquetamabtgvs)*	*11/09/2022*	*10/01/2023 10/01/2024*	*11/09/2025*
11	*TERLIVAZ® (terlipressin)*	*10/14/2022*	*10/01/2023*	*10/14/2025*
12	*EchoGo Heart Failure 1.0*	*11/23/2022*	*10/01/2023*	*11/23/2025*
13	*SAINT Neuromodulation System*	*09/01/2022*	*10/01/2023*	*09/01/2025*

Specifically, **CMS is proposing to discontinue new technology add-on payments for FY 2026 for CERAMENT® G when used for bone infections.** CMS explains that CERAMENT® G was initially approved for new technology add-on payments with an indication for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities. CMS notes that in this proposed rule, BONESUPPORT, Inc. is also seeking new technology add-on payments for CERAMENT® G for FY 2026 for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to open fractures. CMS believes that cases involving the use of CERAMENT® G related to bone infections, which would no longer be eligible for new technology add-on payment in FY 2026, would be identified by the ICD-10-PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) in combination with the ICD-10-CM codes in category M86 (Osteomyelitis). CMS invites public comments on the use of these codes to exclude the indication for use of CERAMENT® G related to bone infections, which would not be eligible for the new technology add-on payment for FY 2026, if approved.

5. Proposed FY 2026 Applications for New Technology Add-On Payments (Traditional Pathway)

Beginning with FY 2024 applications, CMS publicly posts applications for new technology add-on payment.[55] CMS therefore provides succinct summary information in this proposed rule. The agency refers readers to https://mearis.cms.gov/public/publications/ntap for the publicly posted FY 2026 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), including tables listing the ICD-10-CM codes, ICD-10-PCS codes, and/or MS-DRGs related to the analyses of the cost criterion for certain technologies for the FY 2026 new technology add-on payment applications.

CMS received 19 applications for new technology add-on payments for FY 2026 under the new technology add-on payment traditional pathway. CMS reminds readers that to be eligible for an FY 2026 new technology add-on payments, the technology must have received FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. For technologies that are not already FDA market authorized for the indication that is the subject of the application, applicants must have a complete and active FDA market authorization request and submit proof of this with their CMS NTAP application. Of the 19 applications received under the traditional pathway, 2 applicants were not eligible for consideration for new technology add-on payment because they did not meet these requirements, and 3 applicants withdrew their applications prior to the issuance of this proposed rule. CMS addresses the remaining 14 applications in this proposed rule.

a. AUCATZYL® (obecabtagene autoleucel)

According to the applicant, AUCATZYL® is a fast off-rate cluster of differentiation 19 (CD19) autologous chimeric antigen receptor (CAR) T-cell therapy with tumor burden-

[55] (87 FR 48986 through 48990).

guided dosing designed to improve persistence and reduce immune-mediated toxicity. Per the applicant, AUCATZYL® is indicated for the treatment of adults with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (B-ALL). The application is available at https://mearis.cms.gov/public/publications/ntap/NTP241002GUJHV

Newness: According to the applicant, AUCATZYL® was granted BLA approval from FDA on November 8, 2024, for the treatment of adults with R/R B-ALL, and was commercially available immediately after. CMS provides a summary chart in the proposed rule regarding the applicant's assertions regarding the "substantial similarity" criteria. CMS expresses a concern and belief that TECARTUS® and KYMRIAH® may be substantially similar to AUCATZYL® because they may use the same or similar mechanism of action to achieve a therapeutic outcome, they are assigned to the same MS-DRG, and they treat the same or similar patient population and disease. As such, the newness period would begin on November 22, 2017, the date KYMRIAH® became commercially available. **CMS is interested in information on how these technologies may differ from each other with respect to the substantial similarity criteria and newness criterion.**

Cost: CMS notes that the applicant provided two analyses to demonstrate that the technology meets the cost criterion. These are summarized in a table provided by CMS in the proposed rule. **CMS is inviting public comments on whether AUCATZYL® meets the cost criterion.**

Substantial Clinical Improvement: **CMS is inviting public comments on whether AUCATZYL® meets the substantial clinical improvement criterion.**

CMS summarizes the applicant's assertions related to substantial clinical improvement and refers readers to the online application for complete statements. CMS notes it did not receive any written comments in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical improvement criterion for AUCATZYL®. The agency expresses several concerns: whether the technology meets the substantial clinical improvement criterion, including questioning: whether there is any patient population with R/R B-ALL that is unresponsive to or ineligible for any of the currently available treatments for the condition; the applicant's assertion that following the single treatment of AUCATZYL®, adult patients with R/R B-ALL experienced high response rates, with superior immune mediated toxicity compared to TECARTUS®; and the applicant's claim that AUCATZYL® may be an important, definitive stand-alone treatment for adults with R/R B-ALL versus use as a bridging therapy. **CMS welcomes information about factors besides hemotoxicity that may also be used to inform decisions about the need for subsequent allogenic subsequent stem cell transplant.**

CMS also expresses concerns about potential confounders introduced by pooling the data from two independent trials with different study designs and how those confounders might impact the validity of the findings related to AUCATZYL®'s impact on clinical

outcomes. Moreover, CMS expresses concerns about the availability of evidence on AUCATZYL's effects on the outcomes of the Medicare population of those age 65 years or older. **CMS welcomes evidence about the clinical outcomes of R/R B-ALL patients age 65 years or older who received AUCATZYL®.**

Additionally, **CMS welcomes information about how the technology in Ghorashian et al. (2019) compares with AUCATZYL® as well as additional information comparing TECARTUS® and KYMRIAH® with AUCATZYL® in order to demonstrate that it provides a substantial clinical improvement over existing therapies.**

b. AURLUMYNTM (iloprost injection)

According to the applicant, AURLUMYN™ is an intravenous form of iloprost associated with immediate generalized vasodilation, immunomodulation, and anti-inflammation indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations. The online application is available at: https://mearis.cms.gov/public/publications/ntap/NTP241007QK29V

Newness: According to the applicant, FDA granted NDA approval for AURLUMYN™ on February 13, 2024, for the treatment of severe frostbite in adults to reduce the risk of digit amputations. Per the applicant, the commercial launch of AURLUMYN™ was delayed. **CMS is interested in additional information regarding the cause of any delay in the technology's commercial availability**, including additional details about the preparation for launch that aligned with the beginning of the winter season.

CMS notes that the applicant has submitted a request for a unique ICD-10-PCS procedure code. A list of ICD-10-CM diagnosis codes that may be used to identify the indication for the technology may be found in the online application. CMS provides a table in the preamble of the proposed rule summarizing the applicant's assertions regarding the 'substantial similarity' criteria. Upon review, CMS states its belief that the use of AURLUMYN™ will not change the MS-DRG assignment and will, therefore, map to the same MS-DRGs as other treatments for severe frostbite. Further, CMS notes that there are other severe frostbite treatments that are commonly used including rapid rewarming, fasciotomy, thrombolysis, and sympathectomy. **CMS is inviting public comments on whether AURLUMYN™ is substantially similar to existing technologies and whether AURLUMYN™ meets the newness criterion.**

Cost: CMS notes that the applicant provided multiple analyses to demonstrate that the technology meets the cost criterion, which the agency summarizes in a table in the proposed rule. **CMS is inviting public comments on whether AURLUMYN™ meets the cost criterion.**

Substantial Clinical Improvement: CMS provides a table in the preamble of the purposed rule that summarizes the applicant's assertions related to substantial clinical improvement and supporting evidence provided by the applicant. CMS notes it did not receive any

written comments in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical improvement criterion for AURLUMYN™. After review of the information provided by the applicant, CMS expresses concerns regarding whether AURLUMYN™ meets the substantial clinical improvement criterion. Specifically, CMS lacks clarity on patient groups that are unresponsive to, or ineligible for, the standard-of-care treatment, where AURLUMYN™ does offer a treatment option. Additionally, CMS notes that it appears as though there are other treatment options for frostbite other than AURLUMYN™. **CMS would appreciate any additional information regarding which patient population AURLUMYN™ can treat for severe frostbite for which other existing treatments could not be used.**

CMS questions whether the composition of the AURLUMYN™ and standard of care treatment groups in two published studies provided by the applicant were sufficiently comparable and, consequently, whether outcomes demonstrated are clinically significant. CMS also has concerns related to the generalizability of the research studies cited to the Medicare population. **CMS is inviting public comments on whether AURLUMYN™ meets the substantial clinical improvement criterion.**

c. BREYANZI ® (lisocabtagene maraleucel)

According to the applicant, BREYANZI® is a CD19-directed, autologous CAR T-cell immunotherapy comprised of individually formulated CD8 and CD4 CAR T-cells, and it is indicated for the treatment of adult patients with relapsed/refractory (R/R) chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received two or more prior lines of therapy (LOTs), including a Bruton tyrosine kinase inhibitor (BTKi) and a B-cell lymphoma 2 protein inhibitor (BCL2i). CMS notes that the technology is also indicated for the treatment of adult patients with R/R large B-cell lymphoma, for which the applicant submitted an application for new technology add-on payments for FY 2021 and FY 2022.[56] The online application is available at https://mearis.cms.gov/public/publications/ntap/NTP24100722KTJ

Newness: According to the applicant, BREYANZI® was granted accelerated approval for its supplemental Biologics License Application (sBLA) by FDA on March 14, 2024 for the treatment of adult patients with R/R CLL or SLL who have received two or more prior LOTs including a BTKi and a BCL2i. The applicant states that IDC-10-PCS codes that could be used to uniquely describe procedures involving the use of BREYANZI® are XW033N7 (Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein) or XW043N7 (Transfusion of lisocabtagene maraleucel immunotherapy into central vein). The applicant supplied a list of ICD-10-CM diagnosis codes (C83.00 to .09 and C91.10 and .12) that may be used to identify the indication for the technology and CMS includes these in a table in the proposed rule preamble. **CMS is inviting public comments on the use of these ICD-10-CM diagnosis codes to identify the indication of R/R SLL or CLL for purposes of the new technology add-on payment, if approved.**

[56] As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44996 through 45008).

CMS developed a table summarizing the applicant's assertions regarding the substantial similarity criteria. CMS questions whether BREYANZI® treats a different type of disease or patient population than existing technologies. **CMS is inviting public comments on whether BREYANZI® is substantially similar to existing technologies and whether BREYANZI® meets the newness criterion.**

Cost: In a table found in the preamble of the proposed rule, CMS summarizes the analysis that was provided by the applicant to demonstrate that BREYANZI® meets the cost criterion. **CMS is inviting public comments on whether BREYANZI® meets the cost criterion.**

Substantial Clinical Improvement: A table in the preamble of the proposed rule summarizes the assertions made by the applicant regarding the substantial clinical improvement criterion. CMS also received a public comment from the applicant in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical improvement criterion for BREYANZI® which are summarized in the preamble of the proposed rule. CMS thanks the applicant for the comments. After review of the application and the applicant's public comments, CMS continues to have several concerns regarding whether BREYANZI® meets the substantial clinical improvement criterion, including:

- CMS questions whether there is a particular subpopulation for which BREYANZI® offers a treatment option that is unresponsive to or ineligible for other existing therapies and notes that being the first CAR T-cell therapy for a particular indication relates to mechanism of action and is not relevant to the demonstration of substantial clinical improvement.
- CMS has questions regarding the evidence provided in support of the claim that BREYANZI® is anticipated to significantly improve clinical outcomes in R/R CLL/SLL patients who have received prior BTKi and BCL2i therapy.
- With respect to the applicant's claims that R/R CLL/SLL patients who received prior BTKi and BCL2i therapies have limited treatment options, and that patients with R/R CLL/SLL have poor outcomes on existing therapy, CMS questions whether these claims support that BREYANZI® improves clinical outcomes for this patient population.

CMS is inviting public comments on whether BREYANZI® meets the substantial clinical improvement criterion.

d. COBENFY™ (xanomeline and trospium chloride)

According to the applicant, COBENFY™ is an oral combination drug consisting of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, that is indicated for the treatment of schizophrenia in adults. The online application posting for COBENFY™ is available at https://mearis.cms.gov/public/publications/ntap/NTP241007U99FM

Newness: According to the applicant, COBENFY™ was granted NDA approval from FDA on September 26, 2024, for the treatment of schizophrenia in adults. **CMS is interested in additional information regarding the cause of any delay in the technology's commercial availability,** such as additional information about the ramp-up period for distribution. CMS notes that the applicant submitted a request for approval for a unique ICD-10-PCS procedure code for COBENFY™ beginning in FY 2026. The applicant provided a list of diagnosis codes (including F20.0, F20.1, F20.89, F20.9, F25.0, F25.1, F25.8, and F25.9 for schizophrenia and schizoaffective disorder) that may be used to currently identify the indication for COBENFY™ under the ICD-10-CM coding system. CMS provides a table in the preamble of the proposed rule that summarizes the applicant's assertions regarding the substantial similarity criteria. **CMS is inviting public comments on whether COBENFY™ is substantially similar to existing technologies and whether COBENFY™ meets the newness criterion.**

Cost: The applicant provided an analysis to demonstrate that COBENFY™ meets the cost criterion; this analysis is summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether COBENFY™ meets the cost criterion.**

Substantial Clinical Improvement: With regard to the substantial clinical improvement criterion, the applicant asserts that COBENFY™ offers a treatment option for adult patients with schizophrenia who are unresponsive to, or ineligible for, currently available treatments and significantly improves clinical outcomes relative to existing treatments. The applicant provided several research articles to support these claims which are summarized in a table in the preamble of the proposed rule. CMS notes that the applicant submitted a public comment in response to questions posed at the Town Hall meeting and provided additional information related to this criterion, which are summarized in the preamble of the proposed rule. CMS thanks the applicant for the comments. After review of the application and the applicant's public comments, CMS continues to have concerns regarding whether COBENFY™ meets the substantial clinical improvement criterion, including:

- CMS questions how the trials demonstrate that COBENFY™ can treat patients unresponsive to other therapies. In addition, CMS notes it did not receive data indicating that other antipsychotics cannot manage negative symptoms. CMS therefore questions if COBENFY™ is the only treatment option for patients with inadequate response to current treatments or for those experiencing negative symptoms.
- Per the applicant, there are more than 20 FDA-approved therapies for schizophrenia, and CMS is interested in additional information comparing clinical outcomes with COBENFY™ to these therapies.
- CMS questions the assertion that COBENFY™ improves tolerability and side effects relative to previously available therapies. CMS would appreciate further information comparing the overall benefit-risk profile of COBENFY™ to

previously available antipsychotics in order to assess if COBENFY™ provides a substantial clinical improvement over other available therapies.

- CMS also questions long-term efficacy, given that the only data submitted for this claim was from two 5-week trials (EMERGENT-1 and EMERGENT-3).

CMS is inviting public comments on whether COBENFY™ meets the substantial clinical improvement criterion.

e. DuraGraft® (Vascular Conduit Solution)

Per the applicant, DuraGraft® is a first-in-class product used during coronary artery bypass grafting surgery (CABG) in adult patients to protect the vascular endothelia of harvested vascular grafts during the ischemic graft storage interval. Previous applications for this technology were submitted and withdrawn for FY 2018 and FY 2019,[57] and for FY 2020 and FY 2024.[58] The applicant also submitted an application for new technology add-on payments for FY 2025, but its application was not approved because CMS was unable to determine that DuraGraft® represents a substantial clinical improvement over existing therapies (89 FR 69149). The online application posting for DuraGraft® is available at https://mearis.cms.gov/public/publications/ntap/NTP241007PUDEH

Newness: According to the applicant, DuraGraft® was granted De Novo classification from FDA on October 4, 2023, as a solution indicated for adult patients undergoing CABG and is intended for flushing and storage of the saphenous vein grafts from harvesting through grafting for up to 4 hours. **CMS indicates it would appreciate additional information regarding the cause for any delay in the technology's commercial availability.** The applicant stated that, effective October 1, 2017, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of DuraGraft®: XY0VX83 (Extracorporeal introduction of endothelial damage inhibitor to vein graft, new technology group 3). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for DuraGraft® under the ICD-10-CM coding system. CMS refers readers to the online application posting for the complete list of ICD-10-CM codes provided by the applicant. The agency provides a table in the preamble of the proposed rule that summarizes the applicant's assertions regarding the substantial similarity criteria. CMS notes that it agrees that DuraGraft® has a unique mechanism of action compared to other vein graft storage solutions because it creates a reducing environment for vascular grafts to prevent oxidative damage which occurs during ischemic storage of grafts. **CMS is inviting public comments on whether DuraGraft® is substantially similar to existing technologies and whether DuraGraft® meets the newness criterion.**

Cost: The applicant provided an analysis to demonstrate that COBENFY™ meets the cost criterion; this analysis is summarized by CMS in a table that can be found in the

[57] As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26795)
[58] As summarized in the FY 2020 and FY 2024 IPPS/LTCH PPS proposed rules (84 FR 19305 through 19312, 88 FR 26795 through 26803)

preamble of the proposed rule. **CMS is inviting public comments on whether COBENFY™ meets the cost criterion.**

Substantial Clinical Improvement: The applicant provided documents and background articles to support claims that DuraGraft® represents a substantial clinical improvement over existing technologies, including a supplemental attachment providing responses to CMS' concerns and decision regarding the applicant's FY 2025 application for new technology add-on payments for DuraGraft®.[59] CMS provides a table summarizing the applicant's assertions in the proposed rule preamble.

CMS notes that the applicant submitted a public comment to a notice published in the Federal Register in response to questions raised at the New Technology Town Hall meeting regarding the substantial clinical improvement criterion for DuraGraft®. CMS summarizes the comment and thanks the commenter for the submission. After reviewing the information provided by the applicant and the public comment received in response to the new technology add-on payment town hall meeting, CMS states it continues to have concerns regarding whether DuraGraft® meets the substantial clinical improvement criterion. Concerns include:

- CMS lacks clarity on how improvements demonstrated by use of DuraGraft® as compared to saline controls demonstrate substantial clinical improvement over other existing technologies without an assessment of comparative outcomes to the other vein graft preservation solutions. In addition, CMS is unclear how the lack of differences in the mechanism in pre-clinical and non-clinical studies relates to a demonstration of substantial clinical improvement over those therapies in Medicare patients undergoing CABG. **CMS welcomes comments on the comparison of DuraGraft® to saline alone versus other storage solutions used in contemporary CABG standards of care in the U.S. Additionally, CMS would appreciate evidence comparing DuraGraft® to these currently available standard of care options to demonstrate post-CABG clinical improvement.**
- CMS reiterates a concern raised in prior rulemaking related to interim or surrogate endpoints, noting that early anatomical changes associated with the development of VGD (such as changes in wall thickness and graft narrowing) are surrogate endpoints, and that hs-Tnl levels are also surrogate measure for peri-operative MI. CMS states that they do not demonstrate a clinical outcome as described under the regulations at §412.87(b)(1)(ii)(C).
- CMS also expressed many concerns about the effects on the evidence provided of potential confounders that have not been taken into account in the study designs, specifically citing the Haime study (2018), the Szalkiewicz (2022) study, the Lopez-Mendez (2023) study, and the Cliskan et al (2024) study. **CMS is interested in similar information about the European DuraGraft Registry, including its clinical site-selection standards and patient inclusion and exclusion criteria, as discussed in the Caliskan study. CMS welcomes**

[59] As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69147 through 69149)

information about the mixed evidence from the Caliskan et al. (2024) and Lopez-Menendez et al. (2023) studies. CMS also welcomes information about the choice of all-cause mortality (as opposed to cardiac-related mortality) to represent outcomes as an indicator of the effects of DuraGraft® on clinical outcome improvement. Finally, CMS also welcomes information about how attrition impacted the number of patients in the treatment (DuraGraft®) and control groups at prespecified points of the follow-up period in the Caliskan et al. (2019) study.

CMS is inviting public comments on whether DuraGraft® meets the substantial clinical improvement criterion.

f. FIBRYGA® (fibrinogen (human))

According to the applicant, FIBRYGA® is a concentrated form of human fibrinogen, indicated for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency and the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. CMS notes that the applicant is seeking NTAP for FIBRYGA® for FY 2026 specific to the 2024 supplemental Biologics License Application (sBLA) indicated for the fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency. The online application posting for FIBRYGA® is available at https://mearis.cms.gov/public/publications/ntap/NTP241007YU8UR

Newness: According to the applicant, FIBRYGA® was granted supplemental BLA approval from FDA on July 31, 2024, expanding its previous BLA indication to include the fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency indication and to update the U.S. prescribing information to include this indication. According to the applicant, there are currently no ICD-10-PCS procedure codes to identify FIBRYGA®. CMS notes that the applicant submitted a request for approval for a unique ICD-10-PCS procedure code for FIBRYGA® beginning in FY 2026. The applicant stated that D68.4 (Acquired coagulation factor deficiency) and O72.3 (Postpartum coagulation defects) may be currently used to identify the indication for FIBRYGA® under the ICD-10-CM coding system. However, CMS believes that the relevant ICD-10-CM code to identify the indication of fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency that is relevant to this new technology add-on payment application would be D68.4 (Acquired coagulation factor deficiency). **CMS is inviting public comments on the use of this ICD-10-CM diagnosis code to identify this indication for purposes of the new technology add-on payment, if approved.** In a table in the proposed rule preamble, CMS summarizes the applicant's assertions regarding the substantial similarity criteria.

CMS states that, based on a review of the application, it appears that FIBRYGA® is substantially similar to INTERCEPT® Fibrinogen Complex because they may use the same or similar mechanism of action to achieve a therapeutic outcome, are assigned to the same MS-DRGs, and treat the same or similar patient population and disease. **CMS**

is interested in information on how these technologies may differ from each other with respect to the substantial similarity criteria and newness criterion. CMS notes that if technologies are substantially similar to each other, CMS uses the earliest market availability date as the beginning of the newness period for the technologies which, in this case, would begin on May 5, 2021, the date INTERCEPT® Fibrinogen Complex became commercially available. In addition, because the 3-year anniversary date of the INTERCEPT® Fibrinogen Complex's entry onto the U.S. market (May 5, 2024) occurred in FY 2024, FIBRYGA® would not be considered new and would not be eligible for new technology add-on payments for FY 2026. **CMS invites public comment on whether FIBRYGA® meets the newness criterion, including whether FIBRYGA® is substantially similar to INTERCEPT® Fibrinogen Complex for purposes of new technology add-on payments.**

Cost: The applicant provided an analysis to demonstrate that FIBRYGA® meets the cost criterion; this analysis is summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether FIBRYGA® meets the cost criterion.**

Substantial Clinical Improvement: The applicant asserted that FIBRYGA® represents a substantial clinical improvement over existing technologies because FIBRYGA® is the only currently available, FDA-approved, pharmaceutical-grade therapy for the treatment of acquired fibrinogen deficiency, and it provides a faster, more precise treatment option for patients with life-threatening bleeding. Additionally, the applicant asserted that patients receiving FIBRYGA® have better clinical outcomes relative to technologies previously available. The applicant provided documents and background articles to support its claims and which CMS summarizes in a table in the preamble of the proposed rule.

After review of the supporting evidence provided by the applicant, CMS has concerns regarding whether FIBRYGA® meets the substantial clinical improvement criterion. CMS questions the assertion that FIBRYGA® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. Additionally, CMS notes that while the applicant infers the technology potentially improves safety or outcomes, it did not provide data that tested or demonstrated improvements. Therefore, CMS is unclear how the applicant's claims relate to a demonstration of substantial clinical improvement over existing technologies because they do not pertain to clinical outcomes described in the regulation,[60] such as a reduction in mortality or a decreased rate of at least one subsequent diagnostic or therapeutic intervention. CMS notes that none of the studies submitted demonstrated improvements in clinical outcomes. The agency also expresses concern related to the generalizability of the study results to broader, more diverse clinical use cases for FIBRYGA® in the U.S. Medicare patient population. Finally, CMS notes that the studies compared FIBRYGA® with cryoprecipitate; no studies comparing to the currently available INTERCEPT® Fibrinogen Complex were provided. **CMS is interested in information on clinical outcomes of FIBRYGA® in comparison to INTERCEPT® Fibrinogen Complex in**

[60] §412.87(b)(1)(ii)(C)

order to evaluate whether the use of FIBRYGA® significantly improves clinical outcomes compared to available treatments.

CMS questions applicant's claims that FIBRYGA® permits rapid correction of low serum fibrinogen levels in bleeding patients compared to cryoprecipitate and that FIBRYGA® allows for more rapid availability compared to INTERCEPT® Fibrinogen Complex. Further, CMS questions the applicant's claim that FIBRYGA® decreases the use of allogeneic blood products and questions whether the Lunde et al. (2014) and FIBRES studies provided in support of this claim showed that FIBRYGA® resulted in lower rates of post-transfusion adverse events. CMS additionally notes that, although the FIBRES study was provided to demonstrate that FIBRYGA® decreases the use of allogeneic blood products, the study did not specifically report transfusion-related adverse events. **CMS indicates it would be interested in additional data regarding transfusion-related adverse events, such as urticaria, wheezing, hypotension, tachycardia, nausea, vomiting and/or diarrhea, abdominal pain, severe dyspnea, pulmonary and/or laryngeal edema, and bronchospasm and/or laryngospasm.**

CMS is inviting public comments on whether FIBRYGA® meets the substantial clinical improvement criterion.

g. GRAFAPEXTM (treosulfan)

According to the applicant, GRAFAPEX™ is a novel conditioning agent for use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (allo-HSCT) in adult and pediatric patients one year of age and older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). CMS notes that an application for this technology was previously submitted for FY 2023 under the name treosulfan and withdrawn prior to the issuance of the FY 2023 IPPS final rule.[61] The online application posting for GRAFAPEX™ is available at https://mearis.cms.gov/public/publications/ntap/NTP241007WE8D6

Newness: According to the applicant, GRAFAPEX™ was granted NDA approval from FDA on January 21, 2025, for use in combination with fludarabine as a preparative regimen for allo-HSCT in adult and pediatric patients one year of age and older with either AML or MDS. **CMS is interested in additional information regarding the cause of any delay in the technology's commercial availability**, such as additional information about building inventory and stocking logistic wholesalers. According to the applicant, effective October 1, 2022, the following ICD-10-PCS codes may be used to uniquely describe procedures involving the use of GRAFAPEX™: XW04388 (Introduction of treosulfan into central vein, percutaneous approach, new technology group 8) or XW03388 (Introduction of treosulfan into peripheral vein, percutaneous approach, new technology group 8). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for GRAFAPEX™ under the ICD-10-CM coding system which can be viewed in the online application posting.

[61] As summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28296 through 28302) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 48920).

CMS provides a table in the preamble of the proposed rule to summarize the applicant's assertions that GRAFAPEX™ is not substantially similar to other currently available technologies. CMS questions whether bypassing liver metabolism is the mechanism of action of a conditioning agent, or if it instead relates to clinical outcomes, such as the side effect profile of GRAFAPEX™. In regard to whether GRAFAPEX™ treats the same or similar type of disease and the same or similar patient population compared to existing technologies, CMS questions whether GRAFAPEX™ treats a new patient population since myeloablative conditioning (MAC), nonmyeloablative conditioning (NMA), and reduced intensity conditioning (RIC) are all options for patients. Additionally, while MAC may not be preferred for older or comorbid patients, RIC and NMA may still be options for these patients. **CMS is inviting public comments on whether GRAFAPEX™ is substantially similar to existing technologies and whether GRAFAPEX™ meets the newness criterion.**

Cost: The applicant provided two analyses to demonstrate that GRAFAPEX™ meets the cost criterion; these analyses are summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether GRAFAPEX™ meets the cost criterion.**

Substantial Clinical Improvement: A table in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion. The applicant submitted a public comment in response to the New Technology Town Hall meeting notice published in the Federal Register that summarized claims of substantial clinical improvement from its application and providing additional information related to questions raised at the Town Hall meeting. The applicant also provided information related to three points from its slide presentation at the new technology add-on payment Town Hall: (1) previously available allo-HSCT conditioning agents and regimens create an unmet need for conditioning treatment that minimizes toxicity while maximizing efficacy, especially for older patients and/or those with significant comorbidities; (2) other conditioning agents used to date are all metabolized by the liver, which results in higher toxicity and leads to "excess regimen-related morbidity and mortality observed in older and comorbid patients;" and (3) GRAFAPEX™ reduces treatment-related toxicity because it uniquely bypasses liver metabolism.

After reviewing the information provided, CMS has concerns regarding whether GRAFAPEX™ meets the substantial clinical improvement criterion. CMS questions if GRAFAPEX™-based regimens are the only treatment options for patients ineligible for MAC. With respect to the assertion that GRAFAPEX™ significantly improves clinical outcomes relative to services or technologies previously available, CMS questions whether outcomes seen in the studies presented by the applicant are generalizable to the Medicare population. CMS also questions whether studies with small sample sizes would be generalizable to the Medicare population due to the potential influence of confounding variables. Regarding the applicant's assertion of superior outcomes in non-relapse mortality (NRM), CMS points out that multiple studies showed that GRAFAPEX™ had

a NRM rate that was higher than or similar to other technologies. Finally, regarding the applicant's claim of a significant reduction in several clinically significant adverse events and complications that often lead to treatment-related mortality (such as graft-versus-host disease, veno-occlusive disease, life-threatening infections, and organ toxicities), CMS points out that some studies showed similar or higher rates of adverse effects with the GRAFAPEX™-based regimen.

CMS is inviting public comments on whether GRAFAPEX™ meets the substantial clinical improvement criterion.

h. IMDELLTRA™ (tarlatamab-dlle)

According to the applicant, IMDELLTRA™ is a novel, first-in-class bispecific T-cell engager (BiTE®) molecule for the treatment of adult patients with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. According to the applicant, IMDELLTRA™ works by binding to the delta-like ligand 3 (DLL3) antigen expressed on the surface of SCLC tumor cells and the cluster of differentiation 3 (CD3) co-receptor expressed on the surface of T cells, causing T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells. The online application posting for IMDELLTRA™ is available at https://mearis.cms.gov/public/publications/ntap/NTP241007BQ3UB

Newness: According to the applicant, IMDELLTRA™ was granted accelerated approval of its BLA from FDA on May 16, 2024, for the treatment of adult patients with ES-SCLC with disease progression on or after platinum-based chemotherapy and was commercially available immediately after FDA approval. According to the applicant, there are currently no ICD-10-PCS procedure codes to distinctly identify IMDELLTRA™ and the applicant has submitted a request for approval for unique ICD-10-PCS procedure codes for IMDELLTRA™ beginning in FY 2026. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for IMDELLTRA™ under the ICD-10-CM coding system, and CMS refers the reader to the online application for the complete list. A table in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial similarity criteria.

CMS questions the applicant's assertion that IMDELLTRA™ treats a unique patient population compared to existing technology. First, CMS notes that other FDA-approved therapies for the treatment of the same patient population (patients who have ES-SCLC with disease progression on or after platinum-based chemotherapy) are currently available, such as lurbinectedin and topotecan. Further, CMS believes that other applicant statements related to this assertion are more relevant to substantial clinical improvement rather than newness. **CMS is inviting public comments on whether IMDELLTRA™ is substantially similar to existing technologies and whether IMDELLTRA™ meets the newness criterion.**

Cost: The applicant provided two analyses to demonstrate that IMDELLTRA™ meets the cost criterion; these analyses are summarized by CMS in a table that can be found in

the preamble of the proposed rule. **CMS is inviting public comments on whether IMDELLTRA™ meets the cost criterion.**

Substantial Clinical Improvement: The applicant asserted that IMDELLTRA™ represents a substantial clinical improvement over existing technologies because IMDELLTRA™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments and the technology significantly improves clinical outcomes relative to services or technologies previously available. A table in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Additionally, the applicant submitted a public comment in response to the New Technology Town Hall meeting notice published in the Federal Register in which the applicant responded to questions raised in the Town Hall Meeting.

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, CMS continues to have concerns regarding whether IMDELLTRA™ meets the substantial clinical improvement criterion. CMS questions the assertion that IMDELLTRA™ offers a treatment for a patient population unresponsive to, or ineligible for, currently available treatments. CMS also questions the applicant's statement that IMDELLTRA® improves clinical outcomes. The agency also questions whether the treatment guidelines used in non-U.S. studies could affect generalizability to the Medicare population. CMS questions whether IMDELLTRA™ improves clinical outcomes over existing technologies. While CMS agreed that head-to-head trials, while preferred, are not required for comparing currently available therapy, it notes that among the clinical trial and real-world data provided for alternative therapies to IMDELLTRA™, there was no control for confounding variables to ensure similar patients were being compared to those who took IMDELLTRA™.

CMS is inviting public comments on whether IMDELLTRA™ meets the substantial clinical improvement criterion.

i. IntelliSep Test

According to the applicant, the IntelliSep® Test is a semiquantitative test that assesses cellular host response via a microfluidic deformability cytometry of leukocyte biophysical properties and is intended for use in conjunction with clinical assessments and laboratory findings to aid in the early detection of sepsis with organ dysfunction for adults presenting to the Emergency Department (ED). The IntelliSep® Test generates an index value that falls within 1 of 3 discrete interpretation bands based on the probability of sepsis with organ dysfunction manifesting within the first 3 days after testing. The online application posting for the IntelliSep® Test is available at https://mearis.cms.gov/public/publications/ntap/NTP24100553685

Newness: According to the applicant, the IntelliSep® Test was granted 510(k) clearance from FDA on December 20, 2022, for use in adult patients with signs and symptoms of infection who present to the ED. According to the applicant, the IntelliSep® Test was

commercially available immediately after FDA marketing authorization. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the IntelliSep® Test using the ICD-10-CM coding system. CMS refers the reader to the online application posting for the complete list of ICD-10-CM codes provided by the applicant.

The preamble of the proposed rule displays a table summarizing the applicant's assertions regarding the substantial similarity criteria. CMS notes several concerns, including that the applicant did not compare the IntelliSep® Test's mechanism of action to those of other sepsis tests or detection tools, such as the Early Sepsis Indicator for monocyte distribution width (MDW), SeptiCyte® RAPID, and Sepsis ImmunoScore™. CMS questions whether the IntelliSep® Test's measurement of leukocytes and their deformities is a unique mechanism of action, particularly in comparison to the Early Sepsis Indicator. Further, CMS questions whether the measurement of different biomarkers or gene expression to determine the risk of sepsis is different than the measurement of leukocyte properties to determine the risk of sepsis. **CMS is interested in information regarding how the IntelliSep® Test's mechanism of action differs from other such sepsis tests and detection tools.**

CMS questions the assertion that there are no existing technologies other than the IntelliSep® Test that are involved with the diagnosis of sepsis in adult patients who have signs and symptoms of infection. CMS notes that the IntelliSep® Test is a diagnostic tool to evaluate patients with suspected infection, as are other FDA-cleared sepsis diagnostic tools, such as those that calculate Quick Sequential Organ Failure Assessment (qSOFA) scores (for example, SpassageQ or NAVOY CDS®), and that there are other means of assessing for suspected infection. CMS also questions whether a patient's location—whether in the ED, admitted to the hospital, or in the intensive care unit (ICU)—constitutes a different population. Finally, CMS notes that there are existing sepsis diagnostic technologies that are also approved for use in the ED such as the Early Sepsis Indicator and Sepsis ImmunoScore™, which were FDA market-authorized on March 18, 2019 and April 2, 2024, respectively. **CMS is inviting public comments on whether the IntelliSep® Test is substantially similar to existing technologies and whether the IntelliSep® Test meets the newness criterion.**

Cost: The applicant provided an analysis to demonstrate that IntelliSep® meets the cost criterion; this analysis is summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether IntelliSep® meets the cost criterion.**

Substantial Clinical Improvement: The applicant provided studies to support these claims, as well as background articles about international sepsis guidelines, antimicrobial therapy initiation, timing of antibiotic administration, and other topics related to sepsis detection. The preamble of the proposed rule includes a table summarizing the applicant's assertions regarding the substantial clinical improvement criterion. The applicant submitted a public comment in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical

improvement criterion for the IntelliSep® Test, which CMS summarizes in this section. In its public comment, the applicant responded to questions asked at the Town Hall regarding the comparison of the IntelliSep® Test to other sepsis tests, namely to technology that assesses MDW and SeptiCyte® RAPID and also submitted an additional study (Sarani et al., 2024).

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, CMS has concerns regarding whether the IntelliSep® Test meets the substantial clinical improvement criterion. CMS states that the claims made by the applicant do not address the ability of the IntelliSep® Test to diagnose a patient population where sepsis is currently undetectable nor does the technology offer the ability to diagnose sepsis earlier than other technologies. **CMS would appreciate evidence comparing time to diagnosis for the IntelliSep® Test and other existing sepsis detection tools also developed to address the length of time to definite sepsis diagnosis with blood cultures, such as Early Sepsis Indicator or Sepsis ImmunoScore, in order to demonstrate the applicant's assertion that the IntelliSep® Test allows for faster detection of sepsis compared to existing technologies.**

CMS notes that it did not receive any information demonstrating that clinicians changed the management of patients due to the use of the IntelliSep® Test. Further, CMS states that it is unclear whether the results of certain reviewed studies may be influenced by potential confounding factors and whether they are generalizable to other EDs or geographic regions as well as to the Medicare population. Additionally, CMS notes that the applicant made several claims regarding the assertion that the IntelliSep® Test significantly improves clinical outcomes relative to services or technologies previously available. However, CMS notes that a number of the claims do not address the substantial clinical improvement criterion. Specifically, CMS questions the claim that IntelliSep® Test reduces door-to-bed time and the strength of the direct association between time from door-to-bed and clinical outcome improvement or whether any outcomes are inferred from surrogate endpoints. CMS is also unclear about the direct association between the IntelliSep® Test and antibiotic initiation for sepsis consistent with current guidelines as this is also only inferred. CMS states that the provided evidence does not demonstrate that the IntelliSep® Test decreases mortality. CMS notes that the claims do not pertain to clinical outcomes described at §412.87(b)(1)(ii)(C), such as a reduction in mortality or a decreased rate of at least one subsequent diagnostic or therapeutic intervention.

CMS notes that the claims and the provided evidence regarding the IntelliSep® Test's ability to significantly improve clinical outcomes relative to services or technologies previously available lack a comparison of the IntelliSep® Test to existing technologies used to diagnose sepsis, such as the previously discussed Early Sepsis Indicator, SeptiCyte® RAPID, and Sepsis ImmunoScore™. **CMS is interested in comparative evidence for other sepsis diagnostic technologies in order to evaluate the IntelliSep® Test's clinical outcomes relative to other technologies.** CMS also notes that since much of the evidence provided across claims is unpublished, the details provided do not

include study protocols or statistical methods and measures. As such, CMS is unable to account for differences in the outcome measures or determine if the results are statistically significant. Further, because these study results are from one academic medical center, CMS questions whether the results are generalizable to other hospitals and more broadly to the Medicare population. CMS also questions the impact from varying confounders, such as changes in clinical policy related to studies intended to support the assertion of reductions in length of stay (LOS). Lastly, CMS questions how much capability should be attributed to the IntelliSep® Test when making clinical judgments and improving clinical outcomes, and **CMS welcomes additional information.**

CMS is inviting public comments on whether the IntelliSep® Test meets the substantial clinical improvement criterion.

j. Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection

According to the applicant, the Neuroguard IEP® System combines a carotid stent with an integrated 40 μm embolic protection filter and post-dilation balloon. Per the applicant, the Neuroguard IEP® System restores and maintains vessel patency while stabilizing plaque, and by capturing small emboli during critical phases, it reduces the risk of stroke during the procedure and helps prevent future stroke. The online application posting for the Neuroguard IEP® System is available at https://mearis.cms.gov/public/publications/ntap/NTP241004CNKB9

Newness: According to the applicant, the Neuroguard IEP® System was granted premarket approval (PMA) from FDA on October 11, 2024 for improving the carotid luminal diameter in subjects at high risk for adverse events from a carotid endarterectomy who require carotid revascularization and meet the following criteria: patients with symptomatic stenosis of the common or internal carotid artery with ≥ 50 percent as determined by angiography using North American Symptomatic Carotid Endarterectomy Trial (NASCET) methodology or patients with asymptomatic stenosis of the common or internal carotid artery with ≥ 80 percent as determined by angiography using NASCET methodology; and patients with reference vessel diameters 4.0 mm to 8.0 mm. The applicant and FDA approval letter stated that this technology is also indicated for post-dilation of the stent component with simultaneous capture and removal of embolic material. The Neuroguard IEP® System is used in conjunction with an available primary distal embolic protection device as described in the Instructions for Use.

The applicant submitted a request for approval for a unique ICD-10-PCS procedure code for the Neuroguard IEP® System beginning in FY 2026. The applicant stated that codes I65.21 (Occlusion and stenosis of right carotid artery), I65.22 (Occlusion and stenosis of left carotid artery), I65.23 (Occlusion and stenosis of bilateral carotid arteries), or I65.29 (Occlusion and stenosis of unspecified carotid artery) may be used to currently identify the indication for the Neuroguard IEP® System under the ICD-10-CM coding system.

CMS provides a table in the preamble of the proposed rule that summarizes the applicant's assertions regarding the substantial similarity criteria.

CMS has concerns with regard to the newness criterion. In particular, CMS states that it appears that the Neuroguard IEP® System and existing carotid stents or stent systems—such as the GORE Carotid Stent, RX Acculink™ Carotid Stent System, or Carotid WALLSTENT® Monorail® Endoprosthesis, or the Paladin System with IEP used with any available carotid artery stent—may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS-DRG, and would treat the same or similar patient population and disease. If the technologies are substantially similar to one another, CMS states that the Neuroguard IEP® System would not be considered new because the 3-year anniversary of the FDA clearance of all these current technologies occurred prior to FY 2026. **CMS is inviting public comment on whether the Neuroguard IEP® System is substantially similar to existing technologies and whether the Neuroguard IEP® System meets the newness criterion.**

Cost: The applicant provided two analyses to demonstrate that Neuroguard IEP® System meets the cost criterion; the analyses are summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether Neuroguard IEP® System meets the cost criterion.**

Substantial Clinical Improvement: The preamble of the proposed rule includes a table that summarizes the applicant's assertions regarding the substantial clinical improvement criterion. After review of the information provided by the applicant, CMS has concerns regarding whether the Neuroguard IEP® System meets the substantial clinical improvement criterion. CMS states it did not receive information comparing the Neuroguard IEP® System with other currently available treatments developed more recently, such as GORE Carotid Stent, Sterling SL Balloon Dilatation Catheters, or Paladin System, and **CMS would appreciate additional information comparing these technologies in order to inform its assessment of substantial clinical improvement.**

CMS questions whether the observed lower stroke rate was at least partly the result of a more advanced and comprehensive treatment protocol compared to protocols used in the cited studies and their historical controls. CMS also question whether growth in carotid artery stenting (CAS) volume, a multitude of commercially available FDA-approved carotid stents, changes in standard of care, and trends in the prevalence of diabetes and hypertension in the U.S. population during the last two decades were considered in the interpretation of the findings of the two PERFORMANCE trials.

CMS is also concerned about the use of historical controls, given the differences among the trials, and questions how these differences were taken into account in the development of the performance goal and in the comparison with the Neuroguard IEP® System on improving clinical outcomes. CMS further notes that differences in study populations' comorbidities and lesion characteristics may impact outcomes. CMS questions whether the lack of adjustment for differences across trials could have impacted accuracy of the performance goal which was based on the results of these trials. **CMS**

welcomes information about how these differences were accounted for in the development of the performance goal. CMS also welcomes comments on how to consider the use of historical controls to compare the Neuroguard IEP® System's effects on clinical outcome improvement. Moreover, **CMS is interested in information about the weighted objective performance criteria approach used to adjust for comorbid and anatomic high-risk factors. CMS also welcomes information about how the comparative studies were selected.**

CMS questions whether the observed differences in clinical outcomes between the Neuroguard IEP® System and the performance goal based on the historical comparator trials are statistically significant and clinically meaningful. **CMS welcomes information about whether these differences were statistically significant and clinically meaningful, and how statistical significance was determined. CMS also welcome information about the weighted Z-test for the primary endpoint and how it may fully account for variability in patient comorbidities or procedural differences and enhance generalizability.**

CMS is inviting public comments on whether the Neuroguard IEP® System meets the substantial clinical improvement criterion.

k. RYSTIGGO® (rozanolixizumab-noli)

According to the applicant, RYSTIGGO® is a neonatal Fc receptor (FcRn) blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive (ab+). The online application posting for RYSTIGGO® is available at https://mearis.cms.gov/public/publications/ntap/NTP2410073H0PQ

Newness: According to the applicant, RYSTIGGO® was granted BLA approval from FDA on June 26, 2023, for the treatment of gMG in adult patients who are AChR ab+ or MuSK ab+. The applicant stated that the typical inpatient stay for patients with gMG is 11 to 13 days, and thus 2 doses would usually be administered during a typical inpatient stay. According to the applicant, there are currently no ICD-10-PCS procedure codes to distinctly identify RYSTIGGO® and thus the applicant submitted a request for approval for a unique ICD-10-PCS procedure code for RYSTIGGO® beginning in FY 2026. The applicant stated that G70.00 (Myasthenia gravis without (acute) exacerbation) and G70.01 (Myasthenia gravis with (acute) exacerbation) may be used to currently identify the indication for RYSTIGGO® under the ICD-10-CM coding system.

A table in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial similarity criteria. CMS notes that VYVGART® is also an FcRn inhibitor approved for use in patients with gMG, and per FDA prescribing information, both technologies bind to the FcRn resulting in the reduction of circulating IgG. **CMS welcomes additional information about how the mechanism of action for RYSTIGGO® differs from other existing FDA-approved therapies, including FcRn inhibitors such as VYVGART®.** CMS notes that there are other standard of care

treatment options for patients with AChR ab+ and MuSK ab+ gMG, such as pyridostigmine, glucocorticoid therapy, and plasmapheresis. In addition, VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS® are also treatment options for patients with AChR ab+ gMG. Therefore, CMS questions the assertion that RYSTIGGO® does not involve the treatment of the same or similar type of disease and the same or similar patient population when compared to existing technology. **CMS is inviting public comments on whether RYSTIGGO® is substantially similar to existing technologies and whether RYSTIGGO® meets the newness criterion.**

Cost: The applicant provided an analysis to demonstrate that RYSTIGGO® meets the cost criterion; this analysis is summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether RYSTIGGO® meets the cost criterion.**

Substantial Clinical Improvement: The applicant asserts that the technology represents a substantial clinical improvement over existing technologies because it is the only FDA approved product for anti-MuSK ab+ gMG in adult patients, and is an option for patients unresponsive to, and not treated by, conventional therapies. Further, the applicant asserts that the technology significantly improves clinical outcomes relative to services or technologies previously available. The applicant provided several articles and a meta-analysis regarding efficacy of newer therapies for MG to support its claims. CMS provides a table in the preamble of the proposed rule that summarizes the applicant's assertions, along with supporting evidence provided by the applicant.

The applicant submitted a comment in response to questions raised at the Town Hall in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical improvement criterion for RYSTIGGO®. Specifically, the applicant provided additional information related to study sample sizes, clinical significance of findings, validity, endpoints and outcome measures, trial variability, and how the technology compares with existing standards of care.

The applicant stated that it appreciates that CMS is not bound by FDA determinations, but asserted that it is practically impossible, particularly in rare disease trials, to use different assessment measures when government agencies suggest conflicting measurements. Additionally, CMS received a few comments expressing general support for new technology add-on payments for RYSTIGGO®.

After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, CMS has concerns regarding whether RYSTIGGO® meets the substantial clinical improvement criterion. CMS questions that RYSTIGGO® offers a treatment option for patients with MuSK ab+ gMG who have no other treatment options and whether the evidence provided demonstrates that there is a population of patients with gMG with no other treatment options. Further, CMS questions if variability in dosing with conventional therapies may have affected the results of at least one of the studies. In addition, other standard of care treatment options for patients were excluded, including rituximab products,

VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS®, and CMS therefore questions if RYSTIGGO® is the only treatment option for patients with gMG who have failed conventional therapy. CMS questions whether a subgroup analysis based on stratification on the number of prior therapies provides evidence that RYSTIGGO® is the only treatment option for patients unresponsive to conventional therapies.

With respect to the applicant's evidence and assertion that RYSTIGGO® improves clinical outcomes over existing therapies, CMS is uncertain as to how significant the results are and notes that various other standard of care therapies were excluded such as rituximab products, VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS®. Without a comparison to these therapies, CMS questions whether RYSTIGGO® improves clinical outcomes relative to all previously available therapies. The agency also questions how remission rates, adverse events, and natural changes in symptoms were accounted for in shorter trials. **CMS is interested in more information on the lack of a dose-response effect with RYSTIGGO® and would appreciate clarification on how the MycarinG study defined clinically meaningful improvement.** Further, CMS questions how baseline differences in patients in the Habib et al. (2024a) study may have impacted the placebo group's outcomes relative to the those of the treatment groups, and whether exclusion criteria used would affect the generalizability of the results for the MuSK ab+ subpopulation.

Additionally, CMS questions how this meta-analysis demonstrates RYSTIGGO® improves clinical outcomes relative to previously available therapy for patients with MuSK ab+ gMG. **CMS would appreciate additional information comparing RYSTIGGO® to these other therapies in order to inform its assessment of whether RYSTIGGO® demonstrates a substantial clinical improvement over existing technologies. CMS would further appreciate additional information on how the administration method for RYSTIGGO® demonstrates that the technology significantly improves one or more of the clinical outcomes described under the regulations at §412.87(b)(1)(ii)(C).**

CMS is inviting public comments on whether RYSTIGGO® meets the substantial clinical improvement criterion.

l. SYMVESS™ (acellular tissue engineered vessel-tyod)

According to the applicant, SYMVESS™ is a bioengineered, implantable blood vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss and when autologous vein grafting is not feasible. The online application posting for SYMVESS™ is available at https://mearis.cms.gov/public/publications/ntap/NTP24100639G2M

Newness: According to the applicant, SYMVESS™ was granted BLA approval from FDA on December 19, 2024. The applicant stated that, effective October 1, 2024, the following ICD-10-PCS codes may be used to uniquely describe procedures involving the use of SYMVESS™: X2R50WA (Replacement of right upper extremity artery using

bioengineered human acellular vessel, open approach, new technology group 10), X2R60WA (Replacement of left upper extremity artery using bioengineered human acellular vessel, open approach, new technology group 10), X2R70WA (Replacement of right lower extremity artery using bioengineered human acellular vessel, open approach, new technology group 10), or X2R80WA (Replacement of left lower extremity artery using bioengineered human acellular vessel, open approach, new technology group 10).

The applicant asserted that SYMVESS™ is not substantially similar to other currently available technologies because it does not use the same or a similar mechanism of action compared to existing technologies. A table in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial similarity criteria.

CMS has concerns with regard to the newness criterion. **CMS is interested in more information about how the composition of SYMVESS™ is associated with its post-operative regenerative properties, and specifically how these regenerative properties are associated with its mechanism of action to achieve a therapeutic outcome, as well as how the association between the technology's regenerative properties and mechanism of therapeutic action differs from that of autologous vein grafts.** In addition, CMS questions whether physiological changes should be considered part of the mechanism of action and whether synthetic grafts have a similar mechanism of action to SYMVESS™ and/or autologous vein grafts.

CMS is inviting public comments on whether SYMVESS™ is substantially similar to existing technologies, including whether post-implantation physiological changes should be considered as part of a technology's mechanism of action, and whether SYMVESS™ meets the newness criterion.

Cost: The applicant provided an analysis to demonstrate that SYMVESS™ meets the cost criterion; this analysis is summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether SYMVESS™ meets the cost criterion.**

Substantial Clinical Improvement: A table in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Two commenters submitted public comments in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical improvement criterion for SYMVESS™, which CMS summarizes in this section. Both commenters expressed concerns related to whether SYMVESS™ meets the substantial clinical improvement criterion. One commenter stated that SYMVESS™ has not demonstrated non-inferiority to synthetic grafts or provided evidence for when SYMVESS™ should be used instead of a synthetic graft in any of what the commenter described as underpowered, non-comparative trauma clinical trials. The second commenter stated that SYMVESS™ does not represent a meaningful improvement of the standard of care and in fact is inferior to standard of care alternatives that are already approved in trauma. In particular, this commenter expressed concerns related to lack of transparency in the analyses and availability of trial data and identified

other issues with study design and reported outcomes. Furthermore, the commenter stated that SYMVESS™ should be compared with Artegraft®, a biological off-the-shelf solution approved for trauma, hemodialysis, and lower extremity bypass surgeries and owned by LeMaitre.

After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, CMS has concerns regarding whether SYMVESS™ meets the substantial clinical improvement criterion. CMS expresses concern related to study design and interpretation of results, and comparability of studies. CMS believes that it is unclear that SYMVESS™ offers a treatment option for patients ineligible for or unresponsive to currently available treatments. CMS questions the reliability and validity of the synthetic graft benchmarks against which Moore et al. (2024) compared SYMVESS™ effects on clinical outcomes. In some cases, CMS questions if samples were sufficiently powered to detect statistically significant and clinically meaningful differences between synthetic grafts and comparators on clinical outcomes. **CMS interested in additional information on the reliability and validity of the Moore et al. (2024) study's synthetic graft benchmarks, which were developed based on 12 studies with heterogeneous study designs, injury types, interventions, and follow-up protocols.** Also, given the variation by data source as to whether SYMVESS™ performed better than the synthetic grafts benchmarks for primary and secondary patency and amputation rates, CMS questions the applicant's assertion of clinical improvement compared to synthetic grafts. The agency also questions whether it is appropriate to combine the results from certain trials, and whether any outcomes from the trials are generalizable to the Medicare population. Further, with regard to the study intended to demonstrate that SYMVESS™ provides improved infection rate compared to synthetic grafts, CMS questions the extent to which the infection rates of SYMVESS™ in ESRD patients can be extrapolated to patients with extreme arterial injury, for which the technology is indicated. While the applicant provided studies comparing SYMVESS™ to synthetic grafts to demonstrate improved outcomes, CMS remains unclear about how the clinical outcomes of SYMVESS™ recipients compared to those who receive other currently available treatments for extremity vascular trauma, like cryopreserved human grafts or xenografts. **CMS would be interested in additional evidence comparing SYMVESS™ and these grafts in order to inform its assessment of substantial clinical improvement over existing technologies.** Finally, CMS questions the applicant's claim that SYMVESS™ enables quicker reperfusion of injured extremities (compared to autologous vein grafts) which reduces the risk of complications. According to the indication, SYMVESS™ is used when autologous vein graft is not feasible. Thus, SYMVESS™ would not be an alternative for nor comparable to autologous vein grafts. **CMS welcomes clarification or further information about this claim.**

CMS is inviting public comments on whether SYMVESS™ meets the substantial clinical improvement criterion.

m. TECELRA® (afamitresgene autoleucel)

According to the applicant, TECELRA® is a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T-cell immunotherapy (also referred to as an autologous T-cell receptor (TCR) therapy) indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02 subtype positive, and whose tumor expresses the MAGE-A4 antigen. Per the applicant, TECELRA® is composed of T cells genetically modified to express affinity-enhanced TCRs specific to the MAGE-A4 protein, which is expressed by synovial sarcoma tumor cells at varying frequencies. The online application posting for TECELRA® is available at https://mearis.cms.gov/public/publications/ntap/NTP241004LTDY2

Newness: According to the applicant, TECELRA® was granted BLA accelerated approval from FDA on August 1, 2024 for treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy; are HLA-A*02:01P, HLA-A*02:02P, HLA-A*02:03P, or HLA-A*02:06P positive; and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. The applicant stated that, effective October 1, 2022, the following ICD-10-PCS codes may be used to uniquely describe procedures involving the use of TECELRA®: XW03368 (Introduction of afamitresgene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8) or XW04368 (Introduction of afamitresgene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 8).

The applicant asserted that TECELRA® is not substantially similar to other currently available technologies because TECELRA® is the first FDA-approved engineered TCR T-cell therapy with a unique mechanism of action that is distinct from that of other marketed therapeutic products, the only therapy approved for synovial sarcoma assigned to MS-DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies), and the only therapy studied specifically in the synovial sarcoma patient population and FDA-approved specifically for the treatment of synovial sarcoma. In the proposed rule preamble, a table summarizes the applicant's assertions regarding the substantial similarity criteria.

CMS questions whether existing treatments indicated for soft tissue sarcoma (STS), which can be used for the treatment of specific subtypes of STS such as synovial sarcoma, would treat the same or similar patient population as TECELRA®. **CMS is inviting public comments on whether TECELRA® is substantially similar to existing technologies and whether TECELRA® meets the newness criterion.**

Cost: The applicant provided four analyses to demonstrate that TECELRA® meets the cost criterion; the analyses are summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether TECELRA® meets the cost criterion.**

Substantial Clinical Improvement: A table in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial clinical improvement criterion. CMS did not receive any written comments in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical improvement criterion for TECELRA®.

After reviewing the supporting evidence provided by the applicant, CMS has concerns regarding whether TECELRA® meets the substantial clinical improvement criterion. Specifically, CMS notes that TECELRA® being the first approved TCR therapy may relate to mechanism of action under the newness criterion but is not relevant to the demonstration of substantial clinical improvement. CMS questions whether the applicant's claim supports that TECELRA® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments given there are other available treatments for patients with STS that would also treat patients with unresectable or metastatic synovial sarcoma.

With regard to the claim that TECELRA® offers a significant clinical improvement in overall response rate and overall survival compared to existing therapies, CMS noted that some results of trials appear comparable and questions whether the baseline characteristics of the study population, such as biomarkers of resistance to TECELRA® rather than the treatment itself, may account for the observed survival outcomes. Furthermore, CMS questions whether the provided historical benchmark results for other treatments in which study participants were not tested for biomarkers, such as MAGE-A4, may represent different target populations from that of TECELRA®. CMS questions whether differences in studies may introduce confounders which could reduce the validity of the results of the comparison. Additionally, CMS is unclear why the applicant compared the safety profile of TECELRA® to CAR T-cell therapies (which are not approved for use in STS) rather than other available therapies that treat unresectable or metastatic synovial sarcoma. Therefore, **CMS is interested in evidence comparing TECELRA®'s safety profile to other, non-CAR T-cell treatments for unresectable or metastatic synovial sarcoma.** CMS notes that no evidence was provided to support the claim that because TECELRA® is a single administration, recipients are less likely to experience repeated adverse events from the infusion compared to treatments requiring multiple/regular continuous or cyclical administrations.

CMS is inviting public comments on whether TECELRA® meets the substantial clinical improvement criterion.

n. ZIIHERA® (zanidatamab-hrii)

According to the applicant, ZIIHERA® is a bispecific human epidermal growth factor receptor 2 (HER2)-directed antibody for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC). The online application posting for ZIIHERA® is available at https://mearis.cms.gov/public/publications/ntap/NTP240925MW5YD

Newness: According to the applicant, ZIIHERA® was granted BLA approval from FDA on November 20, 2024, for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC as detected by an FDA-approved test. ZIIHERA®'s market availability was delayed. **CMS is interested in additional information regarding the cause of any delay in the technology's commercial availability, such as related to packaging and shipment to channel distribution points.** The applicant stated that effective October 1, 2024, the following ICD-10-PCS codes may be used to uniquely describe procedures involving the use of ZIIHERA®: XW033CA (Introduction of zanidatamab antineoplastic into peripheral vein, percutaneous approach, new technology group 10) or XW043CA (Introduction of zanidatamab antineoplastic into central vein, percutaneous approach, new technology group 10). The applicant stated that C22.1 (Intrahepatic bile duct carcinoma), C23 (Malignant neoplasm of gallbladder), C24.0 (Malignant neoplasm of extrahepatic bile duct), C24.8 (Malignant neoplasm of overlapping sites of biliary tract), C24.9 (Malignant neoplasm of biliary tract, unspecified), or Z51.11 (Encounter for antineoplastic chemotherapy) may be used to currently identify the indication for ZIIHERA® under the ICD-10-CM coding system.

The applicant asserted that ZIIHERA® is not substantially similar to other currently available technologies because ZIIHERA's novel and distinct mechanisms of action are not the same or substantially similar to those of other currently available therapies used for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC. In addition, the applicant asserted that ZIIHERA® is the first and only bispecific HER2-directed antibody indicated for this population and that therefore the technology meets the newness criterion. A table presented in the preamble of the proposed rule summarizes the applicant's assertions regarding the substantial similarity criteria.

After review of the information provided by the applicant, CMS notes that it is unclear how ZIIHERA® treats a new patient population or disease as compared to existing treatments such as FOLFOX, FOLFIRI, STIVARGA®, or ENHERTU®.

CMS is inviting public comments on whether ZIIHERA® is substantially similar to existing technologies and whether ZIIHERA® meets the newness criterion.

Cost: The applicant provided multiple analyses to demonstrate that ZIIHERA® meets the cost criterion; the analyses are summarized by CMS in a table that can be found in the preamble of the proposed rule. **CMS is inviting public comments on whether ZIIHERA® meets the cost criterion.**

Substantial Clinical Improvement: The applicant asserted that ZIIHERA® represents a substantial clinical improvement over existing technologies because it is a bispecific HER2-directed antibody with multiple, distinct mechanisms of action and a differentiated clinical profile, and it is the first and only FDA-approved treatment for HER2+ (IHC 3+) BTC. In addition, the applicant asserted that ZIIHERA® fulfills an unmet need for this patient population by providing an optimal chemotherapy-free treatment option, where

patients also have the potential to achieve meaningfully improved clinical benefits. A table in the preamble of the proposed rule summarizes the applicant's assertions and supporting evidence provided by the applicant regarding the substantial clinical improvement criterion.

CMS did not receive any written comments in response to the New Technology Town Hall meeting notice published in the Federal Register regarding the substantial clinical improvement criterion for ZIIHERA®. After review of the information provided by the applicant, CMS has concerns regarding whether ZIIHERA® meets the substantial clinical improvement criterion. CMS questions whether ZIIHERA® offers a treatment option for a patient population unresponsive to, or ineligible for other existing therapies. The agency also questions whether the location of clinical trial sites being outside of the U.S. could affect the generalizability of the findings to the U.S. Medicare patient population. CMS also questions whether the certain studies' sample size may have impacted the ability to perform or interpret comparative analyses within and between the two different patient cohorts.

CMS notes that while the applicant provided background studies comparing FOLFOX and FOLFIRI to ZIIHERA®, the supporting evidence provided did not compare ZIIHERA® to other FDA-approved therapies used for unresectable/metastatic BTC such as ENHERTU®. CMS also questions whether the differences in the studies' reported responses are comparable given that the studies are different in design, protocol, and methodology, which may limit the ability to interpret the outcomes. **CMS would appreciate additional information on the comparison of outcomes with ZIIHERA® to those with other FDA-approved therapies used for advanced/metastatic BTC.**

CMS is concerned that the safety and quality of life data were combined in several studies. CMS questions whether this analysis provides sufficient evidence as to ZIIHERA's overall benefit-risk profile and how it compares to other treatments given that Wasan et al. and Pant et al., which are unpublished and non-peer-reviewed conference posters, do not include full details of the study and methodology, which therefore may limit CMS' ability to interpret the results. CMS further notes that HERIZON-BTC-01 was a single arm study and that the clinical outcome and health-related quality of life data are not specific to IHC 3+ BTC patients, in accordance with ZIIHERA®'s FDA indication.

CMS is inviting public comments on whether ZIIHERA® meets the substantial clinical improvement criterion.

6. Proposed FY 2026 Applications for New Technology Add-On Payments (Alternative Pathways)

Beginning with FY 2021, a medical product that is designated by FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal

Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Such technologies will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2-to-3-year newness period to be considered "new," and must also still meet the cost criterion.

Applicants for new technology add-on payments for FY 2026 for Breakthrough Devices must have FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Applicants for new technology add-on payments for FY 2026 for QIDPs and technologies approved under the LPAD pathway must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under current CMS policy, CMS may conditionally approval a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

CMS received 34 applications for new technology add-on payments under the alternative pathway. One application was not eligible for consideration because it did not meet the newly finalized requirement: For technologies 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 new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. Four applicants withdrew their applications prior to the issuance of this proposed rule. Of the remaining 29 applications, 27 of the technologies received a Breakthrough Device designation from FDA. The remaining two applications were designated as a QIDP by FDA. CMS did not receive any applications for technologies approved through the LPAD pathway.

In this proposed rule, CMS provides a table summarizing background information and the cost analysis for each alternative pathway application and proposes to approve or disapprove each of the 29 applications for FY2026 new technology add-on payments. More detailed information can be found in the publicly posted FY 2026 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 which are available at https://mearis.cms.gov/public/publications/ntap. In addition, CMS makes available 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. These are available in "Table 10 Relevant ICD-10 Codes for Certain FY 2026 New Technology Add-On Payment Applications" which is accessible at https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.

a. Alternative Pathway for Breakthrough Devices

(1) 4WEB Medical Ankle Truss System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the 4WEB Medical Ankle Truss System (ATS) is for use with a premarket authorized tibiotalocalcaneal (TTC) nail as part of a TTC fusion system to manage ankle bone defects that occur after a failed ankle arthrodesis or arthroplasty. The technology received FDA Breakthrough Device designation on March 21, 2024. The Breakthrough Device designation includes the use of the device after a failed ankle arthrodesis or failed ankle arthroplasty, which would be considered a salvage procedure as indicated in the FDA-cleared indication. Its online application can be found at: https://mearis.cms.gov/public/publications/ntap/NTP241005L44VA.

CMS believes that the FDA-cleared indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. CMS also agrees with the applicant that the 4WEB Medical ATS meets the cost criterion and therefore **CMS is proposing to approve the 4WEB Medical ATS for new technology add-on payments for FY 2026** for use as an accessory to the Stryker T2 Ankle Arthrodesis Nail or the Stryker Valor Hindfoot Fusion Nail as part of a TCC fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk for loss of limb. Based on preliminary information, the total cost of the 4WEB Medical ATS to the hospital is estimated to be $23,500 per patient. **CMS proposes that the maximum new technology add-on payment for a case involving the use of the 4WEB Medical ATS would be $15,275 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the 4WEB Medical ATS meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026.

(2) AeroPace ® System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the AeroPace® System is intended for temporary stimulation of the phrenic nerve(s) to increase diaphragmatic strength. The AeroPace® System received FDA marketing authorization on December 4, 2024 and is indicated to improve weaning success—increase weaning, reduce ventilator days, and reduce reintubation—in patients ages 18 years or older on MV ≥96 hours and who have not weaned. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. This online application can be viewed at: https://mearis.cms.gov/public/publications/ntap/NTP241004B25FM.

CMS notes that it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. CMS agrees with the applicant that the AeroPace® System meets the cost criterion.

Therefore, **CMS is proposing to approve the AeroPace® System for new technology add-on payments for FY 2026**, for use to improve weaning success in patients ages 18 years or older on MV ≥96 hours and who have not weaned. The applicant has not provided an estimate for the cost of the AeroPace® System at the time of this proposed rule. CMS expects the applicant to submit cost information prior to the final rule, and CMS will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule.

CMS invites public comments on whether the AeroPace® System meets the cost criterion and its proposal to approve new technology add-on payments for FY 2026.

(3) AGENT™ Paclitaxel-Coated Balloon Catheter

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the AGENT™ Paclitaxel-Coated Balloon Catheter is a semi-compliant percutaneous coronary intervention (PCI) catheter; the balloon portion of the device is coated with a TransPax coating. Per the applicant, the AGENT™ Drug Coated Balloon is designed to inhibit restenosis by delivering the drug, paclitaxel, to the diseased coronary arterial tissue. This technology received FDA Breakthrough Device designation on February 29, 2024 and is indicated for Percutaneous Transluminal Coronary Angioplasty (PTCA) in coronary arteries 2.0 mm to 4.0 mm in diameter to treat in-stent restenosis (ISR), up to 26mm in length, for the purpose of improving myocardial perfusion. Its online application can be viewed at: https://mearis.cms.gov/public/publications/ntap/NTP241007T6YMA.

CMS believes that the FDA-cleared indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. CMS agrees with the applicant that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the cost criterion; therefore, **CMS is proposing to approve the AGENT™ Paclitaxel-Coated Balloon Catheter for new technology add-on payments for FY 2026** for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR. The anticipated the total cost of the AGENT™ Paclitaxel-Coated Balloon Catheter to the hospital is estimated to be $6,175 per patient. As a result, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the AGENT™ Paclitaxel-Coated Balloon Catheter would be $4,013.75 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the AGENT™ Paclitaxel-Coated Balloon Catheter meets the cost criterion and its proposal to approve new technology add-on payments for FY 2026.

(4) alfapump® system

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the alfapump® system is an implanted subcutaneous device with rechargeable battery allowing fluid removal from the peritoneal cavity to the urinary bladder where it is then eliminated via urination. Per the applicant, the alfapump® system provides an alternative to standard treatments for refractory ascites, that is, large volume paracentesis (LVP) with albumin and transjugular intrahepatic shunts. This technology received FDA Breakthrough Device designation on December 20, 2024 and is indicated for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination. Its online application can be viewed at: https://mearis.cms.gov/public/publications/ntap/NTP240930MJNT7.

CMS notes that the technology is not expected to be commercially available until July 2025 and expresses interest in additional information regarding any delay. CMS agrees with the applicant that the alfapump® system meets the cost criterion; therefore, **CMS is proposing to approve the alfapump® system for new technology add-on payments for FY 2026**, in adult patients with refractory or recurrent ascites due to liver cirrhosis for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder. The anticipated total cost of the technology to the hospital is estimated to be $30,000 per patient. As a result, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the alfapump® system would be $19,500 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the alfapump® system meets the cost criterion and its proposal to approve new technology add-on payments for FY 2026.

(5) aprevo®-C cervical interbody fusion device

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the aprevo®-C cervical interbody fusion devices are intended to stabilize intervertebral spaces of the cervical spine (C2-T1) and facilitate fusion. Per the applicant, the devices are custom-made to achieve a patient-specific cervical alignment plan and have surfaces that match the irregular topography of each patient's cervical vertebral endplates. This technology received FDA Breakthrough Device designation on November 15, 2024 with an indication for use in skeletally mature patients with degenerative cervical conditions including cervical disc degeneration, stenosis, deformity, and/or instability of the cervical spine (C2-T1) at one or more levels. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. Its online application can be viewed at: https://mearis.cms.gov/public/publications/ntap/NTP241007U130K.

CMS notes that it appears the FDA 510(k) clearance indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

CMS expresses interest in additional information regarding the cause for any delay in the technology market availability. CMS agrees with the applicant that the aprevo®-C cervical interbody fusion device meets the cost criterion; therefore, **CMS is proposing to approve the aprevo®-C cervical interbody fusion device for new technology add-on payments for FY 2026** as interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with the following degenerative cervical conditions: cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. The anticipated total cost of the technology to the hospital is estimated to be $32,500 on average per patient. As a result**, CMS is proposing that the maximum new technology add-on payment for an average case involving the use of the aprevo®-C cervical interbody fusion device would be $21,125 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the aprevo®-C cervical interbody fusion device meets the cost criterion and its proposal to approve new technology add-on payments for FY 2026.

(6) CERAMENT® G

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, CERAMENT® G is an implantable bone void filler (device/drug combination product), consisting of calcium sulfate, hydroxyapatite, and gentamicin sulfate. Per the applicant, CERAMENT® G elutes 17.5 mg gentamicin/mL paste. CERAMENT® G received FDA Breakthrough Device designation on March 13, 2024. Under the FDA designation, the technology is indicated for use as a bone void filler as part of the surgical procedure where there is a risk of bacterial contamination such as open, fresh fractures with osseous defects which are surgically created or a result of traumatic injury to the bone. The online application can be found here: https://mearis.cms.gov/public/publications/ntap/NTP2410079G5KA.

CMS notes that CERAMENT® G is also indicated for use for bone infections and was approved by CMS for new technology add-on payment for that indication in the FY 2023 IPPS final rule. CMS emphasizes that under this alternative pathway, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment. Therefore, for this application, only the use of CERAMENT® G for open fractures is relevant. CMS believes that cases involving the use of CERAMENT® G related to bone infections would be identified by the ICD-10-PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) in combination with the ICD-10CM codes in category M86 (Osteomyelitis). In section II.E.4, CMS is proposing to discontinue making new technology add-on payments for FY2026 for use of CERAMENT® G related to bone infections**. CMS is inviting public comments on the use of these codes to exclude the indication for use of CERAMENT® G related to bone infections, which would not be eligible for the new technology add-on payment for FY 2026, if approved.**

CMS agrees that the technology meets the cost criterion. Therefore, **CMS is proposing to approve CERAMENT® G for new technology add-on payments for FY 2026** for use as a bone void filler intended for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to open fractures. Based on preliminary information, the total cost of 10cc of CERAMENT® G is $8,750 per patient. **CMS proposes that the maximum new technology add-on payment for a case involving CERAMENT® G would be $5,687.50 for FY 2026** (that is, 65 percent of the average cost of the technology).

(7) Dexcom G7 Hospital Continuous Glucose Monitoring (CGM) System

CMS provides a table with summary information about this product in the proposed rule preamble. The Dexcom G7 Hospital Continuous Glucose Monitoring System (Dexcom Hospital System) is a real-time CGM device indicated for use by healthcare professionals to monitor and manage glucose levels of patients ages 18 years and older in a hospital environment. The Dexcom Hospital System anticipates a De Novo classification decision from the FDA before May 1, 2025. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed at: https://mearis.cms.gov/public/publications/ntap/NTP241007GNM42.

CMS notes that it appears that the use of the Dexcom Hospital System only for insulin-treated diabetes, and the FDA Breakthrough Device designation it received for that use, would be relevant for purposes of the new technology add-on payment application for FY 2026. CMS therefore believes that the relevant ICD-10-CM codes would be Z79.4 (Long term (current) use of insulin) in combination with additional ICD-10-CM codes related to diabetes mellitus, as specified in more detail in the preamble of the proposed rule. **CMS is inviting public comment on the use of these ICD-10-CM diagnosis codes to identify the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.**

CMS agrees that the technology meets the cost criterion. Therefore, **CMS is proposing to approve the Dexcom Hospital System for new technology add-on payments for FY 2026**, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025. The applicant has not provided cost information. However, CMS anticipates that the applicant will submit cost information prior to the final rule. CMS will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule.

CMS invites public comments on whether the Dexcom G7 Hospital CGM System meets the cost criterion and its proposal to approve new technology add-on payments for the Dexcom G7 Hospital CGM System for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(8) DrugSorb-ATR Device

CMS provides a table with summary information about this product in the proposed rule preamble. The applicant anticipates a De Novo classification decision from FDA before May 1, 2025, consistent with its Breakthrough Device designation. Per the applicant, the expected FDA indication for this device includes a subset of procedures that are included in the Breakthrough Designation indication. The expected FDA indication is for the removal of ticagrelor in CABG procedures as opposed to the broader Breakthrough Designation indication in emergent and urgent cardiothoracic surgery. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP24100700MP6.

CMS agrees with the applicant that the DrugSorb-ATR device meets the cost criterion. Therefore, **CMS is proposing to approve the DrugSorb-ATR device for new technology add-on payments for FY 2026**, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025. The applicant anticipated the total cost of the DrugSorb-ATR device to the hospital to be $7,000 per patient. **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the DrugSorb-ATR device would be $4,550 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the DrugSorb-ATR device meets the cost criterion and its proposal to approve new technology add-on payments for the DrugSorb-ATR device for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(9) Emily's Care Nourish Test System (Model 1)

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the Emily's Care Nourish Test System (Model 1) is an FDA cleared Breakthrough Device as of May 3, 2024. Per the applicant, the macronutrient breast milk test strip quantitatively measures the concentration of fat, carbohydrate, and protein in human milk. The associated smartphone app provides a calculated value for energy (calories) and is intended to be used in conjunction with other clinical assessments to aid in the nutritional management and treatment of very low birth weight (VLBW) in the NICU, for both neonates and infants less than 6 months of age. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The online application can be found at: https://mearis.cms.gov/public/publications/ntap/NTP241006EAA50.

CMS notes that under the eligibility criteria for approval under the alternative pathway, only the use of the Emily's Care Nourish Test System (Model 1) for VLBW neonates

and infants in the NICU, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2026. Additionally, CMS expresses several concerns with respect to the cost criterion, including concerns related to the data used in the applicant's cost analysis, incomplete cost criterion codes and MS-DRGs worksheet, and assumptions the applicant used in calculating case volume. CMS also questions assumptions used in the cost analysis regarding the potential Medicare volume for the technology, as well as how the average charge per case was calculated. Therefore, **CMS is proposing to disapprove new technology add-on payments for the Emily's Care Nourish Test System (Model 1) for FY 2026. CMS invites public comment on whether Emily's Care Nourish Test System (Model 1) meets the cost criterion. Additionally, CMS invites comment regarding costs of this technology to the hospital per inpatient stay.**

CMS notes that in the event it receives updated information to establish that the Emily's Care Nourish Test System (Model 1) meets the cost criterion, CMS identifies several ICD-10-CM codes that CMS believes to be relevant to identify the Breakthrough Device designated indication. These include P05.01-.05, P05.11-.15, and P07.00-03, and P07.14-.15. **CMS is inviting public comments** on the use of these ICD-10-CM diagnosis codes, if the application is approved for a new tech add-on payment.

(10) Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the Esprit™ BTK Everolimus Eluting Resorbable Scaffold is a temporary scaffold that will resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI). The applicant received FDA marketing authorization on April 26, 2024 and is indicated for improving luminal diameter in infrapopliteal lesions in patients with critical limb ischemia (CLI). In all cases, the treated lesion length should be less than the total scaffolding length with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241004V78CP.

CMS indicates that it appears that the FDA marketing authorization is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. Additionally, CMS agrees with the applicant that thesprit™ BTK Everolimus Eluting Resorbable Scaffold meets the cost criterion. The anticipated the total cost of the Esprit™ BTK Everolimus Eluting Resorbable Scaffold to the hospital is $6,000 per patient. **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the Esprit™ BTK Everolimus Eluting Resorbable Scaffold would be $3,900 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the Esprit™ BTK Everolimus Eluting Resorbable Scaffold meets the cost criterion and its proposal to approve new technology add-on payments for FY 2026.

(11) EUROPA™ Posterior Cervical Fusion System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the EUROPA™ Posterior Cervical Fusion System is a posterior cervical screw system intended to provide structural stability and mechanical support to the cervical spine through posterior cervical fusion. The technology received FDA marketing authorization on November 19, 2024. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241007BVT6M.

CMS notes that it appears that the FDA marketing authorization is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. CMS expresses interest in additional information regarding the cause of any delay in the technology's market availability. Since it agrees that the technology meets the cost criterion, **CMS is proposing to approve the EUROPA™ Posterior Cervical Fusion System for new technology add-on payments for FY 2026**, to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the acute and chronic instabilities of the cervical spine (Cl to C7) and the upper thoracic spine (T1 to T3) listed in both the Breakthrough Device designation and FDA clearance letter. Further, after analysis of the cost information provided by the applicant, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the EUROPA™ Posterior Cervical Fusion System would be $80,548 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the EUROPA™ Posterior Cervical Fusion System meets the cost criterion and its proposal to approve this new technology add-on payments for FY 2026.

(12) iFuse TORQ TNT™ Implant System

CMS provides a table with summary information about this product in the proposed rule preamble. The iFuse TORQ TNT™ Implant System received FDA marketing authorization on August 19, 2024 and has a Breakthrough Device designation indication for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241002J7XRV.

CMS notes that the FDA clearance indication is broader than the FDA Breakthrough Device designation indication. However, under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2026. CMS refers the reader to "Table 10.2 – iFuse TORQ TNT™ Implant System" for a list of the ICD-10-PCS procedure codes that CMS believes would be appropriate to exclude when reported

in combination with the use of the technology. **CMS invites comment on the ICD-10-PCS exclusion list**.

CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the iFuse TORQ TNT™ Implant System for new technology add-on payments for FY 2026** when used for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures and sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis. Based on the cost information provided by the applicant, CMS estimates that any add-on payment for the technology would include only the weighted average cost per pelvic fixation case and cost per sacroiliac joint fusion case of the TNT Implant and Washers. Therefore, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the iFuse TORQ TNT™ Implant System would be $3,960.45 for FY 2026** (that is, 65 percent of the average cost of the technology).

(13) Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE)

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the proposed Breakthrough Device designation indications for use of this technology includes treatment of stenosis or occlusion within the dialysis outflow circuit, including stenosis or occlusion: (1) within the peripheral veins in the arm of the Arteriovenous Fistula (AVF) patients, and (2) within the thoracic central veins, up to the superior vena cava, in Arteriovenous Graft (AVG) patients. The technology received FDA marketing authorization on December 19, 2024. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP2410062MPCC.

CMS agrees it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. **CMS expresses interest in additional information related to any delay in commercial availability, including if the device was available for sale prior to January 2, 2025.** Additionally, CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the Merit Wrapsody® CIE for new technology add-on payments for FY 2026,** for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis access outflow circuit. Based on preliminary information provided by the applicant, CMS notes that it provides new technology add-on payments based on the cost of the actual technology and not for additional costs related to the use of the device. **CMS is therefore proposing that the maximum new technology add-on payment for a case involving the use of the Merit Wrapsody® CIE would be $3,770 for FY 2026** (that is, 65 percent of the average cost of the technology).

(14) Minima Stent System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the Renata Minima Stent System received FDA marketing

authorization on August 28, 2024 with a Breakthrough Device designation indication for use in the treatment of common congenital and post-operative discrete coarctation of the aorta without significant arch hypoplasia in patients less than 20kg and in the treatment of pulmonary artery stenoses. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241004LBYDY.

CMS agrees that it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway Criteria. CMS expressed concerns related to the cost criterion, questioning whether using total charges for the Medicare claims for the 6 MS-DRGs identified by the applicant would provide an accurate estimate for eligible cases in a pediatric patient population where the device would be used. **Subject to the applicant adequately addressing this concern, CMS is proposing to approve the Minima Stent System for new technology add-on payments for FY 2026** for use in the treatment of native or acquired pulmonary artery stenoses or coarctation of the aorta in neonates, infants, and children at least 1.5 kg in weight. Based on preliminary cost information provided by the applicant, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the Minima Stent System would be $22,685 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the Minima Stent System meets the cost criterion and its proposal to approve new technology add-on payments for the Minima Stent System for FY 2026.

(15) MY01 Continuous Compartmental Pressure Monitor

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the MY01 device is used for real-time and continuous measurement of muscle pressures. The technology received FDA marketing authorization on March 13, 2025 and has a Breakthrough Device designation indication for storing and displaying identical pressure values from the MY01 device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241007X55AR.

CMS notes that it appears that the FDA marketing authorization is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. CMS is interested in additional information on when the MY01 Continuous Compartmental Pressure Monitor became available for sale. CMS agrees that the technology meets the cost criterion and, therefore, **CMS is proposing to approve the MY01 Continuous Compartmental Pressure Monitor for new technology add-on payments for FY 2026**, for real-time and continuous measurement of the muscle compartment pressure. Based on the preliminary information submitted by the applicant, **CMS is proposing that the maximum new technology add-on payment for a case**

involving the use of the MY01 Continuous Compartmental Pressure Monitor would be $2,112.50 for FY 2026 (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the MY01 Continuous Compartmental Pressure Monitor meets the cost criterion and its proposal to approve new technology add-on payments for FY 2026.

(16) Nelli Seizure Monitoring System

CMS provides a table with summary information about this product in the proposed rule preamble. CMS notes that the technology was evaluated in the FY 2024 OPPS proposed rule but failed to meet the applicable deadline for FDA approval or clearance. Another application was submitted for FY 2024; however, it was withdrawn prior to issuance of the FY 2024 IPPS final rule.[62] Per the applicant, the Nelli Seizure Monitoring System is a prescription-only device that is designed to be used as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age and older. The applicant anticipates a 510(k) clearance decision from FDA before May 1, 2025. Per the applicant, the FDA indication is currently being pursued for adults only.

After review of the information provided by the applicant, CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the Nelli Seizure Monitoring System for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.** Additionally, based on preliminary cost information provided by the applicant, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the Nelli Seizure Monitoring System would be $650 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the Nelli Seizure Monitoring System meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(17) Positive Blood Culture (PBC) Separator with Selux AST System

CMS provides a table with summary information about this product in the proposed rule preamble. CMS notes that the technology was previously submitted and summarized in the FY 2024 IPPS proposed rule[63] but was subsequently withdrawn prior to issuance of the FY 2024 IPPS final rule.[64] Per the applicant, the PBC Separator with Selux AST System is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to

[62] 88 FR 58919
[63] 88 FR 26946 through 26949
[64] 88 FR 58919

specific antimicrobial agents. The technology received FDA marketing authorization on February 15, 2024, with a Breakthrough Device designation indication for use with bacteria separated from monomicrobial positive blood cultures and sterile body fluid culture samples from non-charcoal-containing types of BACTEC, BacT/ALERT, VIRTUO and VersaTREK blood culture bottles. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241007LLY3U.

CMS notes that it appears that the FDA-cleared indication is appropriate for consideration for new technology add-on payment under the alternative pathway Criteria. CMS further notes that the Selux AST System first received FDA 510(k) clearance on January 18, 2023, and therefore the components of the Selux AST System would still be new for FY 2026. CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the PBC Separator with Selux AST System for new technology add-on payments for FY 2026** for use as an automated inoculum preparation system that uses lysis, centrifugation and sequential optical density measurements to generate a McFarland equivalent suspension from positive blood culture samples that can be used for quantitative in vitro AST by the Selux AST System. Based on preliminary cost information from the applicant, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the PBC Separator with Selux AST System would be $87.78 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the PBC Separator with Selux AST System meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026.

(18) PearlMatrix P-15 Peptide Enhanced Bone Graft

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the PearlMatrix P-15 Peptide Enhanced Bone Graft is a composite bone graft material consisting of a synthetic peptide, found naturally occurring in human Type I collagen (P-15). The applicant anticipates a PMA decision from FDA before May 1, 2025. Per the applicant, the P-15L Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241003MHP1H.

CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the PearlMatrix P-15 Peptide Enhanced Bone Graft for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.** Based on preliminary cost information from the applicant, CMS notes it would only include the operation costs in a new technology add-on payment and that capital costs are not eligible. As a result, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the**

PearlMatrix P-15 Peptide Enhanced Bone Graft would be $3,380 for FY 2026 (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the PearlMatrix P-15 Peptide Enhanced Bone Graft meets the cost criterion and CMS' proposal to approve new technology add-on payments for the PearlMatrix P-15 Peptide Enhanced Bone Graft for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(19) Provizio® SEM Scanner

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the Provizio® SEM Scanner is a wireless, hand-held, bedside device with a touch-screen interface. The applicant anticipates a De Novo Classification decision from FDA before May 1, 2025, consistent with its Breakthrough Device designation. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP2410076TVHF.

CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the Provizio® SEM Scanner for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.** Based on preliminary cost information from the applicant, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the Provizio® SEM Scanner would be $410.70 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the Provizio® SEM Scanner meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(20) RECELL® Autologous Cell Harvesting Device

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the RECELL® Autologous Cell Harvesting Device is a stand-alone, single-use, battery-powered medical device that is used to process and apply a skin cell suspension autograft for the treatment of thermal burn wounds and full thickness skin defects. Per the applicant, this NTAP application is for the full thickness skin defects indication. The technology received FDA marketing authorization on June 7, 2023. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241007VBAM0.

CMS notes that only the use of the RECELL® Autologous Cell Harvesting Device for acute nonthermal full thickness skin wounds after traumatic avulsion, surgical excision (for example, necrotizing soft tissue infection), or resection (for example, skin cancer),

and the FDA Breakthrough Device designation it received for those uses are relevant for purposes of the new technology add-on payment application for FY 2026. **CMS invites public comments on the use of the ICD-10-CM diagnosis and ICD-10-PCS procedure codes found in Tables 10.1.A. and 10.1.B. to identify use of this technology for the Breakthrough Device designated indications for purposes of the new technology add-on payment, if approved.** Additionally, CMS agrees that the technology meets the cost criterion and **therefore CMS proposes to approve the RECELL® Autologous Cell Harvesting Device for new technology add-on payments for FY 2026.** Based on preliminary cost information from the applicant at the time of this proposed rule, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the RECELL® Autologous Cell Harvesting Device would be $4,875 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the RECELL® Autologous Cell Harvesting Device meets the cost criterion and its proposal to approve new technology add-on payments for FY 2026.

(21) restor3d TIDAL™ Fusion Cage

CMS provides a table with summary information about this product in the proposed rule preamble. CMS notes that the applicants previously submitted an application which was summarized in the FY 2025 IPPS proposed rule[65] but subsequently withdrew prior to the issuance of the FY 2025 IPPS final rule.[66] Per the applicant, the restor3d TIDAL™ Fusion Cages are additively manufactured porous cages intended to be used as an accessory to an intramedullary nail for internal bone fixation for bone fractures, bone voids, or surgical resections in the hindfoot and tibia. The applicant anticipates a 510(k) clearance decision from FDA before May 1, 2025, consistent with its Breakthrough Device designation. The Breakthrough Device designation indication is for tibiotalocalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle with critical size bone defect, in lieu of bulk allograft in procedures. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP2410022M84U.

CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the restor3d TIDAL™ Fusion Cage for new technology add-on payments for FY 2026 subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.** Based on preliminary cost information from the applicant at the time of this proposed rule, CMS notes that any add-on payment for the restor3d TIDAL™ Fusion Cage would include only the cost of the restor3d TIDAL™ Fusion Cage ($27,995). As a result, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the restor3d TIDAL™ Fusion Cage would be $18,196.75 for FY 2026** (that is, 65 percent of the average cost of the technology).

[65] 89 FR 36124 through 36125
[66] 89 FR 69204

CMS invites public comments on whether the restor3d TIDAL™ Fusion Cage meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(22) ShortCut™

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the ShortCut™ is indicated for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk of coronary obstruction. The technology received FDA marketing authorization on September 27, 2024. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP2410045YWFH.

CMS agrees that the technology meets the cost criterion and is therefore proposing to approve the ShortCut™ for new technology add-on payments for FY 2026 for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk for coronary obstruction. Based on preliminary cost information from the applicant, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the ShortCut™ would be $9,750 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the ShortCut™ meets the cost criterion and CMS' proposal to approve new technology add-on payments for the ShortCut™ for FY 2026.

(23) Spur Peripheral Retrievable Stent System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the Bare Temporary Spur Stent System is intended for the treatment of de novo or restenotic lesions of the infrapopliteal arteries to increase luminal gain. The applicant stated that it anticipates a De Novo Classification decision from FDA before May 1, 2025. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241004UTR2W.

CMS raises concerns related with regard to the cost criterion analysis. Specifically, CMS notes that the applicant provided a list of ICD-10-CM codes to identify indications relevant to use of the technology for patients with de novo or restenotic lesions in the infrapopliteal arteries. However, in the cost analysis, the applicant used only ICD-10-PCS codes to identify eligible cases. CMS therefore questions whether using a combination of ICD-10-CM and ICD-10-PCS codes would more accurately identify eligible cases. Subject to the applicant adequately addressing this concern, CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the Spur Peripheral Retrievable Stent System for new technology add-on payments**

for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025. CMS expects the applicant to submit cost information prior to the final rule, and CMS will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule.

CMS invites public comments on whether the Spur Peripheral Retrievable Stent System meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(24) The WiSE CRT System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, The WiSE CRT System is indicated for patients who meet current guidelines for cardiac resynchronization therapy (CRT) with previously acute or chronic failed implants or patients that are high-risk upgrades to a traditional CRT device. The applicant stated that it anticipates a PMA decision from FDA before May 1, 2025. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP2410056PHBK.

CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve The WiSE CRT System for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025**. Based on preliminary cost information from the applicant at the time of this proposed rule, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of The WiSE CRT System would be $41,145 for FY** 2026 (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether The WiSE CRT System meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(25) TriVerity Test

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the TriVerity Test is an automated, semi-quantitative in vitro diagnostic test that measures the relative expression levels of host response genes in RNA isolated from whole blood collected in the PAXgene Blood RNA tube using reverse transcription loop-mediated isothermal amplification (RT-LAMP) on the Myrna instrument. FDA marketing authorization was granted January 10, 2025. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in

FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241007260BW.

CMS expresses interest in additional information regarding the cause of any delay in the technology's commercial availability, including the significance of building up TriVerity cartridge inventory on its availability for routine clinical use. With regard to the cost criterion, CMS questions whether diagnosis codes related to newborns are applicable to this technology because it is indicated for use in adult patients, and whether the applicant should remove these diagnosis codes to identify eligible cases more accurately. Subject to the applicant adequately addressing this concern, CMS would agree that the technology meets the cost criterion. Therefore, **CMS is proposing to approve the TriVerity Test for new technology add-on payments for FY 2026, for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial infections, viral infections, and noninfectious illness, as well as to determine the likelihood of 7-day need for mechanical ventilation, vasopressors, and/or renal replacement therapy in adult patients with suspected acute infection or suspected sepsis presenting to the emergency department.**

Based on preliminary cost information from the applicant, CMS notes that it appears that only the cost of the TriVerity Cartridge is appropriate for consideration for new technology add-on payment. As a result, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the TriVerity Test would be $243.75 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the TriVerity Test meets the cost criterion and its proposal to approve new technology add-on payments for the TriVerity Test for FY 2026.

(26) Ventura® Interatrial Shunt System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the V-Wave Shunt is a permanent implant, which is designed to enable shunting of blood from the left to the right atrium and thus improve symptoms in NYHA Class III and ambulatory Class IV heart failure patients, with reduced or preserved left ventricular systolic function. The applicant anticipates a PMA decision from FDA before May 1, 2025. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241004DLXGV.

With regard to the unique ICD-10-PCS procedure code request, CMS believes that other technologies currently in clinical trials may also be able to be reported using this code. CMS believes that the ICD-10-CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) should be used in combination with the ICD-10-PCS procedure code 02173J6 to exclude new technology add-on payment for cases involving technologies that are used in clinical trial settings, as costs for the investigational item or service, unless otherwise covered outside of the

clinical trial, are not covered by Medicare under the routine costs of a clinical trial. **CMS is inviting public comments on the use of this ICD-10-CM diagnosis code to exclude cases involving technologies that are used in clinical trial settings, which would not be eligible for the new technology add-on payment, if approved.**

CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the Ventura® Interatrial Shunt System for new technology add-on payments for FY 2026 subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.** Based on preliminary cost information from the applicant at the time of this proposed rule, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the Ventura® Interatrial Shunt System would be $22,100 for FY 2026** (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the Ventura® Interatrial Shunt System meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

(27) VITEK® REVEAL™ AST System

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, the Reveal Rapid AST System is indicated for use as an IVD automated system for quantitative AST of organisms direct from positive blood culture or isolate dilution. The Reveal GN BC AST Assay is indicated for susceptibility testing of specific gram-negative pathogenic bacteria commonly associated with or causing bacteremia. Results are intended to be used in conjunction with Gram stain, organism identification and other clinical laboratory findings. FDA marketing authorization was received on June 20, 2024. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241007GL4LH.

CMS agrees that it appears that the FDA-cleared indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. CMS is interested in additional information regarding the cause for any delay in the technology's commercial availability, as it received FDA clearance on June 20, 2024, and it is not clear how lead times in the supply chain affected its availability on the market and what system modifications were required. Further, CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve the VITEK® REVEAL™ AST System for new technology add-on payments for FY 2026,** indicated for susceptibility testing direct from positive blood culture samples signaled positive by a continuous monitoring blood culture system and confirmed to contain gram-negative bacilli by Gram stain. Based on preliminary cost information from the applicant at the time of this proposed rule, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of the**

VITEK® REVEAL™ AST System would be $81.25 for FY 2026 (that is, 65 percent of the average cost of the technology).

CMS invites public comments on whether the VITEK® REVEAL™ AST System meets the cost criterion and CMS' proposal to approve new technology add-on payments for FY 2026.

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

(1) EMBLAVEO™ (aztreonam-avibactam)

CMS provides a table with summary information about this product in the proposed rule preamble. Per the applicant, ATM-AVI is designated as a QIDP for treatment of complicated intra-abdominal infections (cIAI), complicated urinary tract infections (cUTI), and hospital-acquired bacterial pneumonia (HABP)/ventilator-associated bacterial pneumonia (VABP). FDA marketing authorization was received on February 7, 2025. The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP241005WY6F6.

CMS agrees it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria. CMS expresses interest in additional information regarding the cause for any delay in the technology's market availability as the technology received FDA approval on February 7, 2025. CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve EMBLAVEO™ for new technology add-on payments for FY 2026** for use in patients 18 years and older who have limited or no alternative options for the treatment of cIAI.

The applicant had not provided an estimate for the cost of the technology at the time of issuance of the proposed rule. CMS expects the applicant to submit cost information prior to the final rule, and CMS will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule.

CMS invites public comments on whether EMBLAVEO™ meets the cost criterion and CMS' proposal to approve new technology add-on payments for EMBLAVEO™ for FY 2026.

(2) CONTEPO™ (fosfomycin)

CMS provides a table with summary information about this product in the proposed rule preamble. CMS notes that an application for CONTEPO™ was submitted for FY 2021 and FY 2022 and received conditional approval subject to the technology receiving FDA marketing authorization before July 1 of the applicable fiscal year. However, CONTEPO™ did not receive FDA marketing authorization by the applicable July 1 deadlines and was therefore not eligible for new technology add-on payments for FY

2021 or FY 2022.[67] Per the applicant, the technology rights have been acquired by Meitheal Pharmaceuticals Inc. which is submitting the new technology add-on payment application for FY 2026.

The applicant anticipates an NDA decision from FDA before July 1, 2025, consistent with its QIDP designation. According to the applicant, the QIDP designation indication refers to ZTI-01 and the generic name fosfomycin disodium, as the brand name CONTEPO™ was not yet established at the time of QIDP designation. The application can be viewed here: https://mearis.cms.gov/public/publications/ntap/NTP2410073U85N.

CMS would appreciate more information on the reasons for any delay in the commercial availability of CONTEPO™ following FDA approval. CMS agrees that the technology meets the cost criterion and therefore **CMS is proposing to approve CONTEPO™ for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the QIDP designation by July 1, 2025.** As an application submitted under the QIDP alternative pathway, CONTEPO™ is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by July 1, 2025, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2026). If CONTEPO™ receives FDA marketing authorization before July 1, 2026, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2026, no new technology add-on payments would be made for cases involving the use of CONTEPO™ for FY 2026.

Based on preliminary cost information from the applicant at the time of this proposed rule, **CMS is proposing that the maximum new technology add-on payment for a case involving the use of CONTEPO™ would be $8,775 for FY 2026** (that is, 75 percent of the average cost of the technology).

CMS invites public comments on whether CONTEPO™ meets the cost criterion and its proposal to approve new technology add-on payments for CONTEPO™ for FY 2026, subject to the technology receiving FDA marketing authorization consistent with its QIDP designation by July 1, 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

[67] 86 FR 44972; 87 FR 48909

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 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. 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. Beginning with FY 2025, CMS has been using OMB delineations based on the 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data (OMB Bulletin 23-01).

C. Worksheet S-3 Wage Data

The proposed rule wage index values are based on data from FY 2022 submitted cost reports. CMS is not proposing any changes to the categories of included and excluded costs for FY 2026 relative to prior years.

CMS notes that it reviewed and evaluated the audited wage data for potential impacts of the COVID-19 public health emergency and has not identified any significant issues with the FY 2022 wage data. The proposed rule calculations of the FY 2026 wage index are based on wage data of 3,027 hospitals. The data file used to construct the proposed wage index includes FY 2022 data submitted to CMS as of January 24, 2025.

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, if those data did not fail any edits for reasonableness. CMS removed the data for seven IPPS hospitals included in the FY 2022 data that have converted to CAH or Rural Emergency Hospital status as of January 24, 2025.

General wage index policies are unchanged from prior years. CMS notes that it proposes to exclude 79 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 2026 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 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 the public use files made available during the wage index development process. All deadlines are eastern standard time. For the FY 2026 wage index timetable go to: FY 2026 Wage Index Home Page | CMS

D. Method for Computing the Unadjusted Wage Index

For the FY 2026 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 $57.70.

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 will be used for the occupational mix adjustment applied to FY 2025 through FY 2027 IPPS wage indexes.

CMS reports having occupational mix data for 97 percent of hospitals (2,945 of 3,029) used to determine the FY 2026 proposed rule wage index. The FY 2026 national average hourly wage, adjusted for occupational mix, is $57.63.

F. Geographic Reclassifications

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

1. Urban to Rural Reclassification. Hospitals that meet specific criteria in statute may request that a CMS Regional Office treat an urban hospital as rural for all IPPS payment purposes. Unlike Medicare Geographic Classification Review Board (MGCRB) reclassifications that are effective based on a fiscal year and only for the wage index, 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. When a multi-campus hospital reclassifies from urban to rural, the reclassification applies to all the hospital's campuses. In addition, if a multi-campus urban hospital is reclassified as rural, the rural status will apply to all its campuses for such policies as Sole Community Hospitals (SCH), Medicare Dependent Hospital (MDH) or Rural Referral Center (RRC) status.

An approved urban to rural reclassification remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. For instance, an urban to rural reclassification would no longer be valid if the hospital is no longer located within a rural census tract of an urban county as determined by the Office of Rural Health Policy within the Health Resources and Services Administration. CMS encourages all hospitals and CAHs with active urban rural reclassifications to review their original reclassification application and determine whether the reclassification status would still apply.

Reclassifications would be considered cancelled for the purposes of calculating the area wage index for any hospital with a CCN listed as terminated as of the date that the hospital ceased to operate with an active CCN. CMS will obtain and review the best available CCN termination status lists when determining the FY 2026 wage index 60 days after the proposed rule is on public display with the Office of the Federal Register (known as the "lock-in" date). Any hospital with a CCN listed as terminated is not intended to alter or affect the qualification for CAH, SCH, or Rural Emergency Hospital (REH) statuses or to have other effects unrelated to hospital wage index calculations.

2. Geographic Reclassification. Geographic reclassification is a process where hospitals apply to use another area's wage index. To use another area's wage index, the applying hospital must be within a specified distance of the area being requested (15 miles for urban hospitals and 35 miles for rural hospitals) and have wages that are different than their 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 their 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 639 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2026. There are 280 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2024 that will continue for FY 2026. There are 278 hospitals approved for wage index reclassification in FY 2025 that may continue for FY 2026. CMS indicates that there will be 1,197 hospitals (36 percent of all hospitals) in MGCRB reclassification status for FY 2026 (with 279 of these hospitals reclassified back to their home area).

The deadline for withdrawing or terminating a wage index reclassification for FY 2026 approved by the MGCRB is the later of: 1) 45 days from the date of display of the FY 2026 proposed rule (May 26, 2025) or 2) seven calendar days of receiving an Administrator's decision appealing an MGCRB decision.

The proposed rule discussed various aspects of the MGCRB process. For instance, if a hospital or a county-wide group of hospitals has a geographic reclassification in process, it may apply for

a second geographic reclassification while the first one has not yet been completed. If the second MGCRB reclassification is accepted, the first one is permanently terminated.

Alternatively, the applicant may decline the second geographic reclassification and "fallback" or reinstate the first MGCRB reclassification. Also, the applicant may withdraw a previously pending MGCRB reclassification for one or more years without accepting a second MGCRB reclassification and reinstate the pending MGCRB reclassification in a subsequent year provided one or more years remain in the approved reclassification.

CMS also explains that county-wide group reclassification withdrawals must include all parties to the application, while a termination may be submitted by any individual hospital that is party to the application. The basis for this policy is that an individual hospital should not be allowed to withdraw from an MGCRB application before it has gone into effect to manipulate the wage index to the benefit or detriment of other hospitals reclassified to the labor market area. CMS argues this policy improves stability in the wage index.

While CMS is not making any policy changes, it is proposing the following changes to 42 CFR §412.273 to make the process for withdrawing or terminating an MGCRB reclassification more understandable:

- "Termination" refers to the termination of an already existing 3-year MGCRB reclassification where such reclassification has already been in effect for 1 or 2 years, and there are 1 or 2 years remaining on the 3-year reclassification. A termination is effective only for the full fiscal year(s) remaining in the 3-year period at the time the request is received. Requests for terminations for part of a fiscal year are not considered. Once a reclassification is terminated, it may not be reinstated.
- CMS is proposing to modify several references in §412.273(d) from "cancelling" or a "cancellation" to "reinstating" or "reinstatement" to address situations where a hospital is temporarily forgoing a previously approved 3-year reclassification that it intends to activate in a subsequent year.
- "Withdrawal" refers to the withdrawal of a 3-year MGCRB reclassification that has not yet gone into effect or where the MGCRB has not yet issued a decision on the application.
- County group reclassification withdrawals must include all parties to the application.

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 2026 wage index values. For more information, CMS refers readers to 42 CFR §412.273.

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 45 days from May 26, 2025, 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 from the date of display of the FY 2026 proposed rule (May 26, 2025).

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).

G. Wage Index Floors, Outmigration Adjustment and Other Wage Index Policies

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 FY 2026 wage index for 565 urban hospitals requiring a budget neutrality adjustment factor of 0.985942 (-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 rural. It does note that an urban to rural reclassified hospital is considered 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. CMS is proposing to continue the imputed floor policies unchanged for FY 2026.

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 40 hospitals will receive the frontier floor value of 1.0000 for FY 2026. 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.

Outmigration Adjustment. CMS proposes to apply the same policies for the FY 2026 outmigration adjustment that it has been using since FY 2012. 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. On July 23, 2024, the Court of Appeals for the D.C. Circuit in *Bridgeport Hosp. v. Becerra*[68] held that the Secretary lacked authority to adopt the low wage index hospital policy for FY 2020 and the related budget neutrality adjustment. The proposed rule does not indicate how CMS plans to remedy prior years where the policy was deemed to lack statutory authority.

CMS ended the low-wage index policy beginning with FY 2025 and established a non-budget neutral transitional adjustment to the wage index for low-wage hospitals. CMS justified applying the transitional adjustment without applying budget neutrality because it was being adopted in an interim final rule just prior to October 1, 2024, with insufficient time to implement the Bridgeport decision and provide public comments.

As explained in the following section, CMS is allowing hospitals with a wage index that was increased by the low-wage index policy to benefit from a transition policy that will mitigate the reduction to their wage indexes, that is subject to budget neutrality. With more time available for public comment, CMS believes the circumstances are different to justify applying budget neutrality to the transitional wage index for low wage index hospitals in 2026.

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 -0.69 percent for FY 2025.

[68] *Bridgeport Hosp. v. Becerra*, 108 F.4th 882, 887–91 & n.6 (D.C. Cir. 2024)

For low-wage index hospitals, the transitional policy will apply by comparing the hospital's wage index proposed for FY 2026 to its wage index under the low-wage index policy in FY 2024. If the hospital's wage index decreases by more than 5 percent annually (or 9.75 percent over two years)[69], the hospital would be eligible for the transitional policy. The limit on the reduction in the wage index would be 5 percent from the otherwise applicable policy that would apply in FY 2026 if the low-wage index policy had continued. CMS proposes to make the increase in the otherwise applicable wage index without the transitional policy subject to budget neutrality. Analogous policies will apply the geographic adjustment factor applied under the capital IPPS.

H. Wage Index Tables

Proposed rule wage index tables 2, 3 and 4 can be found at: FY 2026 IPPS Proposed Rule Home Page | CMS. Select #2 under FY 2026 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. As described in the next section, CMS is proposing to rebase and revise the IPPS market basket to reflect a 2023 base year beginning in FY 2026. CMS is also proposing to recalculate the labor-related share for discharges occurring on or after October 1, 2025. Using the proposed 2023-based IPPS market basket, CMS proposes a labor-related share of 66.0 percent. CMS will apply a budget neutrality adjustment for the reduction in the national labor-related share from 67.6 percent to 66.0 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 66.0 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 that is less than 1.0.

[69] Over a 2-year period if its wage index were decreasing by more than 5 percent each year, this would mean a hospital's wage index for a FY cannot be lower than (0.95*0.95) times its wage index from two years earlier or 0.9025 which would be a reduction of 9.75 percent.

IV. Rebasing and Revising the Hospital Market Basket

CMS is proposing to rebase and revise the hospital market basket that is used in the annual update to IPPS operating costs and the update to target amounts for facilities excluded from the IPPS (religious non-medical health care institutions, cancer hospitals and short-term acute care hospitals located in the U.S. territories of the Virgin Islands, Guam, Northern Mariana Islands and American Samoa). CMS is also proposing to update the capital input price index (CIPI) used to annually update the capital IPPS. Currently, the hospital market basket and the CIPI use 2018 data for the base year. CMS is proposing to move the base year from 2018 to 2023.

The table below shows the impact from changing to a 2023-based IPPS market basket.

FY	2018-Based IPPS Market Basket % Change	2023-Based IPPS Market Basket % Change
Historical Data		
FY 2021	3.0	2.8
FY 2022	5.7	5.3
FY 2023	4.8	4.9
FY 2024	3.6	3.7
Average: FY 2021 – FY 2024	**4.3**	**4.2**
Forecast		
FY 2025	3.4	3.5
FY 2026	3.3	3.2
FY 2027	3.1	3.0
FY 2028	2.9	2.9
Average FY 2025 – FY 2028	**3.2**	**3.2**

The table below shows how the labor-related share would change from moving to a 2023-based IPPS market basket. The labor share would decline from 67.6 percent to 66.0 percent.

	2018-Based IPPS Market Basket Cost Weight	2023-Based IPPS Market Basket Cost Weight
Wages and Salaries	41.2	40.6
Employee Benefits	11.7	10.5
Professional Fees: Labor-Related	8.6	10.0
Administrative and Facilities Support Services	1.1	0.8
Installation, Maintenance and Repair Services	2.4	1.5
All Other: Labor-Related Services	2.6	2.6
Total Labor-Related Share	**67.6**	**66.0**

The table below shows the impact from changing to a 2023-based CIPI.

FY	2018-Based IPPS Market Basket % Change	2023-Based IPPS Market Basket % Change
Historical Data		
FY 2021	1.0	0.8
FY 2022	2.0	1.8

FY	2018-Based IPPS Market Basket % Change	2023-Based IPPS Market Basket % Change
FY 2023	3.0	2.8
FY 2024	2.8	2.7
Average: FY 2021 – FY 2024	**2.2**	**2.0**
Forecast		
FY 2025	2.7	2.6
FY 2026	2.7	2.6
FY 2027	2.6	2.5
FY 2028	2.5	2.4
Average FY 2025 – FY 2028	**2.6**	**2.5**

V. 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. Supplemental Payments: Indian Health Service (IHS), Tribal and Puerto Rico Hospitals

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), CMS established a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. This payment was established to help mitigate the impact of

the decision to discontinue the use of low-income insured days as proxy for uncompensated care costs for these hospitals. The supplemental payment for a fiscal year is determined as the difference between the hospital's base year amount (what the hospital would have received in 2022 when it used low-income insured days as a proxy) and its uncompensated care payment for the applicable fiscal year (based on using uncompensated care data from Worksheet S-10).[70] This policy was to prevent undue long-term financial disruption for these providers. If the base year amount is higher than the hospital's uncompensated care payment for the current fiscal year, then the hospital would receive a supplemental payment based on the difference. If it is equal or lower the hospital would not receive a supplemental payment.

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

CMS 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.

C. Uncompensated Care Payments

1. Proposed FY 2026 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 2025 Medicare DSH estimates, which were based on the December 2024 update of the HCRIS and the FY 2025 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 2025 Medicare estimate of DSH payments for FY 2026 is $15.682 billion. **The proposed Factor 1 amount is seventy-five percent of this amount, or $11.761 billion.** The proposed Factor 1 for 2026 is about $1.25 billion more than the final Factor 1 for FY 2025.

The Factor 1 estimate for FY 2026 began with a baseline of $13.018 billion in Medicare DSH expenditures for FY 2022. The table below shows the factors applied to update this baseline to the current proposed estimate for FY 2026.

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

Factors Applied for FY 2023 through FY 2026 to Estimate Medicare DSH Expenditures Using FY 2022 Baseline

FY	Update	Discharge	Case-Mix	Other	Total	Estimated DSH Payment (in billions)
2023	1.043	0.994	0.990	1.0504	1.0784	14.038
2024	1.031	0.998	0.997	1.0310	1.0573	14.842
2025	1.029	0.991	1.005	0.9976	1.0228	15.180
2026	1.024	0.999	1.005	1.0048	1.0331	15.682

- 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). The discharge figures for 2025 and 2026 are assumptions based on recent historical experience and assumptions related to how many beneficiaries will be enrolled in MA plans.
- The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for 2025 and 2026 are assumptions based on the 2021 "Review of Assumptions and Methods of the Medicare Trustees' Financial Projections" report by the 2010-2011 Medicare Technical Review Panel.[71]

- The "other" column shows the changes in other factors affecting Medicare DSH estimates, including the difference between the total inpatient hospital discharges (including inpatient rehabilitation facility (IRF), inpatient psychiatric facility (IPF) and LTCH) 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 including IRF, IPF and LTCH and the IPPS discharges). The "other" column also includes a factor for the estimated changes in Medicaid enrollment through 2023.[72]

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
2023	4.1	-0.3	0.5	4.3
2024	3.3	-0.2	0.0	3.1
2025	3.4	-0.5	0.0	2.9
2026	3.2	-0.8	0.0	2.4

2. Proposed FY 2026 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

[71] https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf
[72] CMS did not provide the annual estimated percent change in Medicaid enrollment used in its projections as it has done in prior rules.

(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.[73]

For FY 2026, CMS estimates that the uninsured rate for the baseline year of 2013 was 14 percent and for CYs 2024 and 2025 is 7.7 percent and 8.7 percent, respectively. As required, the Chief Actuary of CMS certified these estimates.

Using these estimates, CMS calculates the proposed Factor 2 for FY 2026 (weighting the portion of calendar years 2025 and 2026 included in FY 2026) as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2025: 7.7 percent.
- Percent of individuals without insurance for CY 2026: 8.7 percent.
- Percent of individuals without insurance for FY 2026 (0.25 times 0.077) + (0.75 times 0.087): 8.5 percent

Proposed Factor 2 = 1-|((0.085-0.14)/0.14)| = 1 - 0.3929 = 0.6071 (60.71 percent)

CMS calculated Factor 2 for the FY 2026 proposed rule to be 0.6071 or 60.71 percent, and the uncompensated care amount for FY 2026 to be $11.761 billion x 0.6071 = $7.14 billion which is about $1.4 billion more than the FY 2025 UCP total of about $5.706 billion; the percentage increase is 25.1 percent. The past two years CMS estimates of the change in uncompensated care payment have increased in the proposed rule but declined in the final rule because of a re-estimate of the factors affecting uncompensated care between the proposed and final rule in the National Health Expenditures Accounts (NHEA). As the NHEA is revised each June, there could be a significant difference between the proposed and final rule estimates of the uninsured population.

[73]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

The table below shows the Factor 1 and Factor 2 estimates for FY 2025 and the proposed factors for FY 2026.

FY 2026 Proposed Change in UCP
($ in billions)

	FY 2025	FY 2026	Change	% Change
Factor 1	$10.510	$11.761	$1.251	11.9%
Factor 2	0.5428	0.6071	0.0643	11.8%
UCP*	$5.706	$7.14	$1.434	25.1%

* The UCP totals do not include supplemental payments for IHS/Tribal hospital and Puerto Rico hospitals. In FY 2026, these payments are estimated to account for $100.6 million.

3. Proposed Factor 3 for FY 2026

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 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.

b. Methodology for Calculating Factor 3 for FY 2026

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 2020, FY 2021, and FY 2022. This approach will be used for all eligible hospitals, including IHS/Tribal and Puerto Rico hospitals. It is using the December 2024 HCRIS extract to calculate Factor 3 for the proposed rule but intends to use the March 2025 update of HCRIS to calculate 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 8 hospitals for FY 2020 reports, 10 hospitals for FY 2021 reports, and 8 hospitals for FY 2022 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)).

CMS notes that the March HCRIS data extract will be available during the comment period for this proposed rule if providers want to verify that their amended and/or reopened data is reflected in the March HCRIS extract.

c. Per Discharge Amount of Interim Uncompensated Care Payments

Consistent with the policy adopted in FY 2014 and applied in each subsequent fiscal year, CMS calculates a per discharge amount of interim uncompensated care by dividing the hospital's total uncompensated care payment amount in the 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. As finalized in the 2025 IPPS/LTCH PPS final rule, CMS calculates the per-discharge amount for uncompensated care payments using the average of the most recent 3 years of discharge data.

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

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

In the case of hospital mergers, CMS publishes a table on the CMS Web site, in conjunction with the issuance of each fiscal year's proposed and final IPPS rules, containing a list of the mergers known to CMS and the computed uncompensated care payment for each merged hospital. Hospitals 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.[74]

D. 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 2026 across all hospitals by geographic location, number of beds, region, teaching status, type of ownership, and Medicare utilization percent. CMS' analysis includes 2,385 hospitals that are projected to be eligible for DSH in FY 2026.

[74] 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.

The proposed total amount of uncompensated care payments ($7.14 billion) combined with supplement payments for IHS/Tribal hospitals and Puerto Rico hospitals ($100.6 million) is $7.241 billion. This is a 25.1 percent increase (about $1,455 billion) from FY 2025 payments Changes in FY 2025 payments are driven by proposed increases in Factor 1 and Factor 2. As noted above, Factor 2 has changed significantly between proposed and final rule the past two years and may change again this year based on a re-estimate of the uninsured population in the NHEA.

CMS cites two different uncompensated care payment totals in the proposed rule - on page 613 of the display copy, the proposed rule indicates that the uncompensated care payment for FY 2026 is $7,140,406,650 but on page 1,274 CMS cites $7,190,037,075, a difference of approximately $50 million. Using CMS totals in the impact section, uncompensated care payments would increase by 26 percent from FY 2025 levels. The numbers displayed below in the table reflect the estimates from the impact section.

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 26.0 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 26.0 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 2025-FY 2026 ($ in millions)**	**Percent Change (%)**
All Hospitals	1,505	26.0
Urban	1,426	26.1
Large Urban	817	27.0
Other Urban	609	25.0
Rural	81	24.7
Beds: 0-99 (Urban)	50	20.6
Beds: 100 to 249 (Rural)	294	24.5
Beds: 250+ (Urban)	1,082	26.9
New England (Urban)	43	29.9
Middle Atlantic (Urban)	187	30.2
South Atlantic (Urban)	109	18.9
East South Central (Urban)	366	26.1
West North Central (Urban)	90	25.8
West South Central (Urban)	368	29.5
Pacific (Urban)	114	22.4
Middle Atlantic (Rural)	6	34.1
Pacific (Rural)	1	25.8
Puerto Rico	19	26.0
Teaching with 100 or more residents	671	29.3

Hospital Type	Dollar Difference FY 2025-FY 2026 ($ in millions)	Percent Change (%)
Teaching with fewer than 100 Residents	499	24.0
Non-Teaching	337	23.7
Voluntary	809	24.2
Proprietary	203	25.0
Government	495	30.5

Under this proposal, urban hospitals are projected to receive an increase in uncompensated care payments of 26.1 percent compared to an increase in UCP payments of 24.7 percent for rural hospitals in FY 2026 compared to FY 2025. By region, rural and urban hospitals are projected to receive a varied range of payment changes. Non-teaching hospitals and teaching hospitals with fewer than 100 residents are projected to receive a smaller than average payment increase of 23.7 and 24.0 percent, respectively. Teaching hospitals with 100 or more residents are expected to receive a larger than average increase of 29.3 percent. Government ownership hospitals are expected to receive a larger than average increase of 30.5 percent, while proprietary and voluntary hospitals are expected to receive smaller than average increases.

VI. 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.[75] CMS makes payment to the transferring hospital at:

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

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 evaluates each proposed new or revised MS-DRG for whether it should be subject or removed from the post-acute care transfer policy list and subject to the special payment methodology. Based on proposed changes CMS is making to the MS-DRGs, it proposes to add

[75] 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.

MS DRGs 403 and 404 to the list of MS-DRGs subject to the post-acute care transfer policy. These MS-DRGs were new in FY 2025 and not yet evaluated for post-acute transfer policy. In addition, CMS is proposing to add MS-DRGs 463, 464 and 465 to the special payment methodology.

B. Inpatient Hospital Update

The proposed inpatient hospital update for FY 2026 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 2026 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 2026 inpatient hospital update will be reduced by three-quarters of the market basket update.

As stated in section IV, CMS is proposing to rebase and revise the hospital market basket from 2018 to 2023. Using a 2023 base year, IHS Global Insight, Inc. (IGI) 4th quarter 2024 forecast (with historical data through the 3rd quarter of 2024) for the hospital market basket is 3.2 percent. IGI's 4th quarter 2024 forecast of total factor productivity is 0.8 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	3.2	3.2	3.2	3.2
Adjustment for Failure to Submit Quality Data	0.0	0.0	-0.8	-0.8
Adjustment for Failure to be a Meaningful EHR User	0.0	-2.4	0.0	-2.4
Productivity Adjustment	-0.8	-0.8	-0.8	-0.8
Applicable Percentage Increase	**2.4**	**0.0**	**1.6**	**-0.8**

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 September 30, 2025, 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 and 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 2026, CMS proposes to use FY 2024 data to set the CMI criteria. To qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2025, 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 1.7802 (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)	1.499
2. Middle Atlantic (PA, NJ, NY)	1.56165
3. East North Central (IL, IN, MI, OH, WI	1.6175
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.73965
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.635
6. East South Central (AL, KY, MS, TN	1.5901
7. West South Central (AR, LA, OK, TX	1.78085
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.8092
9. Pacific (AK, CA, HI, OR, WA)	1.7793

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

D. Low-Volume Hospitals (LVH)

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

Fiscal Year	Distance Criteria	Discharge Criteria	Payment Methodology
2005 - 2010	25 miles	200 Total Discharges	25%
2011 - 2018	15 miles	1,600 Medicare Discharges	Medicare Discharges<200=25%; Declining Linear Adjustment Up to 1,600

Fiscal Year	Distance Criteria	Discharge Criteria	Payment Methodology
2019 – 2025	15 miles	3,800 Total Discharges	Total Discharges<500=25%; Declining Linear Adjustment up to 3,800 discharges applied to each Medicare Discharge
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 2026. As shown in the above table, the payment adjustment for a qualifying LVH will be 25 percent for each Medicare discharge.

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, 2025, 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 2026 is received after September 1, 2025, CMS proposes that any approval will be effective prospectively within 30 days of the date of the MAC's determination. A hospital that qualified for the low-volume hospital payment adjustment for FY 2025, may continue to receive a low-volume hospital payment adjustment for FY 2026 without reapplying if it meets both the discharge criterion and the mileage criterion applicable for FY 2026.

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 September 30, 2025. Beginning with discharges occurring on or after October 1, 2025, all hospitals that previously qualified for MDH status will no longer be eligible for this special payment methodology and will be paid based on the IPPS Federal rate beginning with discharges occurring on or after October 1, 2025. While the MDH program was set to expire many times previously, it has always been extended by Congress.

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. However, if an MDH classifies as a SCH in anticipation of the MDH program expiration, it would have to reapply for MDH classification and meet the criteria specified in 42 CFR §412.108(a) and (b).

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. Calculating FTE Counts and Caps for Cost Reporting Periods Other than Twelve Months

CMS is not proposing any changes to the regulations for how DGME counts and caps are determined when a Medicare cost report is not equal to 12 months. The FTE counting policy is long-established and widely used in existing cost reporting software and the Intern and Resident Information System (IRIS) software. However, CMS is restating and clarifying its FTE counting policy in rulemaking. The proposed rule provides a detailed step-by-step explanation of how the count and caps are determined for non-standard length cost reporting periods separately for DGME and IME.

The statute also requires that a hospital's count of residents in any individual period be based on a 3-year rolling average of the contemporaneous cost reporting period and the two preceding ones. This policy has the effect of phasing in any payments associated with an increase or decrease in the number of residents over a 3-year period. CMS also provides detailed step-by-step explanation of how to prorate the resident count for DGME when a cost reporting period is not 12 months in length and the count for that period is averaged with two other cost reports that are of the standard 12-month length.

It is unnecessary to make any changes for IME count for the 3-year rolling average as the IME adjustment is made to the MS-DRG amount. The IME FTE count represents an average over the cost reporting period and will be reflected in the MS-DRG amount regardless of the length of the cost reporting period.

3. Notice of Closure of a Teaching Hospital

Section 5506 of the Affordable Care Act authorizes the Secretary to redistribute residency slots of a hospital that trained residents in an approved medical residency program after its closure.

CMS is notifying the public of the closure of Wahiawa General Hospital, located in Wahiawa, HI and Carney Hospital, Boston, MA:

Available Resident Cap FTEs

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME Resident Cap	DGME Resident Cap
120004	Wahiawa General Hospital	Wahiawa, HI	46520	April 2, 2024	17.16	14.31
220017	Carney Hospital	Boston, MA	14454	August 31, 2024	63.15	61.14

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 15, 2025,** to be eligible to receive slots from these closed hospitals.

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 for 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.

G. Nursing and Allied Health Education

1. Nursing and Allied Health Education Medicare Advantage Payments

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 each year. Each hospital's payment is based on its relative share of national nursing and allied health education payments and MA utilization.

In the FY 2026 IPPS proposed rule, CMS indicates proposed nursing and allied health education payments and the proposed reduction in MA DGME payments for 2024. CMS proposes using the 4th quarter 2024 update of the 2022 HCRIS projected forward two years to estimate 2024 payments. For 2024, CMS proposes to distribute the maximum $60 million in nursing and allied health education MA payments with an offset of 2.34 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.

2. Allocation of Indirect Costs to Nursing and Allied Health Education Cost Center

A hospital's reasonable costs for nursing allied health education are net of revenues received from tuition and student fees. Separately, the Medicare cost report instructions indicate how indirect costs are allocated to individual cost centers. On November 17, 2017, CMS issued cost reporting instructions that revenues from tuition and student fees should be subtracted from the costs of nursing and allied health education prior to allocating indirect costs. On February 9,

2024, the U.S. District Court for the District of Columbia issued a ruling on behalf of five plaintiff hospitals finding that CMS' cost report instruction was inconsistent with 42 CFR §413.85 that requires revenues from tuition and fees to be subtracted from the cost of educational activities after the indirect cost allocation is completed.

CMS is proposing to modify 42 CFR §413.85(d)(2)(ii) to indicate that revenues received from tuition, student fees, textbooks purchased for resale and other revenue from or on behalf of students is subtracted before completing the indirect cost allocation effective October 1, 2025. In a circumstance where revenue from or on behalf of students reduces direct nursing and allied health education costs to zero, there would be no indirect costs to allocate to the nursing and allied health education cost center. However, CMS will allow a hospital to seek permission from their MAC to employ a different allocation method to mitigate the reduction in reasonable cost payment for nursing and allied health education in accordance with PRM 15-1, chapter 23, section 2313.

The proposed rule indicates that this alternative allocation of indirect costs would focus on only those costs that are directly related to the operation of approved educational activities under 42 CFR §413.85. CMS provides examples of costs directly related to approved educational activities as those costs that the hospital would not have in the absence of an educational program. Such costs would not include nursing supervisors who oversee floor nurses and student nurses or costs that benefit the hospital as a whole (e.g., admissions or patient registration) and would also exclude the costs of a related organization (such as a home office).

H. Payment Adjustment for Certain Immunotherapy Cases

In some cases, the CAR-T cell or other immunotherapy patients may be part of a clinical trial where the high-cost therapy product is furnished to the hospital at no cost. Beginning with FY 2021, CMS adopted a differential payment for these cases to recognize hospitals' lower costs. CMS has also excluded CAR-T cases from the relative weight calculation where the hospital has no costs for the CAR-T product.

The initial situations where CMS adopted this policy included clinical trial cases where the hospital received the drug at no cost and expanded access use of the immunotherapy. In response to a comment on the FY 2025 IPPS final rule, CMS will apply this policy to other situations where the hospital does not have a cost for the immunotherapy product. In the proposed rule, CMS indicates that it is developing billing instructions in a separate guidance document for applying this expanded policy.

CMS is proposing to adopt these same policies for FY 2026. Using the FY 2024 data for determining the FY 2025 IPPS relative weights, the average costs of cases assigned to MS-DRG 018 that are identified as clinical trial cases ($88,484) were 23 percent of the average costs of the cases assigned to MS-DRG 018 that are identified as non-clinical trial cases ($385,147). Accordingly, CMS is proposing to adjust the payment for MS-DRG 018 by applying an adjustor of 0.23 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. Hospital Readmissions Reduction Program (HRRP)

1. Background

The HRRP is established under section 1886(q) of the Act.[76] 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/procedure-specific 30-day risk-standardized unplanned readmission measures included in the HRRP measure set (collectively referred to as the HRRP measure set) are the following: (i) acute myocardial infarction (AMI); (ii) heart failure (HF); (iii) pneumonia (PN); (iv) elective total hip arthroplasty (THA)/total knee arthroplasty (TKA); (v) chronic obstructive pulmonary disease (COPD); and (vi) 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).

The estimated percentage of hospitals that will be penalized under the HRRP for the FY 2026 HRRP is 82.81 percent (2,342 of the 2,828 eligible hospitals),[77] with total penalties for all such penalized hospitals estimated to be 0.42 percent of total payments for such hospitals.[78]

2. HRRP Measures

a. Proposal to Integrate Medicare Advantage (MA) Beneficiaries into Cohorts of HRRP Measure Set Beginning with the FY 2027 Program Year

Overview of proposal. CMS proposes substantive updates to the HRRP measure set beginning with the FY 2027 Program Year that would integrate MA beneficiaries into each measure's cohorts (i.e., the index admissions that are included when calculating each measure) and reduce the applicable period from a 3-year period to a 2-year period. CMS describes how by 2030 nearly two-thirds of all Medicare beneficiaries are projected to be enrolled in MA plans and therefore believes representing all Medicare beneficiaries (not only FFS) in the measure cohorts is important for quality measurement.

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[76] CMS provides sources for the legislative and regulatory histories of the HRRP. The program's regulatory requirements are under §§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.

[77] A hospital is eligible to receive a penalty if it has 25 or more eligible discharges for at least one measure between July 1, 2021, and June 30, 2024.

[78] See Table I.G.5.-01 in Appendix A of the proposed rule. CMS bases its analysis on the data used to calculate FY 2025 payment adjustment factors of open, non-Maryland subsection (d) hospitals, which is based on discharges from July 1, 2020, through June 30, 2023 and uses hospital characteristics from the 2025 IPPS Proposed Rule Impact File. CMS plans to include in the FY 2026 IPPS/LTCH PPS final rule an updated estimate of the financial impact for the FY 2026 HRRP applicable period (July 1, 2021 through June 30, 2024).

Currently, the inclusion criteria for the measure denominator for each measure in the HRRP measure set includes a criterion that specifies beneficiaries be enrolled in FFS (both Part A and B) for the first 12 months before the date of admission and enrolled in Part A during the index admission. CMS is proposing to change that inclusion criterion for the denominator to be beneficiaries who are "Enrolled in Medicare FFS and/or MA for the 12 months prior to the date of admission; and enrolled in FFS or MA during the index admission".[79] This change would double the cohort size.

The agency also proposes a non-substantive modification that would update the risk adjustment model to use individual ICD-10 codes rather than Hierarchical Condition Categories (HCCs).

Data Submission and Reporting. The updated measure set would use the following data:
Index admission diagnoses and in-hospital comorbidity data from Medicare FFS Part A, MA claims/encounters, or both.
Part A and Part B claims and MA encounters during the 12 months prior to the index admission to assess additional comorbidities before the index admission.
Medicare enrollment data to determine Medicare FFS or MA enrollment status.

For the FY 2027 program year, CMS would use claims and encounter data with admission dates beginning from July 1, 2023, through June 30, 2025. CMS would continue to publicly report the readmission measure results for a fiscal year for each applicable hospital on the Compare tool[80] or successor website and on the Provider Data Catalog.[81]

Pre-Rulemaking. The proposed updated versions of the HRRP measure set specifications were reviewed by the Pre-Rulemaking Measure Review (PRMR)[82] Hospital Recommendation Group during January 2025. The committee recommended the addition of MA data to each measure, with conditions,[83] including (i) revising the inclusion criteria to include care provided in ambulatory settings, (ii) stratification of measure data by FFS and MA, (iii) considering a shorter 7-day or 14-day readmissions period, and (iv) conducting additional testing to review if the measure involved is topped out for all subgroups. The current version of the measures in the HRRP were endorsed by the consensus-based entity (CBE) and CMS states that the proposed updated measures will be considered for future endorsement.

CMS proposes to adopt the updated measure set into the HRRP but acknowledges the conditions specified and notes they are not specific to the addition of MA data into the measures. The

[79] Measure descriptions and specifications are shown in the 2024 Measures Under Consideration List, which is available at https://mmshub.cms.gov/2024/2024-11/2024-measures-under-consideration-list-now-available (see the link on that website for the Excel spreadsheet).
[80] The compare tool is available at https://www.medicare.gov/care-compare.
[81] The Provider Data Catalog is available at https://data.cms.gov/provider-data.
[82] Details about the PRMR process are discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69457-69458). Under the process, consensus is reached on measure recommendations if there is at least agreement among the members of the committee involved.
[83] Of note, except for one measure, 100 percent of the members of the PRMR Hospital Recommendation Group voted to either recommend or recommend with conditions the inclusion of MA data. The exception was for the RSRR following THA and/or TKA Hospitalization measure, with respect to which 1 member voted not to recommend and the remaining members voted either to recommend or recommend with conditions.

agency states it will review the applicability of stratifying the measures by MA and FFS data and will review shortening the readmissions period as well as the criteria to include care provided in ambulatory settings.

CMS invites public comment on the proposal.

b. Technical Updates to the HRRP Measures Specifications

CMS provides notice of a technical measure set update to remove, beginning with the FY 2027 program year, the COVID-19 exclusion from the readmission measures. The update will remove (i) the exclusion of COVID-19 diagnosed patients from the index admissions and readmissions, (ii) the exclusion of certain ICD-10 codes that represented patients with a secondary diagnosis of COVID-19, and (iii) the covariate adjustment for patient history of COVID-19 in the 12 months preceding admission.

3. Additional Policies for the HRRP

a. Proposal to Modify the Applicable Period

The term "applicable period" refers to the period from which data are collected for purposes of calculating excess readmission ratios and adjustments under the HRRP. It is defined under §412.152 as a 3-year period, unless otherwise specified by the Secretary, beginning 1 year advanced from the start of the applicable period for the previous fiscal year.[84]

CMS proposes, beginning in FY 2027, to shorten the applicable period to a 2-year period to allow for more recent data for assessing performance. Specifically, the applicable period for a fiscal year would be the 2-year period beginning 1 year advanced from the start of the applicable period for the previous fiscal year. For the FY 2027 program determination, for example, the applicable period would be July 1, 2023, through June 30, 2025 (meaning that claims/encounter data with admission dates beginning during that period would be used).

CMS invites public comment.

b. Proposal to Identify Aggregate Payments for Each Condition/Procedure and All Discharges Beginning for FY 2027

CMS describes that to calculate the aggregate payments for excess readmissions, it determines the base operating DRG payment amount for each individual hospital for the applicable period for each condition/procedure. The agency does so by using Medicare FFS inpatient claims from the updated MedPAR file with discharge dates within the applicable period. The MedPAR file is updated 6 months after the end of each fiscal year within the applicable period.

Since CMS is proposing (as discussed above) to expand the measure cohorts to include MA beneficiaries, the agency proposes to include data for Medicare FFS and MA beneficiaries for

[84] Note that under §412.152 the applicable period for dual eligibility corresponds to the applicable period for the HRRP, unless otherwise specified by the Secretary.

each applicable condition/procedure to calculate the aggregate payments for excess readmission and would use the MedPAR or the latest available data source (or both) that would provide the most recent comprehensive payment data for FFS and MA beneficiaries.

Table VI.K-01 of the rule shows the agency's estimated total Medicare savings from the proposed changes to the HRRP measure set discussed in this section, including the changes to include MA data, shorten the applicable period, and update the calculations for aggregate payments to include the MA data. Compared to the current methodology, the proposed updates are estimated to result in a total of $41,132,756 in Medicare savings (13 percent reduction) and an additional 75 hospitals subject to the penalty under the HRRP (3 percent increase). The estimated average change in Medicare savings per hospital is $15,579, with 1,424 hospitals having a greater penalty amount and 1,547 hospitals having the same or lower penalty amount. In addition, Table VI.K-02 of the rule shows the estimated impacts of the proposed updates, compared to the current methodology in the HRRP, by hospital characteristic.

CMS invites comment.

c. Proposal to Update and Codify the Extraordinary Circumstances Exception (ECE) Policy

Under the current ECE policy, CMS grants exceptions to exclude data from the HRRP payment reduction calculations for extraordinary circumstances, such as natural disasters or systemic problems with CMS data collection systems that directly affect facilities' ability to submit data.

CMS proposes to update and codify at §412.154(d) its ECE regulations for the HRRP. Specifically, it proposes to update its policy to include, as an additional form of relief, that an ECE could be a deadline extension to allow a hospital additional time to comply with a data reporting requirement if the agency determines such extension would be appropriate. The policy codified at §412.154(d) would specify that CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance beyond the control of the hospital. An extraordinary circumstance would be defined as "an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year." CMS states that the process for request and granting an ECE would remain the same as the current process.[85] As proposed, §412.154(d) would specify that a hospital would be able to request an ECE within 30 calendar days of the date the extraordinary circumstance occurred.[86] In the preamble, the agency clarifies that CMS has the authority to grant an ECE at any time after the circumstance. In addition, the codified provision would clarify that CMS may grant an ECE to hospitals that have not made a request for one if CMS determines that a systemic problem with the CMS data collection system directly impacted the ability of the hospital to comply with the requirements or the circumstance has affected an entire region or locale. Any ECE granted would specify whether the hospital is

[85] The current process is available on CMS QualityNet at https://qualitynet.cms.gov/inpatient/hrrp/participation#tab2.
[86] Note that CMS QualityNet (at the above website), as of the date of this summary, specifies "Hospitals must submit a CMS Quality Program ECE Request form with **all** required information **within 90 calendar days of the extraordinary circumstance**."

(or hospitals are) exempted from reporting requirements or CMS has granted an extension for compliance.

Similar ECE proposals for the Hospital IQR Program, VBP Program, HAC Reduction Program, and PCHQR Program are discussed in section X.C.8, VI.J.5, VI.K.3, and X.D.4 of this summary, respectively.

CMS invites public comment.

J. Hospital Value-Based Purchasing (HVBP) Program[87]

1. Background

a. Program Overview[88]

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

The HVBP Program measure set is specified by CMS through rulemaking for each program (i.e., payment) year. Each hospital's TPS is calculated by summing the greater of the hospital's achievement or improvement points for each measure then creating domain scores that themselves are summed as the TPS. Finally, CMS converts the hospital TPS into a value-based incentive payment percentage through a linear exchange function, under which the sum of all hospitals' payments will equal the total amount of dollars contributed to the VBP funding pool.

b. FY 2025 Program Year Payment Details

The estimated amount of base operating MS-DRG payment reductions for the FY 2026 program year (and also the amount available for the FY 2026 VBP incentive payments) is approximately $1.7 billion, based on the December 2024 update of the FY 2024 MedPAR file.[89]

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[87] These proposals are labeled as section VI.L in the proposed rule.

[88] 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.

[89] The agency is publishing proxy value-based incentive payment adjustment factors in Table 16 of the rule, calculated using the proposed FY 2026 Hospital VBP methodology and historical baseline and performance periods for the FY 2025 Hospital VBP and SEP-1 measure, and by using the December 2024 update to the FY 2024 MedPAR file. The proxy adjustment factors will not be used to adjust hospital payments. CMS intends to provide updated tables in the FY 2026 IPPS/LTCH PPS final rule (and on the CMS website in Fall 2025) that will reflect the March 2025 update to the FY 2024 MedPAR file and the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2026 HVBP.

c. Estimated Impact Analysis

The proposed estimated impact analysis of base operating DRG payment amounts resulting from the FY 2026 HVBP Program is shown in Tables I.G.6-01 and I.G.6-02 of the rule. The estimates were calculated using the FY 2025 program year's Total Performance Scores. Table I.G.6-01 includes the Health Equity Adjustment (HEA) finalized in the FY 2024 IPPS rule, whereas Table I.G.6-02 reflects the proposal to remove the HEA (discussed below in provision 6 of this section of the summary). The analysis shows that for the 2,532 hospitals:
With the HEA, there is an average net percent positive payment adjustment of 0.17 percent, and the number of hospitals with a positive percent change in base operating DRG (51.5 percent) is higher than those with a negative change (48.5 percent).
Without the HEA, as proposed, there would be an average net percent positive adjustment of 0.168 percent, and the number of hospitals with a negative percent change in base operating DRG (50.8 percent) would be higher than those with a positive percent change (49.2 percent).

2. HVBP Program Measures

a. Proposed Updates to Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP-HIP-KNEE Measure)

Background. The COMP-HIP-KNEE measure was adopted for use in the HVBP Program beginning with the FY 2019 program year.[90]

Overview of Proposed Updates. CMS proposes to adopt, beginning with the FY 2033 program year, substantive measure updates to the COMP-HIP-KNEE measure in the HVBP Program under the Clinical Outcomes Domain, contingent on the agency's adoption of the same updates (discussed in section X.C of the summary) to the measure for use in the Hospital IQR program beginning with the FY 2027 payment determination. Specifically, the updates would (i) expand the measure's inclusion criteria to include MA patients, and (ii) shorten the performance period from 3 years to 2 years. CMS believes including MA data would more accurately reflect the quality of care for Medicare beneficiaries (as this would double the cohort size) and that reducing the performance period would provide more relevant and recent quality information for actionable improvements.

The proposed updates would use the following data:

- Index admission diagnoses and procedure codes from Medicare FFS claims and MA encounter data to determine cohort inclusion criteria, complications outcomes, and present on admission (POA) comorbidities.
- Part A inpatient, outpatient, and Part B office visit claims and MA encounters during the 12 months prior to the index admission to assess additional comorbidities before the index admission.

[90] FY 2015 IPPS/LTCH PPS final rule (79 FR 50062-50063).

- Medicare enrollment data to determine Medicare FFS or MA enrollment status.

CMS would begin posting the updated measure data on the Compare tool beginning in July 2026. This would allow the agency to post data on the updated measure for at least one year before the proposed adoption beginning with April 1, 2029, through March 31, 2031, performance period associated with the FY 2033 payment determination.[91]

Pre-Rulemaking. A discussion of the PRMR process for the measure is under section X.C of the summary. The original measure was endorsed by the CBE in July of 2021. CMS submitted the proposed updated measure (CBE #1550) for re-endorsement for the Fall 2024 cycle, but the E&M Cost and Efficiency Committee did not reach consensus, and the measure was not re-endorsed. The committee raised concerns about the case mix of patients, specifically that with the shift to outpatient for these procedures healthier patients may be directed to ambulatory surgical centers, resulting in acute care hospitals left with higher-risk patients. Concern was also raised about the limited scope of the measure including only inpatient complications and about adjusting low-volume provider performance to the average. CMS notes the measure's focus on higher-risk patients is intentionally narrow to capture significant complications and that the adjustment for low patient volume allows for the performance scores to be available for as many providers as possible.

CMS therefore proposes to adopt the updated measure, consistent with the exception for measures not endorsed by the consensus-based entity (non-CBE-endorsed measures),[92] having found no currently available, alternative CBE-endorsed measure on the medical topic.

CMS invites public comment.

b. Technical Updates to the COMP-HIP-KNEE Measure Specifications to Update the Risk Adjustment Model Beginning with the FY 2027 Program Year

CMS provides notice of its intent to make a non-substantive modification to the COMP-HIP-KNEE measure to update the risk adjustment model to use individual ICD-10 codes instead of grouping them into HCCs.[93] CMS states that research indicates that using individual ICD codes for risk adjustment instead of HCCs could improve the risk adjustment model performance with respect to mortality measures.

c. Technical Updates to the 5 Condition- and Procedure-Specific Mortality Measures and COMP-HIP-KNEE Measure Specifications Beginning with the FY 2027 Program Year

CMS provides notice of a technical measure set update to remove, beginning with the FY 2027 program year, the COVID-19 exclusions from certain measures. Specifically, the following changes to the technical specifications will be made:

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[91] Section 1886(o)(2)(C)(i) of the Act requires a measure to be included on the Hospital Compare Internet website for at least 1 year before the performance period for the first fiscal year for which the measure is included in the HVBP Program.
[92] Section 1886(b)(3)(B)(viii)(IX)(bb) of the Act.
[93] See §412.164(c)(1) for the policy to use the subregulatory process for technical updates.

- The measure denominators for the MORT-30-AMI, MORT-30-CABG, MORT-30-COPD, MORT-30-HF, and MORT-30-PN measures[94] will include the ICD-10 codes identifying patients with a principal or secondary diagnosis of COVID-19.
- The numerator and denominator of the COMP-HIP-KNEE measure will include the ICD- codes identifying patients with a principal or secondary diagnosis of COVID-19.
- The covariate adjustment for patient history of COVID-19 in the 12 months prior to admission will be removed for all of the above 6 measures.

d. Summary of Previously Adopted Quality Measures for the HVBP Program

Table V.L-02 in the rule shows the previously adopted measures for the FY 2026 program year and Table V.L-03 in the rule shows the previously adopted measures for the FY 2027 through FY 2031 program years. The below table consolidates the information.

Measure	CBE[95]	2026	2027-2031
Clinical Outcomes Domain			
Acute Myocardial Infarction (AMI) 30-day mortality rate (MORT-30-AMI)	0230	X	X
Heart Failure (HF) 30-day mortality rate (MORT-30-HF)	0229	X	X
Pneumonia (PN) 30-day mortality rate (MORT-30-PN)	0468	X	X
Chronic Obstructive Pulmonary Disease (COPD) 30-day mortality rate (MORT-30-COPD)	1893	X	X
Coronary Artery Bypass Graft (CABG) 30-day mortality rate (MORT-30-CABG)	2558	X	X
Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP-HIP-KNEE)	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	X
Person and Community Engagement Domain			
Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Communication with Nurses Communication with Doctors Responsiveness of Hospital Staff* Communication About Medicines Discharge Information Care Transition* Cleanliness and Quietness of Hospital Environment Overall Rating of Hospital	0166 0228	X	X*

[94] The longer description names for these measures are provided in the table below.
[95] Consensus-based entity identifier number for endorsed measures.

Efficiency and Cost Reduction Domain			
Medicare Spending per Beneficiary (MSPB)	2158	X	X

* In the FY 2025 IPPS/LTCH PPS final rule, the updated HCAHPS measure was adopted into the HVBP Program beginning with the FY 2030 program year (89 69508-69511). The Care Transition and Responsiveness of Hospital Staff dimensions will be included in the survey but not scored for FYs 2027-2029 and will not be included in the survey beginning with FY 2030.

3. Baseline and Performance Periods for the FY 2027 Through FY 2031 Program Years

The below table combines information shown in Tables VI.L.-04 through VI.L.-08 to show the baseline and performance periods previously adopted for FY 2027 through FY 2031.

Baseline and Performance (Perf.) Periods by Measure for the FYs 2027 Through 2031 Program Years										
Measure	Baseline Period 2027	Perf. Period 2027	Baseline Period 2028	Perf. Period 2028	Baseline Period 2029	Perf. Period 2029	Baseline Period 2030	Perf. Period 2030	Base-line Period 2031	Perf. Period 2031
Person and Community Engagement Domain										
HCAHPS	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	1/1/27-12/31/27	1/1/29-12/31/29
Safety Domain										
NHSN Measures *	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	1/1/27-12/31/27	1/1/29-12/31/29
SEP-1	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	1/1/27-12/31/27	1/1/29-12/31/29
Clinical Outcomes Domain										
Mortality measures^	7/1/17–6/3/20**	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	7/1/25-6/30/28	7/1/21-6/30/24	7/1/26-6/30/29
COMP-HIP-KNEE	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	4/1/21-3/31/24	4/1/26-3/31/29
Efficiency and Cost Reduction Domain										
MSPB	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	1/1/27-12/31/27	1/1/29-12/31/29
Source: Tables VI.L.-04 through VI.L.-08 in the rule, excerpted and combined by HPA										

* NHSN measures include CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, and MRSA Bacteremia
^ Mortality measures include MORT-30-AMI; MORT-30-HF; MORT-30-COPD; MORT-30-CABG; MORT-30-PN
** 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 and mortality measures. See the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297-45299).

4. Performance Standards for the HVBP Program

a. Technical Update to 5 National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) Measures

As part of routine measure maintenance, CMS plans to modify the standard population data used to calculate the standardized infection ratio (SIR) for the CDC's NHSN measures. For each of these measures, CDC calculates the SIR. The SIR compares a hospital's observed number of HAIs to the number of infections predicted for the hospital, adjusted for risk factors. The

predicted number of infections is determined by using the amount of exposure for a hospital according to the observed risk factors and infection rates for the same combination of risk factors occurring among a standard population during a specified period (i.e., the standardized population data or baseline data). CDC has been using data collected in 2015 to determine the standard population data.

CMS describes that for this CDC baseline update, both new 2022 standard population data and the 2015 standard population data will be used for HAI SIR calculations reported beginning in 2025. Since the HVBP calculates improvement points by comparing data collected during a baseline period and data from a performance period, CMS explains it cannot compare CDC's new 2022 baseline data to the current 2015 baseline data for calculating improvement points. Therefore, CMS will use the 2015 baseline data for calculating performance standards and measure scores until the FY 2029 program year. Beginning with the FY 2029 program year it will use the new 2022 baseline data.

b. Previously and Newly Established Performance Standards

The previously established performance standards for FY 2027 are not affected by the proposals in the rule. CMS is establishing new performance standards for the measures in the Clinical Outcomes domain for the FY 2028 through 2031 program years because of the technical updates being made to that domain. The newly established and estimated performance standards for the FY 2028 program year are shown in Table VI.L.-11 of the rule. The newly established and estimated performance standards for the FY 2029, 2030, and 2031 program years specifically for the measures in the Clinical Outcomes domain and for the MSPB measure are shown in Table VI.L.-13, Table VI.L.-14, and Tables VI.L.-15, respectively, of the rule. Since the performance standards for the MSPB measure are based on performance period data, CMS is unable to provide numerical equivalents for the standards at this time.

CMS reviews its finalized modifications adopted in the FY 2025 IPPS/LTCH PPS final rule to the scoring of the HCAHPS Survey for the FY 2027 through FY 2029 program years. During that period, the (i) Responsiveness of Hospital and (ii) Care Transition dimensions will be excluded from scoring while the updated survey is publicly reported under the Hospital IQR Program for one year. Scoring was modified to score hospitals on only the remaining 6 HVBP Program dimensions of the survey during that period. Specifically, scoring is modified such that the achievement points (0-10) and improvement points (0-9) are calculated for each of the 6 remaining dimensions, the larger of which is summed up across the dimensions, resulting in a base score of 0-60 points (as compared to 0-80 points). That score will then be multiplied by 8/6 to establish the normalized HCAHPS base score, ranging from 0-80 points. HCAHPS consistency points (ranging from 0-20) are calculated without change and added to the normalized base score (as is currently) for a total score that ranges from 0-100 points. The estimated performance standards for the 6 dimensions for the FY 2028 program year are shown in Table VI.L.12 of the rule.

5. Proposals to Update the ECE Policy

Under the current ECE policy, CMS grants exceptions from the HVBP Program requirements for extraordinary circumstances beyond the control of the hospital.

CMS proposes to update the ECE policy at §412.165(c) to clarify the policy and to include extensions of deadlines, as an additional form of relief. The clarifications would specify that CMS may grant an ECE with respect to reporting requirements in the case of an extraordinary circumstance beyond the control of a hospital. An extraordinary circumstance would be defined as "an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year." CMS states that the process for hospitals to request and CMS to grant an ECE would remain the same as the current process.[96] CMS proposes that a hospital would be able to request an ECE within 30 calendar days of the date the extraordinary circumstance occurred (as opposed to the current 90 days) in order to align with other quality reporting programs. In the preamble of the rule, CMS clarifies its authority to grant an ECE at any time after the circumstance. As proposed, §412.165(c) would state that CMS may grant an ECE to hospitals that have not made a request for one if CMS determines that a systemic problem with the CMS data collection system directly impacted the ability of the hospital to comply with the requirements or the circumstance has affected an entire region or locale. Any ECE granted would specify whether the hospital is (or hospitals are) exempted from reporting requirements or CMS has granted an extension for compliance.

Similar ECE proposals for the Hospital IQR Program, HRRP, HAC Reduction Program, and PCHQR Program are discussed in section X.C.8, VI.I.5, VI.K.3, and X.D.4 of this summary, respectively.

CMS invites public comment.

6. Proposed Removal of Health Equity Adjustment (HEA)

CMS adopted the HEA in the FY 2024 IPPS/LTCH PPS final rule, which is scheduled to apply beginning with the FY 2026 program year to reward top performing hospitals that serve higher proportions of patients with dual eligibility status (DES).

CMS is proposing to remove the HEA because the agency believes that its removal would simplify the HVBP Program's scoring methodology and consequently make the program more understandable and provide clearer incentives to hospitals. The agency states that this proposal is consistent with the Administration's priority to streamline regulations and reduce burdens. If finalized, the HEA would be removed beginning for the FY 2026 program year.

CMS welcomes public comment.

[96] The current process is available on CMS QualityNet at https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.

K. Hospital-Acquired Conditions (HAC) Reduction Program[97]

1. Background

The HACRP 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 HACRP'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.

CMS estimates that for the FY 2026 HAC Reduction Program, out of 2,933 hospitals, 732 hospitals will be included in the worst-performing quartile (and subject to the program's penalty).[98]

2. Measures for FY 2026 and Subsequent Years[99]

a. Current Measure Set

CMS does not propose any additions to or removals from the measure set. There are currently the following 6 measures in the HACRP for FY 2026 and subsequent years:

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

[97] These proposals are labeled as section VI.M in the proposed rule.
[98] See Table I.G.7-01 in the rule.
[99] 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.

- 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).

b. Technical Update to CDC's NHSN HAI Measures

As part of routine measure maintenance, CMS is making changes to the standard population data used to calculate the standardized infection ratio (SIR) for the CDC's NHSN measures. For each of these measures, CDC calculates the SIR, which compares a hospital's observed number of HAIs to the number of infections predicted for the hospital, adjusted for risk factors. The predicted number of infections is determined by using the amount of exposure for a hospital according to the observed risk factors and infection rates for the same combination of risk factors occurring among a standard population during a specified period (i.e., standardized population data). CDC has been using data collected in 2015 to determine the standard population data.

CMS describes that for this CDC baseline update, both new 2022 standard population data and the 2015 standard population data will be used for HAI SIR calculations reported beginning in 2025. CMS anticipates the new 2022 data will affect the HACRP beginning with the FY 2028 program year when both years of the 2-year performance period of the measures (2025 and 2026) will use the 2022 data. The HAI measures using the 2022 data will begin to be publicly reported on the Compare tool in Fall 2026 using four quarters of 2025 data. The 2028 HACRP dataset with the HAI measures using the 2022 data would be publicly reported on the Provider Data Catalog in early 2028.

CMS invites public comment even though it states it is not required to do so on technical updates.

3. Proposal to Codify ECE Policy

Under the current ECE policy, CMS grants under the HACRP exceptions from quality data reporting requirements when there are extraordinary circumstances beyond the control of the hospital.

CMS proposes to codify the ECE policy at §412.172(c) and to include extensions of deadlines, as an additional form of relief. The regulatory section would specify that CMS may grant an ECE with respect to reporting requirements in the case of event of extraordinary circumstances that are beyond the control of the hospital. An extraordinary circumstance would be defined as "an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year." CMS states that the process for hospitals to request and CMS to grant an ECE would remain the same as the current process.[100] CMS proposes that a hospital would be able to request an ECE within 30 calendar days of the date the extraordinary circumstance occurred, and to

[100] The current process is available on CMS QualityNet at https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.

clarify its authority to grant an ECE at any time after the circumstance. CMS would also clarify that it may grant an ECE to hospitals that have not made a request for one if CMS determines that a systemic problem with the CMS data collection system directly impacted the ability of the hospital to comply with the requirements or the circumstance has affected an entire region or locale. Any ECE granted would specify whether the hospital is (or hospitals are) exempted from reporting requirements or CMS has granted an extension for compliance.

Similar ECE proposals for the Hospital IQR Program, HRRP, HVBP Program, and PCHQR Program are discussed in section X.C.8, VI.I.3.c, VI.J.5, and X.D.4 of this summary, respectively.

L. 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. There are currently 20 hospitals participating in the demonstration.

In 2024, CMS published a solicitation (CMS-5051-N2; 89 FR 105049) to select 10 additional qualifying hospitals to participate in the demonstration program; however, applications were only accepted from hospitals in the 20 least densely populated States. Applications were due March 1, 2025; CMS will select hospitals on a rolling basis beginning May 1, 2025. Because the demonstration program will terminate on June 30, 2028, CMS will align performance dates for the selected hospitals with the last performance day for the currently authorized extension of the program. Thus, even though previous agreements ran for 5-year periods, agreements for hospitals selected under CMS-5051-N2 will run only until June 30, 2028.

The statute requires CMS to make the demonstration program budget neutral by applying an adjustment to IPPS rates that affect 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 2026 Budget Neutrality Adjustment

CMS proposes to continue to use its general budget neutrality methodology applied in previous years for the 20 hospitals currently participating in the program. Using data from "as submitted"

cost reports with a cost report end date in CY 2023, CMS estimates that the demonstration program will cost $47,527,557, which will be incorporated into the budget neutrality offset adjustment for FY 2026.

As of the date of publication of the proposed rule, not all the finalized cost reports for the 20 hospitals that completed cost reporting periods beginning in FY 2020 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 2020 as determined from finalized cost reports within the budget neutrality offset amount in the final rule.

The total budget neutrality adjustment for FY 2026 is estimated to be $47,527,557. 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 2020 upon receipt of all finalized cost reports for that fiscal year.

VII. Changes to the IPPS for Capital-Related Costs

National Capital Federal Rate for FY 2026. For FY 2025, CMS established a national capital Federal rate of $512.14. CMS is proposing a national capital Federal rate of $528.95 for FY 2026.

Update Factor:

For FY 2026, CMS will increase the national capital Federal rate by 3.28 percent based on the capital input price index (CIPI) of 2.6 percent and other factors shown in Table 1 below as well as further adjustments under "*Other Adjustments*."

CMS is not adopting any change to the capital update for intensity. For FY 2026, CMS projects a 0.5 percent increase in the total case-mix index (CMI). CMS estimates that the real case-mix increase will equal 0.5 percent for FY 2026. 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 is 0.0 percent, CMS is not proposing to apply an adjustment for case mix change in the FY 2026 capital update framework.

The reclassification and recalibration adjustment accounts for the difference between the budget neutrality adjustment that CMS applied in FY 2024 compared to what it would be based on later data. CMS is not proposing to make an adjustment for FY 2024 reclassification and recalibration in the update framework for FY 2026.

CMS makes a forecast error correction if the forecast CIPI used for the update in a past year (FY 2024 for FY 2026) differs from the actual CIPI based on later information by more than 0.25 percentage point. The CIPI used in the FY 2024 update was 2.9 percent. Its later determined level was 2.8 percent or a difference of -0.1 percentage points. As the -0.1 percentage point

difference is less than the 0.25 percentage point threshold for making a forecast error correction adjustment, CMS is not proposing to make an adjustment to the capital update for forecast error correction.

Table 1

CMS FY 2026 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE		
FY 2026-based CIPI		2.6
Intensity		0.0
Case-Mix Adjustment Factors:		
Projected Case Mix Change	0.5	
Real Across DRG Change	0.5	
Net Case-Mix Adjustment (Projected - Real)		0.0
Effect of FY 2024 Reclassification and Recalibration		0.0
Forecast Error Correction		0.0
Total Update		2.6

Other Adjustments:

For FY 2025, CMS estimated that outlier payments would be 4.23 percent of total capital IPPS payments. For FY 2026, CMS estimates that outlier payments will be 4.16 percent of total capital payments before accounting for outlier reconciliation and 4.13 percent after subtracting 0.03 percentage points for outlier reconciliation. Therefore, the FY 2026 outlier adjustment factor is 0.9587 (-4.13 percent), compared to 0.9577 (-4.23 percent) in FY 2025. The net change is 1.0011 (0.9587/0.9577) or 0.11 percent. Thus, the outlier adjustment increases the FY 2026 capital federal rate by 0.11 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 in the budget neutrality adjustment. To determine the GAF budget neutrality factors, CMS compares estimated aggregate capital Federal rate payments based on the MS-DRG classifications and relative weights in combination with the GAFs.

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

Isolate the impact of the change to the wage index (including changes to wage data, geographic reclassification and the rural floor but excluding the 5 percent cap on wage index decreases and the transitional exception for low-wage index hospitals).
Isolate the impact of the 5 percent cap on wage index decreases and the transitional exception for low-wage index hospitals.

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 5 percent cap on the wage index, CMS proposes to divide the capital Federal rate by 0.9992, which was the effect of the 5 percent cap in FY 2025. (As no budget neutrality was applied in FY 2025 for the transitional exception wage index for low-wage index hospitals, this factor only reflects the 5 percent cap in FY 2025).

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

Isolate the impact of the change to the wage index (e.g., without the 5 percent cap on reductions to the wage index and the transitional exception for low-wage index hospitals). CMS determined a budget neutrality adjustment of 1.0140 for this factor for FY 2026.
Isolate the impact of the 5 percent cap and the transitional exception for low-wage hospitals. CMS determined a GAF budget neutrality factor of 0.9927 for FY 2026.

CMS also incorporates an adjustment for FY 2026 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 0.9982. The incremental adjustment for the 10 percent cap on reductions to the DRG relative weights is 0.9999. The total adjustment is 0.9982 (0.9982 x 0.9999) for DRG reclassification and recalibration.

The combined adjustment due only to the wage index in step 1 above and for changes for MS-DRGs and recalibration is 1.0121 (1.0140 x 0.9982, or 1.21 percent). The wage index and transitional exception for low-wage index hospitals of 0.9927 (or -0.73 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 2026 national capital Federal rate compared to the FY 2025 national capital Federal rate.

Comparison of Factors and Adjustments:
FY 2025 and FY 2026 Capital Federal Rate

	FY 2025	Proposed FY 2026	Change	Percentage Change
Update Factor[1]	N/A	1.0260	1.0260	2.60
GAF/DRG Adjustment Factor[1]	N/A	1.0121	1.0121	1.21
WI Cap/Transitional Exception[2]	0.9992	0.9927	0.9935	-0.65
Outlier Adjustment Factor[2]	0.9577	0.9587	1.0011	0.11
Capital Federal Rate	$512.14	$528.95	1.0328	3.28

[1] 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 2025 to FY 2026 resulting from the application of the GAF/DRG budget neutrality adjustment factor for FY 2026 is a net change of 1.0121 or 1.21 percent).
[2]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 2026 outlier adjustment factor is 0.9587/0.9577, or 1.0011

(or 0.11 percent). The net change to the wage index cap and transitional exception is 0.9927/0.9992 or 0.9935 (-0.65 percent).

Considering the update factor and the budget neutrality adjustments, CMS is proposing to adopt a national capital Federal rate for FY 2026 of $528.95, a 3.28 percent increase over the FY 2025 rate of $512.14.

VIII. 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 and one hospital classified as an extended neoplastic disease care hospital. 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 2024 4th quarter forecast of the hospital market basket for FY 2026 with historical data through the 3rd quarter of 2024 and is 3.2 percent. The FY 2026 market reflects CMS proposal to rebase and revise the hospital market basket from a 2018 to 2023 base year.

B. Critical Access Hospitals (CAHs)

The Frontier Community Health Integration Project (FCHIP) Demonstration[101] 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

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

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's 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 a result of the demonstration extension period.

CMS is not proposing to make any budget neutrality adjustment in FY 2026 for the FCHIP demonstration project.

IX. 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 those 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 2026:

- 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.[102] 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.

[102] 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.

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 qualifying period), it must demonstrate that it has the requisite ALOS for 5 consecutive months during that qualifying period.

Summary of Proposed Changes to LTCH PPS Rates for FY 2026*	
Standard Federal Rate, FY 2025	$49,383.26
Proposed Rule Update Factors	
Update per Section 1886(m)(3)(C) of the Act (including MFP reduction)	+2.6%
Penalty for hospitals not reporting quality data (including MFP reduction)	-2.0%
Net update, LTCHs reporting quality data	+2.6% (1.026)
Net update LTCHs not reporting quality data	+0.6% (1.006)
Proposed Rule Adjustments	
Proposed area wage index budget neutrality adjustment	1.0012146
Proposed Standard Federal Rate, FY 2026	
LTCHs reporting quality data ($49,383.26 x 1.026 x 1.0012146)	$50,728.77
LTCHs not reporting quality data ($49,383.26 x 1.006 x 1.0012146)	$49,739.90
Proposed Fixed-loss Amount for High-Cost Outlier (HCO) Cases	
LTCH PPS standard federal payment rate cases	$91,247
Site neutral payment rate cases (same as the IPPS fixed-loss amount)	$44,305
Impact of Proposed Policy Changes on LTCH Payments in FY 2026	
Total estimated impact	2.5% (~ $61 million)
LTCH standard federal payment rate cases (90% of LTCH cases)	2.2% (~ $52 million)
Site neutral payment rate cases (10% of LTCH cases)**	8.5% (~ $9 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 2026". 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 2025, the annual recalibration of the MS-LTC-DRG relative weights for FY 2026 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 would be incorporated into the MS-LTC-DRG system for FY 2026 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 43 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 2026 MS-LTC-DRG Relative Weights Methodology

For FY 2026, as it did 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 2026 MS-LTC-DRG relative weights.

a. Proposed Relative Weights Source Data

FY 2026 proposed relative weights are derived from the December 2024 update of the FY 2024 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 section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID-19 PHE period. Thus, 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. For purposes of setting rates for LTCH PPS standard federal rate cases for FY 2026 (including MS-LTC-DRG relative weights), CMS proposes to

identify FY 2024 cases that meet the statutory patient criteria depending on date of admission as follows. First, it would use LTCH PPS cases in the FY 2024 MedPAR file with an admission date after May 11, 2023, that met the criteria for exclusion from the site neutral payment rate under §412.522(b) and were paid the LTCH PPS standard Federal rate in FY 2024 (based on the claim payment amount). Second, it would also use LTCH PPS cases in the FY 2024 MedPAR file with an admission date on or before May 11, 2023, that would have met the criteria for exclusion from the site neutral payment rate if the CARES Act waiver had not been in effect; for these cases, CMS proposes to use its historical process for identifying cases that would have met the criteria for exclusion from the site neutral payment rate rather than how those cases were paid in FY 2024.

The filtered data are trimmed to exclude all-inclusive rate providers, Medicare Advantage claims (which are identified based on the presence of a GHO Paid indicator value of "1" in the MedPAR files), and demonstration project participants; this yields "applicable LTCH data."

b. Remove cases with a length of stay of 7 days or less

CMS proposes to remove cases with a length of stay of 7 days or less from applicable LTCH cases.

c. 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 239 such MS-LTC-DRGs in the claims, and the quintiles each contained at least 47 MS-LTC-DRGs (239/5 = 47 with a remainder of 4). 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. In cases where these initial assignments of low-volume MS-LTC-DRGs to quintiles results in nonmonotonicity within a base-DRG, CMS proposes to make adjustments to the resulting low-volume MS-LTC-DRGs to preserve monotonicity.

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.)

d. Remove Statistical Outliers

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

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

e. 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 2026.

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

CMS proposes to continue to use its HSRV methodology in FY 2026 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.

g. 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 continues to believe 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 2026 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.

h. 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 (419 of these MS-LTC-DRGs are identified for the proposed rule), CMS proposes to continue to cross-walk that no-volume 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 391 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 355 (774 – 419 = 355) MS-LTC-DRGs for which it calculated relative weights based on the trimmed applicable LTCH cases in the FY 2024 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 2026 MS-LTC-DRGs with no applicable LTCH cases. The agency notes that this system is dynamic and that it is entirely possible that the number of MS-LTC-DRGs with no volume would vary in the future.

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).

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 using its existing methodology to achieve budget neutrality for the FY 2026 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 2026; one before the application of the 10-percent cap (referred to as the "uncapped relative weights") and the other after application of that cap.

(1) Normalizing the Relative Weights

CMS proposes to normalize relative weights using its established methodology for FY 2026. 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 2026, 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."

(2) Budget neutrality for uncapped relative weights.

As noted above, 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 2024 MedPAR file, and groups them using Version 43 of the GROUPER and the proposed recalibrated FY 2026 MS-LTC-DRG uncapped relative weights to calculate the average case-mix index. Next, it groups the same

applicable LTCH cases using the FY 2025 GROUPER (Version 42) and FY 2025 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 2025 by the average case-mix index for FY 2026. As a result, in determining the proposed MS-LTC-DRG relative weights for FY 2026, each recalibrated MS-LTC-DRG uncapped relative weight is multiplied by the proposed normalization factor of 1.24603 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 2026 LTCH PPS standard federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2026 LTCH PPS standard federal payment rate payments for applicable LTCH cases after reclassification and recalibration. CMS calculates a proposed budget neutrality factor of 1.0112216, which is applied to each uncapped normalized relative weight.

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

Under its policy to limit reductions in relative weights to 10 percent in a given year, the 10-percent cap is only applied to the relative weights for MS-LTC-DRGs with at least 25 applicable LTCH cases. For any MS-LTC-DRG where the FY 2025 relative weight would otherwise have been reduced by more than 10 percent, CMS proposes a capped FY 2026 MS-LTC-DRG relative weight equal to 90 percent of that MS-LTC-DRG's FY 2025 relative weight.

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

CMS proposes to continue using 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 2026 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2026 (determined in Step 10) and proposed GROUPER Version 43;
- Simulate estimated total FY 2026 LTCH PPS standard federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2026 (determined in Step 9) and proposed GROUPER Version 43; and
- Calculate the ratio of the estimated total payments.

The proposed budget neutrality adjustment factor for the 10-percent cap is 0.9984259. To determine the proposed FY 2026 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 11-step process to determine MS-LTC-DRG relative weights is provided in the proposed rule (pages 786 through 806 of the display copy).

C. Payment Rates and Other Changes

1. Overview LTCH PPS Standard Federal Payment Rates

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

2. Proposed FY 2026 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

CMS adopted the 2022-based LTCH market basket for use under the LTCH PPS beginning in FY 2025, which was primarily based on the Medicare cost report data submitted by LTCHs and used data from cost reporting periods beginning on and after April 1, 2021, and before April 1, 2022. The agency proposes to use the 2022-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2026.

The proposed update to the 2022-based LTCH market basket is 3.4 percent (based on IGI's fourth quarter 2024 forecast of the 2022-based LTCH market basket) less 0.8 percentage points for multifactor productivity (renamed by BLS to be the total factor productivity (TFP)), which results in an update factor of 1.026 to the FY 2025 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 (PP). CMS notes that the "other adjustment" under section 1886(m)(4)(F) of the Act does not apply for FY 2026. The proposed LTCH updates for FY 2026 are as follows:

Factor	Full Update	Reduced Update for Not Submitting Quality Data
LTCH Market Basket	3.4%	3.4%
Multifactor Productivity	-0.8 PP	-0.8 PP
Quality Data Adjustment	0.0	-2.0 PP
Total	2.6%	0.6%

3. Area Wage Levels and Wage-Index

a. Proposed Labor Market Areas

CMS adopted the revised labor market area delineations announced in OMB Bulletin No. 23-01[103] (issued on July 21, 2023) effective for FY 2025 under the LTCH PPS. It proposes to continue their use for FY 2026.

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

The proposed FY 2026 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 2026 labor-related share of 73.1 percent based on IGI's fourth quarter 2024 forecast of the 2022-based LTCH market basket. This is based on the sum of the labor-related portion of operating costs (69.2 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 2026 LTCH PPS labor-related share if the data are available before the publication of that final rule.

c. Proposed Wage Index for FY 2026 for the Standard Federal Rate

To determine the applicable area wage index values for the FY 2026 LTCH PPS standard federal payment rate, CMS proposes to use the same data it would use to compute the proposed FY 2026 acute care hospital inpatient wage index, which uses wage data for cost reporting periods beginning during FY 2022. The FY 2026 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. CMS 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 for 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 2026 LTCH PPS standard federal payment rate area wage level adjustment budget neutrality factor of 1.0012146.

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 2026 which are unchanged from the COLAs in effect for FY 2025.

Area	Proposed FY 2026
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

CMS seeks comment on any possible data sources that could be considered in the development of the COLA factors beyond its current methodology.[104]

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 2024 update of the Provider Specific File (PSF). Thus, it proposes a LTCH total CCR ceiling of 1.359 under the LTCH PPS for FY 2026 for HCO cases under either payment rate and for the site neutral payment rate.

[104] See discussion in the FY 2022 IPPS/LTCH PPS final rule, 86 FR 45559.

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 2024 update of the PSF. They would be effective for discharges occurring on or after October 1, 2025, through September 30, 2026.

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.

(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 2024 update of the FY 2024 MedPAR file and the December 2023 update of the FY 2023 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 1.125512, and a 2-year charge inflation factor of 1.266777 (calculated by squaring the 1-year factor). It proposes to inflate the billed charges obtained from the FY 2024 MedPAR file by this 2-year charge inflation factor of 1.266777 when determining the proposed fixed-loss amount for LTCH PPS standard federal payment rate cases for FY 2026.

(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. For FY 2026, 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 2026, CMS used the December 2024 PSF as the most recently available PSF and the December 2023 PSF as the PSF that was made available one year prior to the most recently available PSF. It also used claims from the December 2024 update of the FY 2024 MedPAR file in calculating the average case-weighted CCRs in the last step of the methodology. CMS calculated a December 2023 national average case-weighted CCR of 0.238634 and a December 2024 national average case-weighted CCR of 0.226588, which results in a proposed 1-year national CCR adjustment factor of 0.949522.

(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 2024 update of the FY 2024 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2024 update of the PSF, CMS calculated a proposed fixed-loss amount for standard federal rate cases of $91,247 for FY 2026.

CMS notes that the proposed fixed-loss amount for FY 2026 ($91,247) is approximately $14,000 higher than the fixed-loss amount for FY 2025 ($77,048). Comment is sought on the proposed fixed-loss amount, which the agency will consider when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 in the final rule. CMS does not propose any alternatives to its established methodology in the proposed rule.

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 2026, CMS proposes a fixed-loss amount for site neutral payment rate cases of $44,305. CMS also proposes a budget neutrality factor of 0.949 for site neutral payment rate cases for FY 2026. 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 2026, the DSH/uncompensated care amount would equal 70.53 percent of the operating Medicare DSH payment amount, based on the statutory Medicare DSH payment formula prior to the amendments made by the ACA, adjusted to account for reduced payments for uncompensated care resulting from expansion of the insured population under the ACA.

D. Impacts

CMS projects that the overall impact of the proposed payment rates and factors for all LTCHs will result in an increase of 2.5 percent (or approximately $61 million) in aggregate payments.

Based on the FY 2024 LTCH cases that were used for the analysis in this proposed rule, approximately 10 percent of those cases were classified as site neutral payment rate cases. CMS estimates that aggregate LTCH PPS payments for these site neutral payment rate cases would increase by approximately 8.5 percent (or approximately $9 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. The agency estimates payments to site neutral payment rate cases in FY 2026 will represent approximately 4.5 percent of estimated aggregate FY 2026 LTCH PPS payments.

CMS found that approximately 90 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2026, which 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 2026 will increase by approximately 2.2 percent (or approximately $52 million), which is primarily due to the projected 2.6 percent

annual update to the LTCH PPS standard federal payment rate being partially offset by a projected 0.3 percent decrease in high-cost outlier payments as a percentage of total LTCH PPS standard federal payment rate payments.

CMS estimates that aggregate FY 2026 LTCH PPS payments will be approximately $2.558 billion, as compared to estimated aggregate FY 2025 LTCH PPS payments of approximately $2.497 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 2026" 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. Selected excerpts from that table are shown below.

Summary of Impact of Changes to LTCH PPS Standard Federal Payment Rate Cases for FY 2026		
	Number of LTCHs	**Estimated Percent Change in Payments per Discharge**
All LTCH providers	327	2.2%
By Location:		
Rural	17	2.5%
Urban	310	2.2%
By Ownership Type:		
Voluntary	53	2.8%
Proprietary	266	2.1%
Government	8	1.8%
By Region		
New England	10	2.1%
Middle Atlantic	20	3.5%
South Atlantic	60	2.4%
East North Central	46	2.8%
East South Central	32	3.0%
West North Central	21	3.2%
West South Central	90	1.2%
Mountain	25	1.6%
Pacific	23	1.7%
*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 2026" on pages 1328-1329 of the display copy.		

X. Quality Data Reporting Requirements for Specific Providers and Suppliers

A. Overview

In this section, CMS issues an RFI on digital quality measurement in the CMS quality programs, as well as seeks comment on and proposes changes to the Hospital Inpatient Quality Reporting (HIQR) 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. Toward Digital Quality Measurement in CMS Quality Programs - RFI

1. Background.

In support of the agency's transition to digital quality measurement (dQM), CMS is seeking feedback on its anticipated approach to use the Health Level Seven® (HL7) Fast Healthcare Interoperability Resources® (FHIR) in electronic quality measure (eCQM) reporting. The HIQR Program, Hospital Outpatient Quality Reporting (HOQR) Program, and Medicare Promoting Interoperability Program all use (or are considering using) eCQMs. The agency is seeking comment on FHIR-based eCQM activities in those programs and anticipates including a similar RFI in the 2026 Physician Fee Schedule proposed rule with respect to the Medicare Shared Savings Program (MSSP) and Merit-based Incentive Payment System (MIPS) quality performance category. CMS is also seeking comment in this RFI for the IPFQR Program, and in addition is seeking feedback in a similar RFI issued in section IV.H.3 of the FY 2026 Inpatient Psychiatric Facility Prospective Payment System proposed rule as well.

CMS reviews its collaboration efforts with the Assistant Secretary for Technology Policy (ASTP), the Office of the National Coordinator for Health Information Technology (ONC), and other federal agencies for data standardization and alignment of requirements for developing and reporting digital quality measures. CMS describes many collaboration efforts to modernize and standardize reporting of quality data, including CMS' collaboration with ASTP and ONC on future versions of the United States Code Data for Interoperability (USCDI), USCDI+, and the advancement of interoperability of patient assessment data, as well as CMS' collaboration with the CDC National Healthcare Safety Network (NHSN) on transitioning to fully automated digital quality measures for reporting quality measures to CMS through the NHSN data system.[105] CMS believes that using the FHIR standard will help the transition to future digital quality measures, which in turn the agency believes will reduce provider burden, support the patient experience, and improve quality of care.

2. Approach to eCQM Reporting using FHIR: HIQR, HOQR, and Medicare Promoting Interoperability Programs

CMS requests comment on each of the following four components of the dQM transition to FHIR-based eCQMs for the HIQR Program, HOQR Program, and Medicare Promoting Interoperability Program: (i) eCQM FHIR conversion activities, (ii) Data standardization, (iii) Timeline for FHIR-based eCQM reporting, and (iv) Measure development and reporting tools.

a. eCQM FHIR Conversion Activities

CMS describes that ensuring current eCQMs are specified using the FHIR standard and allowing eCQMs to be calculated consistently using standardized data is an important step in the transition to dQMs. The eCQMs currently use structured data defined by the Quality Data Model (QDM) and CMS is converting these eCQMs to ones using the HL7 FHIR Quality Improvement Core

[105] USCDI establishes a baseline of data elements referenced in health information exchange certification criteria under the ONC Health IT Certification Program. USCDI+ supports domain-specific datasets that build upon the USCDI framework.

Implementation Guide (QI-Core IG). CMS is considering requiring all future measures added to CMS programs be specified in FHIR. **CMS seeks comment** on (i) Any specific eCQMs or elements of existing eCQMs that may present particular challenges specifying in FHIR; (ii) Any gaps in the QI-CORE IG that are likely to impact the agency's ability to effectively specify current eCQMs in FHIR; and (iii) Supplementary activities that would encourage additional engagement in FHIR testing activities that support the development of current and future IGs to advance adoption and use of FHIR-based eCQMs.

b. Data Standardization

CMS describes the QI-Core IG, including that it is incorporated in the "Standardized API for patient and population services" health IT certification criterion and widely implemented across certified health IT systems. CMS also reviews the development of USCDI+ Quality, which includes data elements to support program-specific measures, and that the agency anticipates QI-Core IG will align with the USCDI Quality data element list. CMS is also considering the Data Exchange for Quality Measures (DEQM) IG,[106] specifically for supporting FHIR-based reporting to CMS. The agency further reviews other IG options, including Bulk Data Access IG,[107] which it is considering for facilitating the exchange and standardization of large volumes of data. **CMS seeks feedback** on: (i) Any experiences or challenges reviewing, implementing, or testing QI-Core, DEQM, or Bulk FHIR standards, including regarding Bulk FHIR Import versus Bulk FHIR Export; (ii) Any deficiencies or gaps in the DEQM IG that must be addressed before it could potentially be used for reporting to CMS on eCQMs using FHIR APIs, and (iii) Any additional baseline requirements or capabilities that need to be considered before FHIR-based eCQMs could be reported to CMS using Bulk FHIR.

c. Timeline Under Consideration for FHIR-Based eCQM Reporting

CMS is considering proposing (but is not proposing in this rule) a transition period (referred to as a "reporting options period") of at least 2 years during which providers would be able to report either QDM-based or FHIR-based eCQMs for satisfying quality reporting requirements. **CMS seeks feedback** on: (i) Whether 24 months from the effective date of an FHIR-based eCQM reporting option using ONC Health IT Certification Program criteria would provide enough time for implementation (including measure specification review, certified health IT updates, workflow changes, training, and testing); (ii) Resources or guidance that CMS could provide to assist with the transition; (iii) Any challenges anticipated with the reporting timeline (i.e., at least a 2-year reporting options period before any future proposal to require FHIR-based reporting); and (iv) Resources, guidance, or other support that CMS could provide to encourage early adoption and reporting of FHIR-based eCQMs during the reporting options period.

d. Measure Development and Reporting Tools

CMS seeks feedback on: (i) Capabilities that would be most useful for CMS to support in an FHIR-based eCQM reporting model, and (ii) Any additional concerns that CMS should consider when developing FHIR-based reporting requirements for systems receiving quality data.

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[106] CMS provides this website for further information on DEQM: https://build.fhir.org/ig/HL7/davinci-deqm/.
[107] CMS provides this website for further information on Bulk Data Access IG: https://hl7.org/fhir/uv/bulkdata/.

3. Approach to FHIR Patient Assessment Reporting in the IPFQR Program

Section 1886(s)(4)(E) of the Act requires IPFs participating in the IPFQR Program to collect and submit standardized patient assessment data using a new standardized patient assessment instrument (PAI) beginning for rate year 2028. CMS is considering ways to advance FHIR-based reporting of patient assessment data for the IPF PAI. Therefore, **CMS seeks feedback** on many questions regarding health IT use in IPFs. Some of the areas of feedback requested include: (i) The extent to which IPFs use health IT systems to maintain and exchange patient records, (ii) For IPFs that use electronic records, the types of health IT used, whether or not the health IT systems used are certified under the ONC Health IT Certification Program, and for those that are not so certified if the systems use standards and implementation specifications adopted by HHS for data exchange, (iii) Specific information on whether patient data is submitted to CMS directly from health IT systems of the IPFs or through a third-party intermediary (TPI), including the type of any such TPI used, how the facility exchanges information with other providers or systems, and any challenges faced with the electronic exchange of health information, (iv) Any issues regarding internet connectivity or access, (v) Steps taken by the IPF relating to health IT security and privacy requirements and the extent to which SAFER Guides is used, (vi) Challenges to successful quality measure data submission to CMS, (vii) Types of technical assistance, guidance, training, or other resources that would be helpful for CMS to provide for IPFs to implement FHIR-based technologies for submitting IPF-PAI to CMS, and (viii) Specific information on the use of technology by IPFs, if any, that utilizes APIs based on the FHIR standard.

4. General Solicitation of Comments

In addition to the above, **CMS seeks input** on (i) Any additional factors or considerations that may help foster data harmonization and reduce reporting burden across entities in regards to FHIR-based quality reporting; and (ii) How the Trusted Exchange Framework and Common Agreement (TEFCA) framework could support exchange of FHIR-based quality measures and patient assessment submissions consistent with the FHIR Roadmap[108] and how TEFCA could enable the use of patient assessment data for uses such as treatment and research.

C. Hospital Inpatient Quality Reporting (IQR) Program

CMS proposes changes to the HIQR program, including to (i) update 2 measures to expand their inclusion criteria to include MA beneficiaries and to shorten the performance periods for the measures from 3 years to 2 years, (ii) remove 4 measures from the measure set, (iii) change the reporting requirements for 2 hybrid measures to lower the submissions thresholds for core clinical data elements (CCDEs) and linking variables, and (iv) make clarifications regarding the ECE policy. In addition, CMS issues an RFI on future measure concepts under the HIQR Program.

CMS estimates if the proposals are adopted there would be, across 3,050 IPPS hospitals, a total maximum reduction in information collection burden of approximately 660,577 hours at a

[108] https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/.

maximum savings of $18,008,959 for the FY 2026 payment determination or subsequent years, compared to the currently approved information collection burden estimates.

CMS reviews that historically, an average of 100 hospitals that participate in the HIQR Program do not receive the full market basket rate update factor increase for failure to meet the Program requirements, and anticipates that number to remain approximately the same for FY 2026.

CMS invites public comment on the proposed changes to the HIQR Program under this section.

1. Background

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

2. Considerations in Expanding and Updating Quality Measures[109]

a. RFI: Measure Concepts Under Consideration for Future Years in the HIQR Program: Well-Being and Nutrition

CMS issues an RFI to seek feedback on well-being and nutrition measures for future years in the HIQR Program. The agency describes well-being as a comprehensive approach to disease prevention and health promotion, which integrates mental and physical health and emphasizes preventative and person-centered care. CMS seeks comment on tools and measures that assess "overall health, happiness, and satisfaction in life." CMS is also seeking comment on tools and measures that assess optimal nutrition and preventative care in the HIQR Program. The agency will not respond in the FY 2026 IPPS/LTCH PPS final rule to specific comments submitted but intends to use the feedback to inform future measure development efforts.

3. Proposed Refinements to Current Measures in the HIQR Program Measure Set

a. Proposed Modification of Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Hospitalization (MORT-30-STK) Measure

Background. The MORT-30-STK measure was adopted into the HIQR Program measure set beginning with the FY 2016 payment determination to assess the hospital-level, risk-

[109] Section 1890A(a)(2) of the Act requires CMS to make public certain quality and efficiency measures being considered for adoption through rulemaking. The Consensus-Based Entity (CBE), which is currently Battelle, convenes the Partnership for Quality Measurement (PQM) as part of the pre-rulemaking and measure endorsement process, consistent with these requirements.

standardized mortality rate after admission for acute ischemic stroke.[110] The measure cohort currently includes Medicare FFS patients who are 65 years of age or older. The MORT-30-STK measures 30-day, all-cause mortality. Mortality is defined as death from any cause within 30 days of the start of the index admission for patients discharged from the hospital with a principal discharge diagnosis of acute ischemic stroke.

Proposed Substantive Updates. CMS proposes to make the following two substantive updates to the MORT-30-STK measure beginning with the FY 2027 payment determination: (i) Expand the inclusion criteria to include MA patients; and (ii) Shorten the performance period from 3 years to 2 years.[111]

The expansion of the inclusion criteria would roughly double the cohort size and CMS believes the inclusion of MA data would improve measure reliability and more accurately reflect quality of care for all Medicare beneficiaries. The modified cohort would include admissions for patients aged 65 years or older discharged from the hospital with a principal diagnosis of acute ischemic stroke who are enrolled in Medicare FFS or MA for the 12 months prior to the date of admission and enrolled in FFS or MA during the index admission. The following admissions would still be excluded from the measure cohort: Patients with inconsistent or unknown vital status or other unreliable demographic data; Patients who were transferred from another acute care facility; Patients enrolled in hospice during the 12 months prior to the index hospitalization; and Patients discharged against medical advice.

The proposed new reporting period for the FY 2027 payment determination would be July 1, 2023 through June 30, 2025 (instead of July 1, 2022 through June 30, 2025). CMS believes the shortened reporting period would allow measure results to reflect more recent hospital performance and consequently provide more actionable data for quality improvement.

Technical Updates. CMS is making 2 technical measure updates beginning with the FY 2027 payment determination to (i) update the risk adjustment model to use the individual ICD-10 codes instead of HCCs, and (ii) remove the exclusion of (thus including) patients with a secondary diagnosis code of COVID-19 present on admission.[112]

Data Sources, Submission, and Public Reporting. The measure is calculated using administrative claims data, which includes MA and FFS data, so 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 data from the reporting period. Measure results would be publicly reported on the Compare tool[113] beginning in July 2026 or as soon as feasible.

Pre-Rulemaking. The update to expand the inclusion criteria of the MORT-30-STK measure was included on the 2024 Measures Under Consideration List (MUC List) and considered by the PRMR Hospital Committee in its January 2025 meeting. The committee recommended the

[110] 78 FR 50798-50802.
[111] Further information on the proposed modifications can be found in the 2024 Condition-Specific Measure Updates and Specifications Report available at https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.
[112] Section X.C.5 of the summary discusses removing the COVID-19 exclusion for measures in the HIQR Program.
[113] https://www.medicare.gov/care-compare.

updates to the measure within the HIQR Program with the following conditions: (i) CBE endorsement, (ii) Consideration of restructuring the measure to reduce time lag and provide hospitals with more timely and useful data; and (iii) Consideration of adding risk stratification for pre-existing do-not-resuscitate orders. Since the time of the committee meeting, CBE endorsed the measure (CBE #4595) with the proposed modifications on February 7, 2025. CMS is also proposing (as discussed above) to update the measure to shorten the reporting period to 2 years, which the agency states is the shortest reporting period for which its analysis shows the results remain reliable and valid. With respect to the last condition, CMS states it will consider making a change to stratify pre-existing do-not-resuscitate orders in future updates.

b. Proposed Modification to Hospital-Level, Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure (COMP-HIP-KNEE measure)

Background. The COMP-HIP-KNEE measure, which estimates a hospital-level, risk-standardized complication rate associated with elective primary THA and/or TKA procedures, was adopted in the HIQR Program in the FY 2013 IPPS/LTCH PPS final rule and in the FY 2023 IPPS/LTCH PPS final rule a re-evaluated form of the measure was adopted to include expanded outcomes.[114] In the FY 2024 IPPS/LTCH PPS final rule, the re-evaluated measure was adopted into the HVBP Program and the agency finalized removal of the measure from the HIQR Program beginning with the FY 2030 payment determination.[115] CMS is proposing modifications to the COMP-HIP-KNEE measure in the HIQR Program beginning with the FY 2027 payment determination (and until its removal with the 2030 payment determination). The same updates are being proposed (as discussed in section VI.J.2 of the summary) for the measure in the HVBP Program beginning with the FY 2033 program year, allowing for the statutorily required 1 year of public reporting of the updated measure in the HIQR Program before adoption in the HVBP Program.

Proposed Substantive Updates. Similar to the proposed updates (discussed above) for the MORT-30-STK measure, CMS proposes to make the following two substantive updates to the COMP-HIP-KNEE measure in the HIQR Program beginning with the FY 2027 payment determination (until it is removed for the FY 2030 payment determination): (i) Expand the inclusion criteria to include MA patients; and (ii) Shorten the performance period from 3 years to 2 years.[116] The proposed expansion would roughly double the cohort size and CMS believes the inclusion of MA data would improve measure reliability and more accurately reflect quality of care for all Medicare beneficiaries. CMS believes the proposed shortened reporting period (from 3 years to 2 years) would allow measure results to reflect more recent hospital performance and consequently provide more actionable data for quality improvement.

[114] 77 FR 53516-53521; 87 FR 49263-49267.
[115] Section 1886(o)(2)(C)(i) of the Act requires measures to be publicly reported for 1 year in the HIQR Program before the beginning of the first performance period for which the measure would be included in the HVBP Program.
[116] Further information on the proposed modifications can be found in the Measure Methodology Report in the Hip and Knee Arthroplasty Complications ZIP folder available at https://qualitynet.cms.gov/inpatient/measures/complication/methodology.

Measure Calculation. The outcome for the proposed updated COMP-HIP-KNEE measure would be a complication occurring during the index admission (not present on admission) through 90 days post the date of the index admission. The outcome is a yes/no outcome. The outcome would be "yes" if the patient experiences any of the specified complications in the applicable period.

The measure would continue to be calculated using a hospital risk-standardized complication rate determined by calculating the ratio of the number of predicted complications to the number of expected complications for each hospital and multiplying the ratio by the national observed complication rate.

The proposed modified inclusion criteria would specify admissions for patients aged 65 years or older having a qualifying elective primary THA or TKA procedure during the index admission who are enrolled in Medicare FFS or MA for the 12 months prior to the date of admission and are enrolled in FFS or MA during the index admission.

Technical Updates. CMS is making 2 technical measure updates beginning with the FY 2027 payment determination to (i) update the risk adjustment model to use the individual ICD-10 codes instead of HCCs, and (ii) remove the exclusion of (thus including) patients with a secondary diagnosis code of COVID-19 present on admission.[117]

The risk-adjustment methodology would use individual ICD-10 codes that use patient-level demographics, health status and clinical conditions, and functional status, which would be identified from inpatient and outpatient claims in the 12-month period prior to the procedure. In comparison, the current risk adjustment method groups ICD-10 codes from the HCC system into clinically relevant categories and CMS evaluates the HCCs for statistical association with the measure's outcome.

Data Source, Submission and Public Reporting. The proposed updates would use the following data:

- Index admission diagnoses and in-hospital comorbidity data from Medicare FFS claims and MA claims/encounter data.
- Part A inpatient, outpatient, and Part B office visit claims and MA encounters during the 12 months prior to the index admission to assess additional comorbidities before the index admission.
- Data from the Medicare Enrollment Database to determine Medicare FFS or MA enrollment status.

The measure is a claims-based measure so hospitals would need to submit only claims data.

CMS would calculate and publicly post the updated measure on an annual basis using a rolling 24 months of prior data for the measurement period. The updated measure data would be posted on the Compare tool beginning in July 2026 or as soon as feasible. The updated measure would

[117] Section X.C.5 of the summary discusses removing the COVID-19 exclusion for measures in the HIQR Program.

apply beginning with claims and encounter data from the April 1, 2023 through March 31, 2025 period associated with the FY 2027 payment determination.

Pre-Rulemaking. The COMP-HIP-KNEE measure (MUC2024-042) was included on the 2024 MUC list and considered by the PRMR Hospital Committee in its January 2025 meeting. The committee supported the addition of MA data to improve statistical reliability and recommended the measure for the HIQR Program, but with the following conditions: (i) stratified reporting, (ii) providing hospitals with feedback on outcome variations between MA beneficiaries and Medicare Shared Savings Program (MSSP) populations, (iii) breaking down performance data by payer, (iv) re-evaluating the risk model as the measure matures to identify adjustments needed for variation at the patient level across plans, and (v) considering if the reporting period is sufficient to avoid time lags. CMS responds that, based on its analysis, the observed complication rate variation between the MA cohort and FFS cohort did not vary significantly and does not raise concerns about uneven distribution of the cohorts. The agency will consider providing additional confidential feedback, including results stratified by MA and FFS beneficiaries, to hospitals in the future. The current confidential feedback does not stratify measure results by payer. The agency also states that the proposed updates to the measure include shortening the reporting period and that its analysis shows the proposed 2 years is the shortest period for which the results remain reliable and valid.

The COMP-HIP-KNEE measure (with the proposed modifications) was endorsed by the CBE on March 31, 2025 with conditions: (i) exploring the proportion of procedures in ASCs and HOPD settings and evaluating any need for adjustments based on case mix, and (ii) exploring other approaches to the reliability assessment to account for low-volume facilities.[118] To address the two conditions, CMS states that (i) the measure is intentionally narrow to capture significant complications which should be treated in the inpatient setting and (ii) adjusting for low volume is to make the performance scores available for as many providers as possible and that facilities with fewer than 25 cases do not have their scores available since the number of cases may be too small for meaningful results. CMS states that since it believes it has addressed the conditions, it considers the measure endorsed.

4. Proposed Removals from the Measure Set

CMS proposes to remove the following 4 measures beginning with the 2024 reporting period/FY 2026 payment determination:

- Hospital Commitment to Health Equity (HCHE) measure,[119]
- COVID-19 Vaccination Coverage among Healthcare Personnel (HCP COVID-19 Vaccination measure),[120]

[118] The measure was initially not re-endorsed on February 10, 2025, but the CBE appeals committee overturned that decision on March 31, 2025, resulting in the endorsement with conditions decision.
[119] The HCHE measure was adopted into the HIQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191-49201).
[120] The HCP COVID-19 Vaccination measure was adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45374-45382) and the updated version to account for updated vaccine guidance was adopted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59137-59144).

- Screening for Social Drivers of Health (SDOH-1),[121] and
- Screen Positive Rate for Social Drivers of Health (SDOH-2).[122]

CMS proposes removal of each of these measures on the basis of Removal Factor 8 – the costs associated with achieving a high score on the measure outweigh the benefits of its continued use in the program. The agency refers to a goal of reducing burden and to its refocus on clinical outcome measures and measures on prevention, nutrition, and well-being. Removal of these measures would allow for resources to be redirected for use for measures that address the refocused goals of the agency. Specifically:

- For the HCHE measure, CMS states that the removal is estimated to result in a reduction of annual burden of approximately 525 hours at a cost of $22,260 across all participating hospitals.
- For the HCP COVID-19 Vaccination measure, CMS states the estimated burden of collecting information on the measure annually across all hospitals is between $1,378,600 and $1,608,570. The agency believes the costs and burden to providers of tracking and monthly reporting on the measure outweighs the benefit of continued information collection on the measure.
- For the SDOH measures, CMS refers to the estimated total annual burdens in the FY 2023 IPPS/LTCH PPS final rule, which estimated for the SDOH-1 measure a cost of $21,917,000 to screen all admitted patients and a total annual burden of 525 hours at a cost of $22,260 across all hospitals for the SDOH-2 measure.

If the proposed removal of a measure is finalized: (i) hospitals that do not report their 2024 reporting data for that measure would not be considered noncompliant with the measure for the FY 2026 payment determination; and (ii) any data received for that measure by CMS would not be used for public reporting or payment purposes.

5. Technical Updates to Measure Specifications Beginning with the FY 2027 Program Year to Include Patients Diagnosed with COVID-19

CMS is removing the COVID-19 exclusion from (i.e., will include patients diagnosed with COVID-19 in) the following HIQR Program measures:

- MORT-30-STK;
- COMP-HIP-KNEE;
- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days);
- Excess Days in Acute Care after Hospitalization for Heart Failure (HF Excess Days);
- Excess Days in Acute Care after Hospitalization for Pneumonia (PN Excess Days);
- Hybrid Hospital-Wide All-Cause Readmission (HWR); and
- Hybrid Hospital-Wide All-Case Risk Standardized Mortality (HWM).

[121] The SDOH-1 measure was adopted at 87 FR 49201-49215.
[122] The SDOH-2 measure was adopted at 87 FR 49215-49220.

CMS had updated the above measures during the COVID-19 PHE to exclude patients diagnosed with COVID-19, including a primary or secondary diagnosis present on admission of COVID-19, from both the index admissions and readmissions. The agency is now providing notice of its intent to (through the subregulatory process for making nonsubstantive measure updates) remove the exclusion from those measures beginning with the FY 2027 program year. CMS believes hospitals have had enough time to adjust to the presence of COVID-19 as an ongoing virus.

6. Summary of Previously Finalized and Proposed HIQR Program Measures

CMS provides tables (Table X.C.2 through Table X.C.4) showing the HIQR Program measure set for each of the FY 2027 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.

Summary Table IQR Program Measures by Payment Determination Year			
	2027	**2028**	**2029**
Chart-Abstracted Process of Care Measures			
Severe sepsis and septic shock: management bundle (SEP-1) (CBE #500)	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) Malnutrition Care Score MCS (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 MCS 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 HH-HYPO AND HH-HYPER AND 3 of the following eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 HH-ORAE MCS HH-PI HH-AKI IP-ExRad HH-FI HH-RF	Report 4 calendar quarters of data for Safe Use of Opioids AND Cesarean Birth AND Severe Obstetric Complications AND HH-HYPO, HH-HYPER, and HH-ORAE AND 3 of the following eCQMs: STK-02 STK-03 STK-05 VTE-1 VTE-2 MCS HH-PI# HH-AKI# IP-ExRad HH-FI HH-RF

Summary Table IQR Program Measures by Payment Determination Year			
	2027	**2028**	**2029**
National Healthcare Safety Network Measures			
Healthcare Personnel Influenza Vaccination (CBE #0431)	X	X	X
Healthcare Personnel COVID-19 Vaccination^ (CBE# 3636)	Proposed Removal	Proposed Removal	Proposed Removal
CAUTI-onc (CBE #0138)		X	X
CLABSI-onc (CBE #0139)		X	X
Claims-Based Measures			
Mortality			
Stroke 30-day mortality rate (MORT-30-STK)^^ (CBE 4595)	X	X	X
Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA (COMP-HIP-KNEE)^^ (CBE # 1550)	X	X	X
Coordination of Care			
Excess days in acute care after hospitalization for AMI (AMI Excess Days) (CBE #2881)	X	X	X
Excess days in acute care after hospitalization for HF (HF Excess Days) (CBE #2880)	X	X	X
Excess days in acute care after hospitalization for PN (PN Excess Days) (CBE #2882)	X	X	X
Claims and Electronic Data Measures (Hybrid)			
Hybrid HWR (all-cause readmission) (CBE #2879e)**	X	X	X
Hybrid HWM (all-cause mortality) (CBE #3502e)**	X	X	X
Patient Safety			
30-day Risk Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Complications Mortality Rate) (CBE #4125)	X	X	X
Payment			
MSPB-Hospital (CBE#2158)	X		
Patient Experience of Care			
HCAHPS survey (CBE #0166) (0228)	X	X	X
Patient-Reported Outcome-Based Performance Measure (PRO-PM)			
Hospital-Level THA/TKA PRO-PM (CBE 3559)	X	X	X
Structural Measures			
Maternal Morbidity	X	X	X
Hospital Commitment to Health Equity HCHE^	Proposed Removal	Proposed Removal	Proposed Removal
Age Friendly Hospital	X	X	X
Patient Safety	X	X	X

Summary Table IQR Program Measures by Payment Determination Year			
	2027	2028	2029
Process Measures			
SDOH-1 Screening for social Drivers of Health^	Proposed Removal	Proposed Removal	Proposed Removal
SDOH-2 Screen Positive Rate for Social Drivers of Health^	Proposed Removal	Proposed Removal	Proposed Removal
^ Proposed in this rule for removal beginning with FY 2026 payment determination. ^^ Refinements to these measures are proposed beginning with the FY 2027 payment determination under section X.C. of the summary. * The NHSN measures are being updated in alignment with CDC's efforts to rebaseline using 2022 data. See section VI.K.2. of the summary for where the technical updates are discussed in more detail to rebaseline CDC's NHSN Healthcare-Associated Infection measures for the HAC Reduction Program. ** CMS is proposing modified reporting thresholds for linking variables and CCDEs beginning with the 2028 payment determination. In the FY 2025 OPPS/ASC final rule (89 FR 94495 through 94499) CMS finalized an extension of voluntary reporting of linking variables and core clinical data elements for the Hybrid HWR measure and the Hybrid HWM measure for the FY 2026 and FY 2027 payment determinations. ***The Malnutrition Care Score (MCS) used to be called the Global Malnutrition Composition Score (GMCS). # These eCQMs will be mandatory rather than among the list for self-selection beginning for the 2030 payment determination.			

7. Form, Manner, and Timing of Quality Data Submission[123]

CMS is proposing changes to the reporting and submission requirements for the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measures.

Hybrid measures use more than one data source for measure calculation. The Hybrid HWR and Hybrid HWM measures use: (i) core clinical data elements (CCDEs), which are a set of clinical variables derived from EHRs that can be used to risk adjust outcome measures; (ii) linking variables, which are administrative data that can link or merge the CCDEs and claims data to calculate measures; and (iii) claims data. For both measures, hospitals must report CCDEs (vital signs and laboratory test results) on 90 percent of discharges and submit four linking variables on 95 percent of discharges for each reporting period, beginning with mandatory reporting for the FY 2028 payment determination. Hospitals are required to report 13 CCDEs for the Hybrid HWR and 10 CCDEs for the Hybrid HWM. Three-fourths of the hospitals (mostly large, non-rural, non-critical access, and non-safety net hospitals) that submitted measure data during the 2024 voluntary reporting period did not meet the submission thresholds.

CMS describes that the results of an internal analysis showed that allowing fewer CCDEs to be submitted and lowering the percentage of discharges meeting the CCDE lab values and vital signs threshold to 70 percent of discharges, as well as lowering the threshold for linking variables to 70 percent of discharges, significantly improved hospitals' ability to meet the reporting thresholds while still demonstrating good reliability for measure calculation.

[123] Data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at https://qualitynet.cms.gov. The Annual Update for the Hospital Quality Reporting Programs (which contains updated measures specifications for the year prior to the reporting period) and implementation guidance documents are available on the Electronic Clinical Quality Improvement Resource Center website at http://ecqi.healthit.gov.

CMS, therefore, proposes for both hybrid measures, beginning with the FY 2028 payment determination (performance period of July 1, 2025, through June 30, 2026) to:

- Lower the submission thresholds for CCDE and linking variables to require at least 70 percent (instead of 90 and 95 percent, respectively) of discharges; and
- Lower the number of required CCDE data elements to allow for up to two missing laboratory results and up to two missing vital signs.

8. Extraordinary Circumstances Exception (ECE) Policy

Under the current ECE policy, CMS grants exceptions from the quality data reporting requirements for extraordinary circumstances beyond the control of the hospital.

CMS proposes to update the ECE policy at §412.140(c)(2) to clarify the policy and to include extensions of deadlines as an additional form of relief. The clarifications would specify that CMS may grant an ECE with respect to reporting requirements in the case of an extraordinary circumstance beyond the control of a hospital. An extraordinary circumstance would be defined as "an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year." CMS states that the process for hospitals to request and CMS to grant an ECE would remain the same as the current process.[124] CMS proposes that a hospital would be able to request an ECE within 30 calendar days of the date the extraordinary circumstance occurred (as opposed to the current 90 days) in order to align with CMS systems implementation requirements across quality reporting programs. In the preamble of the rule CMS clarifies its authority to grant an ECE at any time after the circumstance. As proposed, §412.140(c)(2) would state that CMS may grant an ECE to hospitals that have not made a request for one if CMS determines that a systemic problem with the CMS data collection system directly impacted the ability of the hospital to comply with the requirements or the circumstance has affected an entire region or locale. Any ECE granted would specify whether the hospital is (or hospitals are) exempted from reporting requirements or CMS has granted an extension for compliance.

Similar ECE proposals for the HRRP, HVBP Program, HAC Reduction Program, and PCHQR Program are discussed in sections VI.I.3.c, VI.J.5, VI.K.3, and X.D.4 of this summary, respectively.

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).

[124] The current process is available on CMS QualityNet at https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.

The program requires quality reporting by PCHs and measure data are publicly available, but the results have no associated payment consequences.

CMS proposes to remove 3 measures, publicly report data under the PCHQR Program on both the Provider Data Catalog and Compare tool website, and make clarifications to the ECE policy.

If the proposals are adopted, CMS estimates a maximum reduction in the total information collection burden for the 11 PCHs of 153 hours and savings of $7,765 for the FY 2026 program year or subsequent years, compared to the currently approved information collection burden estimates.

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

2. PCHQR Program Measures

a. Proposed Removal of the Hospital Commitment to Health Equity (HCHE) and Social Drivers of Health (SDOH) Measures Beginning with 2024 Reporting Period/FY 2026 Program Year

CMS proposes to remove the following 3 measures beginning with the 2024 reporting period/FY 2026 Program Year:

- Hospital Commitment to Health Equity (HCHE),[125]
- Screening for Social Drivers of Health (SDOH-1),[126] and
- Screen Positive Rate for Social Drivers of Health (SDOH-2).[127]

CMS proposes removal of each of these measures on the basis of Removal Factor 8 – the costs associated with achieving a high score on the measure outweigh the benefits of its continued use in the program. The agency refers to a goal of reducing burden and to its refocus on clinical outcome measures and measures on prevention, nutrition, and well-being. Removal of these measures would allow for resources to be redirected to address the refocused goals of the agency. Specifically:

- For the HCHE measure, CMS states that the removal is estimated to result in a reduction of annual burden of approximately 2 hours at a cost of $90 across all PCHs.
- For the SDOH measures, CMS refers to the estimated total annual burdens in the FY 2023 and 2024 IPPS/LTCH PPS final rules, which estimated for the SDOH-1 measure a total annual burden of 101 hours across all PCHs at a cost of $2,092 to screen all admitted patients and a total annual burden of 2 hours across all PCHs at a cost of $90 across all hospitals for the SDOH-2 measure.

If the proposed removal of a measure is finalized any data received for that measure by CMS would not be used for public reporting purposes.

[125] The HCHE measure was adopted into the PCHQR in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59204-59210).
[126] The SDOH-1 measure was adopted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59210-59219).
[127] The SDOH-2 measure was adopted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59219-59222).

b. Summary of Previously Adopted PCHQR Program Measures for FY 2028 Program Year and Subsequent Years

CMS summarizes the PCHQR program's measure set in table X.D.-01 and the previously finalized display policies in table X.D.-02 of the rule. The below table combines information provided in those tables and shows the previously adopted measure set with the proposed changes, if finalized, and with corresponding public display start date.

PCHQR Program Measures for FY 2028 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
Influenza vaccination coverage among health care personnel CBE #0431)	2019
NHSN COVID-19 vaccination coverage among health care personnel * *Proposed for Removal Beginning for FY 2026 program year*	October 2022
NHSN CLABSI (CBE #0139)^	October 2022
NHSN CAUTI (CBE #0138)^	October 2022
Patient Safety Structural Measure	October 2026 or as soon as feasible thereafter
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
The Proportion of Patients Who Died from Cancer Not Admitted to Hospice (EOL-Hospice) (CBE #0215)	July 2024
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
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
Patient Experience of Care	
HCAHPS (CBE #0166)	2016
Documentation of Goals of Care Discussions Among Cancer Patients	July 2026 or as soon as feasible thereafter
Outcome Measures	
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
Health Equity Measures	
Hospital Commitment to Health Equity (HCHE) * *Proposed for Removal Beginning for FY 2026 program year*	July 2026 or as soon as feasible thereafter
Screening for Social Drivers of Health (SDOH-1) * *Proposed for Removal Beginning for FY 2026 program year*	July 2027 or as soon as feasible thereafter
Screen Positive Rate for Social Drivers of Health (SDOH-2) * *Proposed for Removal Beginning for FY 2026 program year*	July 2027 or as soon as feasible thereafter
Source: Tables X.D.-01 and X.D.-02 of the rule, consolidated and modified by HPA ^ NHSN measures are being updated in alignment with CDC's efforts to rebaseline using 2022 data. These updates are discussed in section VI.K.2 of the summary under the HAC Reduction Program proposals.	

3. Proposal to Publicly Report PCHQR Data on Both Provider Data Catalog and Compare Tool Website

The Provider Data Catalog and the Compare tool websites, launched in 2020, allow patients, caregivers, providers, and others to find and compare information on the quality of care at participating PCHs and hospitals, respectively. The Provider Data Catalog enables analysis and comparison of quality data among PCHs, but CMS describes how the Compare tool is more user-friendly and already includes quality measure information on hospitals for the HIQR Program, HOQR Program, HACRP, HRRP, Inpatient Psychiatric Facility Quality Reporting Program (IPFQRP), and Medicare Promoting Interoperability Program.

CMS proposes to change the public reporting requirements of the PCHQR Program so that the agency can publicly report PCHQR Program data on both the Provider Data Catalog and the Compare tool or successor websites and to make corresponding changes to §412.24(f) to replace references to "Provider Data Catalog" with "CMS websites".

4. ECE Policy Updates

Under the current ECE policy, CMS grants exceptions from the quality data reporting requirements for extraordinary circumstances beyond the control of the PCH.

CMS proposes to update the ECE policy at §412.24(e) to clarify the policy and to include extensions of deadlines as an additional form of relief. The clarifications would specify that CMS may grant an ECE with respect to reporting requirements in the case of an extraordinary circumstance beyond the control of a PCH. An extraordinary circumstance would be defined as "an event beyond the control of a PCH (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the PCH to comply with one or more applicable reporting requirements with respect to a fiscal year." CMS states that the process for PCHs to request and CMS to grant an ECE would remain the same as the current process.[128] CMS proposes that a PCH would be able to request an ECE within 30 calendar days of the date the extraordinary circumstance occurred (as opposed to the current 90 days) in order to align with CMS systems implementation requirements across quality reporting programs. In the preamble of the rule CMS clarifies its authority to grant an ECE at any time after the circumstance. As proposed, §412.24(e) would state that CMS may grant an ECE to PCHs that have not made a request for one if CMS determines that a systemic problem with the CMS data collection system directly impacted the ability of the PCH to comply with the requirements or the circumstance has affected an entire region or locale. Any ECE granted would specify whether the PCH is (or PCHs are) exempted from reporting requirements or CMS has granted an extension for compliance.

Similar ECE proposals for the HRRP, HVBP Program, HAC Reduction Program, and HIQR Program are discussed in section VI.I.3.c, VI.J.5, VI.K.3, and X.C.8 of this summary, respectively.

[128] The current process is available on CMS QualityNet at https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Overview

The LTCH QRP is a pay-for-reporting quality program implemented in FY 2014.[129] LTCHs submit data to CMS on the LTCH Continuity Assessment Record (CARE) and Evaluation Data Set (LCDS) patient assessment instrument using the Internet Quality Improvement Evaluation System Assessment Submission and Processing (iQIES ASAP) system. The LCDS requires reporting of multiple standardized patient assessment data elements (SPADES) that are interoperable and are common to post-acute care (PAC) providers.[130] 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.[131]

CMS proposes changes to the LTCH QRP, including proposals (i) that LTCHs no longer be required to submit the Patient/Resident COVID-19 Vaccine item on the LCDS for patients who have expired in the LTCH, (ii) to remove 4 SPADES, and (iii) to revise the reconsideration request policy and process. The agency also issues requests for information on future measure concepts, revising the final data submission deadline period, and advancing digital quality measurement.

If the proposals are adopted, CMS estimates a total information collection burden increase across 330 LTCHs of 4 hours for a total cost increase of $187.60 for the FY 2026 LTCH QRP (attributable to the updates to the reconsideration policy) compared to the currently approved information collection burden estimates. CMS estimates, if the proposals are adopted, a decrease of 2,633.51 hours and a total cost decrease of approximately $180,016 for the FY 2028 LTCH QRP, compared to the currently approved burden estimates.

CMS invites public comment on the proposals to the LTCH QRP under this section.

2. Current Measure Set

The 18 quality measures currently adopted for the LTCH QRP are shown in Table X.E.-01 of the proposed rule. No new measures are being proposed. A summary table of Program measures for FY 2026 is provided below.

[129] The program is authorized under section 1886(m)(5) of the Act and the regulatory program requirements are under 42 CFR 412.560.
[130] Post-acute care providers required to report SPADEs are long-term care hospitals, inpatient rehabilitation facilities, skilled nursing facilities, and home health agencies.
[131] 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 2026
NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure (CBE #0138)*	X
NHSN Central line-associated Blood Stream Infection (CLABSI) Outcome Measure (CBE #0139)*	X
Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury	X
Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay	X
Ventilator Liberation Rate	X
Influenza Vaccination Coverage among Healthcare Personnel (CBE #0431)	X
NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (CDI) Outcome Measure (NQF #1717)*	X
Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (CBE #0674)	X
Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support (CBE #2632)	X
Medicare spending per beneficiary MSPB-PAC LTCH	X
Discharge to Community PAC LTCH	X
Potentially Preventable Readmissions 30 Days Post LTCH Discharge	X
Drug Regimen Review Conducted with Follow-up	X
Transfer of Health Information to the Provider – PAC Measure (TOH-Provider)	X
Transfer of Health Information to the Patient – PAC Measure (TOH-Patient)	X
COVID-19 Vaccination Coverage among Healthcare Personnel	X
Discharge Function (DC Function) Measure	X
COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date	X

3. Proposed Modifications to Reporting Requirements for COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) Measure Beginning with FY 2028 LTCH QRP

The Patient/Resident COVID-19 measure was adopted beginning with the FY 2026 LTCH QRP. The Patient/Resident COVID-19 Vaccine item has been included on the LCDS discharge assessments for LTCHs to collect data on the measure for patients being discharged and who die during their stay. LTCHs must collect data using the LCDS for the measure beginning with patients discharged on October 1, 2024 for the FY 2026 LTCH QRP. CMS describes how LTCHs have faced challenges in identifying vaccination status once a patient has died and the agency believes collecting this data creates unnecessary burden for LTCHs.

Therefore, CMS proposes that beginning with patients admitted on or after October 1, 2026, LTCHs no longer be required to submit the Patient/Resident COVID-19 Vaccine item on the LCDS for patients who have expired in the LTCH and to remove the item from future LCDS forms used for expired patients.

4. Proposed Removal of Four SPADES Beginning with FY 2028 LTCH QRP

CMS is proposing to remove four SPADES (one Living Situation item, two Food items, and one Utilities item) under the social determinants of health (SDOH) category because of the burden associated with reporting the items. The agency had finalized these SPADES in the FY 2025 IPPS/LTCH PPS final rule. LTCHs are required to report these data elements beginning with patients discharged on or after October 1, 2026 through December 31, 2026 for the FY 2028

LTCH QRP. If finalized, LTCHs would not be required to report these items for these discharges. CMS describes moving its focus towards how data exchange improves care coordination, efficiency, reduction in errors, and improved patience experience, including through standardization of interoperable data to reduce burden associated with collecting and sharing clinical data. CMS states that this proposal would prevent LTCHs from incurring an estimated total of 2,601 hours of burden at a cost of $182,330.

5. Proposals to Amend the Reconsideration Request Policy and Process

The LTCH QRP reconsideration policy and process is codified at §412.560(d). The policy was adopted in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317-50318), which provided in the preamble that an LTCH may file a request for reconsideration of an initial determination, which found that the LTCH did not comply with the LTCH QRP reporting requirements, if the LTCH believes that the determination is erroneous or if the LTCH has a valid and justifiable excuse for its non-compliance. CMS may reverse its initial finding of non-compliance if the LTCH provides proof of compliance with all requirements or provides adequate proof of a valid and justifiable excuse for non-compliance. CMS states that it has become aware of inconsistences in its final rules implementing and amending the regulation text and the regulation text itself, and is therefore proposing clarifications.

CMS proposes the following, with respect to requests for extension to the filing deadline for a reconsideration request:

- To clarify that an LTCH may request, and CMS may grant, an extension to file a reconsideration request if, during the period to request a reconsideration set forth in §412.560(d)(2), the LTCH was affected by extraordinary circumstances beyond the control of the LTCH (for example, a natural or man-made disaster).
    - The FY 2015 IPPS/LTCH PPS final rule had provided for the ability to file such a request, but if the LTCH was affected by "extenuating circumstances," which was not defined. The change to "extraordinary circumstances" would apply the meaning provided to that term for the ECE policy codified at §412.560(c).
    - This language also clarifies when the extraordinary circumstances occurred relative to when the extension request must be filed.
- To require the LTCH to submit the request for an extension to CMS via email no later than 30 calendar days after the date of the written notification of noncompliance.
- To require the request to contain (i) the CCN, business name, and business address for the LTCH, (ii) certain contact information for the LTCH's CEO or designated personnel, (iii) a statement of the reason for the request, and (iv) evidence of the impact of the extraordinary circumstances.
- CMS would notify the LTCH in writing via email of its final decision regarding its request for an extension to file a reconsideration request.

With respect to the bases on which CMS may grant a reconsideration request, CMS proposes to specify that the agency will grant a timely request for reconsideration, and reverse an initial finding of non-compliance, only if CMS determines that the LTCH was in full compliance with the LTCH QRP for the applicable program year. CMS would consider full compliance to include

CMS granting an exception or extension to reporting requirements under the ECE policy at §412.560(c).

CMS is considering proposing similar changes across all post-acute care setting quality reporting program reconsideration policies.

6. RFI: LTCH QRP Measure Concepts Under Consideration for Future Years: Interoperability, Well-Being, Nutrition, and Delirium

CMS is seeking input on the following 4 quality measure concepts for future measures for the LTCH QRP.

- Interoperability: CMS requests comment on approaches to assess interoperability in the LTCH settings, such as measures that address or evaluate the level of readiness for interoperable data exchange or that evaluate the ability of data systems to securely share information.
- Well-Being: CMS requests comment on tools and measures that assess for overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, fulfillment, and self-care.
- Nutrition: CMS requests comment on tools and frameworks that promote healthy eating, exercise, nutrition, or physician activity.
- Delirium: CMS requests comment on the applicability of measures that evaluate for sudden, serious changes in a person's mental state or altered state of consciousness that may be associated with underlying conditions.

7. RFI: Potential Revision to the Final Data Submission Deadline Period from 4.5 Months to 45 Days

CMS describes that a goal of public reporting of data collected under the LTCH QRP and other quality reporting programs is to provide consumers with the most current information in order to facilitate informed decision-making. CMS believes that the time between when data on measures is collected and submitted, and when the data are made publicly available (about 9 months) may be too long for those purposes. CMS further believes that if the data submission timeframe were reduced from its current 4.5 month timeframe to 45 days, the lag between the end of the data collection period and public reporting could be reduced by up to 3 months. According to an analysis conducted by CMS on the potential impact of shortening the data submission timeframe, only 2.5 percent of all LCDS assessments were submitted after the 45-day period.

CMS requests feedback on the potential future reduction of the submission deadline from 4.5 months to 45 days - specifically, on how the potential change could (i) improve the timeliness and actionability of quality measures, (ii) improve public display of the information, and (iii) impact LTCH workflow or require system updates.

8. RFI: Advancing Digital Quality Measurement

CMS is considering ways to advance FHIR-based reporting of patient assessment data for which LTCHs must report. The agency seeks information on how LTCHs integrate technologies into existing systems and how the integration affects workflow, particularly to identify the challenges during the integration and to determine support that is needed. The agency lists many specific questions on which it is seeking feedback regarding the state of health IT use in LTCHs. Some of those areas of inquiry include:

- The extent to which LTCHs use health IT systems to maintain and exchange patient records; for LTCHs that use electronic records, the types of health IT that are used to maintain patient records, whether the systems are certified by the ONC Health IT Certification Program, and any reasons why the systems are not so certified.
- Whether patient assessment data is submitted directly to CMS or through a third party intermediary (TPI); how information is exchanged by the LTCH with other providers or systems, and challenges faced with the electronic exchange of health information or with the LTCH's current electronic devices (such as Internet access or connectivity).
- Steps taken by the LTCH to implement health IT systems that are compliant with security and patient privacy requirements; and whether the LTCH uses the SAFER Guides to self-assess EHR safety practices.
- Challenges faced when submitting quality measure data.
- Types of technical assistance, guidance, training, and resources that would be most beneficial for implementing FHIR-based technology for the submission of LCDS and other systems (such as NHSN) for which LTCHs have reporting requirements.
- Whether the facility is using technology that utilizes APIs based on the FHIR standard, how the adoption of such technology could impact workflow, and any benefits or challenges experienced with implementing technology that uses FHIR-based APIs.
- How the TEFCA could support CMS quality programs' adoption of FHIR-based assessment submissions.
- Any other information that should be considered for adoption and integration of FHIR-based technologies and standardized data for patient assessment instruments.

9. Form, Manner, and Timing of Data Submission under the LTCH QRP[132]

CMS proposes to modify reporting requirements for the Patient/Resident COVID-19 Vaccine measure to exclude patients who have expired in the LTCH. Beginning with patients admitted on or after October 1, 2026, LTCHs would no longer be required to submit the Patient/Resident COVID-19 Vaccine item on the LCDS for patients who have expired in the LTCH. CMS would remove the item from future LCDS forms that LTCHs use for expired patients.

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

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.[133] 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.[134] In the following provisions of this section, the term hospital includes a critical access hospital unless otherwise noted.

2. Proposal to Define the EHR Reporting Period in 2026 and Subsequent Years

a. Definition of EHR Reporting Period

For EHR reporting periods for 2024 and 2025, CMS defines the term "EHR reporting period for a payment adjustment year" at 42 CFR 495.4, to mean, for hospitals that are new or returning participants in the Medicare PIP, a minimum of any continuous 180-day period within the calendar year involved. For example, the EHR reporting period in 2025 is a minimum of any continuous 180-day period within 2025.

CMS proposes to maintain that same definition for an "EHR reporting period for a payment adjustment year" going forward. That is, the EHR reporting period in 2026 (or a subsequent year) would be a minimum of any continuous 180-day period within 2026 (or the subsequent year involved). The agency says it will continue to monitor CEHRT utilization by hospitals to determine if a longer EHR reporting period may be appropriate in the future.

b. CEHRT

Readers are reminded of recent updates to ONC Health Information Technology (Health IT) Certification Program certification criteria that are referenced or incorporated within the definition of CEHRT in 42 CFR 495.4. CMS also notes that in 2026 CEHRT must be certified to applicable certification criteria in 45 CFR 170.315.

CMS explains 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.-05 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[135] that impact certification criteria under the CEHRT definition, including:

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[133] Section 1886(b)(3)(B)(ix) of the Act.
[134] Section 1814(l)(4) of the Act.
[135] See the ONC rule finalized on January 9, 2024, the Health Data, Technology, and Information Sharing (HTI-1) final rule (89 FR 1192).

- Beginning January 1, 2025, the decision support interventions (DSI) criterion replaced 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.
- Beginning January 1, 2026, under the transmission to public health agencies-electronic case reporting criterion, consensus-based, industry-developed electronic standards and implementation guides will replace functional, descriptive requirements.
- The United States Core Data for Interoperability (USCDI) version 3 was adopted. The current USCDI version 1 will expire January 1, 2026.
- The "standardized application programming interface (API) for patient and population services" certification criterion in 45 CFR 170.315(g)(10), which is included in the Base EHR definition, was updated to include newer versions of certain standards, including USCDI version 3 and updated functionality to support the criterion (89 FR 1283).

3. Proposal to Modify the Security Risk Analysis Measure

CMS previously adopted the Security Risk Analysis measure, which requires hospitals to attest "yes" or "no" as to whether they have conducted or reviewed a security risk analysis, as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A). The measure is not scored nor does it contribute any points to the total score for the Protect Patient Health Information objective and measures. However, a "no" attestation results in the hospital not meeting the measure and not satisfying the definition of a meaningful EHR user under 42 CFR 495.4, which subjects the hospital to a downward payment adjustment.

The modification proposed in this rule would require hospitals to attest that they have conducted security risk management in addition to the current requirement under the measure for hospitals to attest "yes" to having conducted or reviewed a security risk analysis. Specifically, hospitals would also be required to attest "yes" to having implemented policies and procedures to support analyzing and managing the security risks to ePHI associated with the implementation and use of EHRs as required by the HIPAA Security Rule implementation specifications for risk analysis and risk management (as described in 45 CFR 164.308(a)(1)(ii)(A) and (B)). The proposed measure text is as follows, and the proposed modifications are shown in italics:

> Conduct or review a security risk analysis *and conduct security risk management activities*, in accordance with the requirements under 45 CFR 164.308(a)(1)*(ii)(A) and (B)*, including addressing the security of data created or maintained by CEHRT *(to include encryption)*, in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the *eligible hospital's or CAH's* risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.

Thus, there would be two separate attestation requirements, both of which would require a "yes" attestation for the hospital to be considered a meaningful EHR user beginning with the EHR reporting period in 2026. Failure to attest "yes" on one of the attestation requirements would subject the hospital to a downward payment adjustment.

CMS does not propose to change the scoring approach for the measure nor would successful attestation contribute to the total score for the objective. Similarly, the proposal would not impact current policies that actions included in the Security Risk Analysis measure may occur any time during the calendar year in which the EHR reporting period occurs and that a hospital must use the capabilities and standards as defined for CEHRT. Comment is welcomed on the proposal.

4. Proposal to Modify the Safety Assurance Factors for EHR Resilience (SAFER) Guides Measure

The SAFER Guides[136] measure was first adopted under the Protect Patient Health Information objective beginning with the EHR reporting period in 2022. It was modified, beginning with the EHR reporting period in 2024, to require hospitals to attest "yes" to conducting an annual self-assessment using all nine of the 2016 SAFER Guides to be considered a meaningful EHR user. Since adoption of that measure, an updated set of SAFER Guides (the 2025 SAFER Guides)[137] was published, which consist of 8 guides organized into three broad groups of Foundational Guides, Infrastructure Guides, and Clinical Process Guides. The guides have been edited, and they contain new recommendations. Table X.F.-01 shows the titles of the various guides, and chapters within the guides, that compare the 2016 SAFER Guides and the 2025 SAFER Guides.

CMS proposes to modify the SAFER Guides measure by requiring hospitals to attest "yes" to completing an annual self-assessment using all eight 2025 SAFER Guides in order to be considered a meaningful EHR user, beginning with the EHR reporting period in 2026. Some stakeholders had raised concerns that the 2016 SAFER Guides were outdated, and they recommended that CMS and ONC review them and make updates. CMS says the 2025 SAFER guides have been updated and streamlined to focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes to build system resilience; it notes they have been condensed into eight SAFER Guides rather than nine.

5. Proposal to Modify the Public Health and Clinical Data Exchange Objective: Adoption of an Optional Bonus Measure for Public Health Reporting Using the Trusted Exchange Framework and Common Agreement™ (TEFCA)

a. Background

Currently, there are eight measures under the Public Health and Clinical Data Exchange objective, six of which are mandatory and two of which are optional bonus measures. Hospitals may receive a total of 5 bonus points for reporting on one or both optional bonus measures. CMS notes that one challenge with the electronic exchange of health information for many different public health purposes is that exchange between public health agencies (PHAs) and hospitals requires different processes; it believes participation in TEFCA could reduce the difficulty of public health information exchange over time by creating a common governance and technical framework for health information exchange.

[136] ASTP SAFER Guides – https://www.healthit.gov/topic/safety/safer-guides
[137] https://www.healthit.gov/topic/safety/safer-guides

CMS says that TEFCA standardizes health information exchange across many different networks, which simplifies health information exchange by reducing the number of connections that health care providers, PHAs, and other interested parties need to make to send and receive health information. TEFCA creates baseline governance, legal, and technical requirements that enable secure health information exchange across different networks nationwide, including the following: (i) a common method for authenticating trusted network participants, (ii) a common set of rules for trusted exchange, (iii) organizational and operational policies to enable the exchange of health information among networks, and (iv) a process for filing and adjudicating noncompliance with the terms of the Common Agreement.[138]

b. Proposal to Add an Optional Bonus Measure Under the Public Health and Clinical Data Exchange Objective Beginning with the EHR Reporting Period in 2026

Beginning with the EHR reporting period in 2026, CMS proposes to add an optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange with a PHA that occurs using TEFCA. As proposed, a hospital could claim 5 bonus points under this objective if it attests that it is in active engagement with a PHA to submit electronic production data for one or more of the measures under this objective using TEFCA. A hospital could only earn 5 bonus points even if it attests "yes" to multiple bonus measures under this objective.

> Public Health Reporting Using TEFCA. The eligible hospital or CAH:
> (1) participates as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the Federal Register and on ASTP's website);
> (2) is not suspended;
> (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective;
> (4) is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and
> (5) uses the functions of CEHRT to exchange with the PHA.

For measures in this objective, hospitals must report their level of active engagement as either Option 1 (pre-production and validation) or Option 2 (validated data production). Further, hospitals may only spend one EHR reporting period at the pre-production and validation level of active engagement (Option 1) before advancing to Option 2 (validated data production) to fulfill measure requirements. Under the proposal, the Public Health Reporting Using TEFCA bonus measure would only be available where the hospital is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the objective.

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[138] The Common Agreement defines "Framework Agreement(s)" as: "any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable." See Common Agreement for Nationwide Health Information Interoperability Version 2.1 (Nov 2024). See https://www.healthit.gov/sites/default/files/2024-11/Common_Agreement_2.1.pdf.

To attest "yes" for this measure, the hospital would have to be a signatory to a TEFCA Framework Agreement, (i.e., either the Common Agreement or an agreement that includes the Participant/Sub-participant Terms of Participation), and it could not be suspended under the respective agreement.

The hospital would have to transmit electronic health information for at least one measure under this objective using TEFCA and use the functions of CEHRT to engage in exchange with a PHA. CMS is not proposing any exclusions for this measure because it would be an optional bonus measure.

CMS clarifies that if the hospital would use TEFCA to fulfill any of the required measures under the Public Health and Clinical Data Exchange objective, the hospital could claim the 5 bonus points if it attests "yes" to the Public Health Reporting Using TEFCA bonus measure in addition to earning points for fulfilling the requirements of the required measure or measures. Comment on the proposal is invited.

6. Overview of Scoring Methodology for the EHR Reporting Period in 2026

There is currently a 70-point minimum scoring threshold that hospitals must meet to satisfy the requirement to report on the objectives and measures of meaningful use in 2025, which will increase to an 80-point minimum in 2026 and subsequent years.

Table IX.F.-02 of the rule (shown below with slight stylistic modifications) includes the scoring methodology beginning in 2026, reflecting previously adopted policies and the proposals for the optional Public Health Reporting Using TEFCA optional bonus measure.

TABLE IX.F.-02: PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN 2026 AND SUBSEQUENT YEARS

Objective	Measures	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of (PDMP)	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (eligible hospital or CAH's must choose one of the three reporting options)
	-AND-		
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following 6 measures: Syndromic Surveillance Reporting Immunization Registry Reporting Electronic Case Reporting Electronic Reportable Laboratory**	25 points	Required

Objective	Measures	Maximum Points	Required/Optional
	Antimicrobial Use Surveillance Antimicrobial Resistance Surveillance		
	Report one of the following measures: Public Health Registry Reporting Clinical Data Registry Reporting *Public Health Reporting Using TEFCA**	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. The ePrior Authorization measure is required beginning with the EHR reporting period in CY 2027. *Signifies a proposal made in this proposed rule. For details on the proposal to add the Public Health Reporting Under TEFCA measure, see section X.F.5. of the preamble of the proposed rule. **In prior rulemaking, CMS inadvertently referenced the measure name incorrectly. To ensure accuracy, CMS corrects the measure's name to Electronic Laboratory Reporting measure. This is a non-substantive change and does not impact the measure's specifications or reporting requirements.			

Table IX.F.-03 shows how points will be redistributed for the EHR reporting period in 2026 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, the 25 points are redistributed to the Provide Patients Electronic Access to Their Health Information.

7. Overview of Objectives and Measures for the EHR Reporting Period in 2026

Table IX.F.-04 lists the objectives and measures for the Medicare PIP for the EHR reporting period in 2026 as revised to reflect the proposals made in the proposed rule. No changes are proposed to the agency's policy for point redistribution in the event an exclusion is claimed.

Table X.F.-05. lists the ONC Health IT Certification Program certification criteria required to meet the Medicare PIP objectives and measures.

8. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

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.[139] Table IX.F.-06 of the proposed rule summarizes the previously finalized required and self-selected eCQMs available for hospitals to report under the Medicare PIP for the 2026 and subsequent year reporting periods.

No changes are proposed to the Medicare PIP eCQMs in this proposed rule.

9. RFI Regarding the Query of Prescription Drug Monitoring Program (PDMP) Measure

a. Background

CMS notes that on August 5, 2024, ONC published its HTI-2 proposed rule[140] (89 FR 63498), which includes a proposal for a PDMP certification criterion in 45 CFR 170.315(f)(9), titled "Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter". This criterion would enable bi-directional interaction and electronic health information exchange between certified Health IT Modules and PDMP databases using a consistent approach to querying PDMP data (89 FR 63547). Specifically, the proposed certification criterion would enable the query of prescription drug monitoring systems and the receipt, validation, parsing, and filtering of medication information from PDMPs. The proposed criterion would be a functional criterion agnostic to a specific PDMP standard, but would include transport, content, and vocabulary standards where appropriate. The proposal for a PDMP certification criterion has not been finalized as of the date of public display of this proposed rule.

The Medicare PIP Query of PDMP measure supports HHS initiatives aimed at improving the treatment of opioid and substance use disorders by helping hospitals avoid inappropriate prescriptions. It provides that for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the hospital uses data from CEHRT to conduct a query of their PDMP for prescription drug history (89 FR 69607). CMS seeks comment on the following policy considerations for the Query of PDMP measure:

- Changing the Query of PDMP measure from an attestation-based measure ("yes" or "no") to a performance-based measure (numerator and denominator), as well as alternative measures designed to more effectively assess the degree to which participants are utilizing PDMPs, and
- Expanding the types of drugs to which the Query of PDMP measure could apply.

b. Changing to a Performance-based Measure

The Query of PDMP measure was initially finalized[141] as a performance-based measure with a numerator and denominator but one year later[142] was changed to an attestation-based measure beginning with the EHR reporting period in 2019 and to an optional measure for the EHR

[139] See sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act for these requirements applied to CAHs and hospitals, respectively.
[140] Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) proposed rule.
[141] See the FY 2019 IPPS/LTCH PPS final rule (83 FR 41649 through 41653).
[142] See the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42595).

reporting period in 2020. At the time, stakeholders believed that it was premature to require the Query of PDMP measure and to score it based on performance. The agency agreed that incorporating the ability to count the number of PDMP queries in the EHR would require implementation of manual processes due to the wide variation in approaches by hospitals querying PDMPs, and that the costs of additional development if further standardization was introduced later would likely be passed on to those providers.

Noting that PDMPs are now widely available across all 50 states and several localities, and PDMP integration with HIEs, EHRs, and PDSs has increased since the Query of PDMP measure was finalized as an attestation measure, CMS seeks comment on whether to adopt a performance-based (numerator/denominator) reporting requirement for the Query of PDMP measure, and, if so, how to define the numerator and denominator. CMS is considering the following description of a numerator and a denominator:

> Denominator: Number of Schedule II opioid or Schedule III or IV drugs electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period.
> Numerator: The number of prescriptions of Schedule II opioid or Schedule III or IV drugs in the denominator for which data from CEHRT is used at the time of prescribing to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law.

Additional issues for which feedback is sought include the following:

- Potential barriers for hospitals meeting the Query of PDMP measure as a performance-based measure;
- How to account for varying levels of readiness and capacity for performance-based reporting, particularly for small and rural providers, including hospitals;
- Exclusions CMS should consider;
- Appropriate timeframe to allow for systems and process changes;
- Whether adoption and use of Health IT Modules certified to ONC's proposed PDMP Databases—Query, receive, validate, parse, and filter certification criterion, if finalized, would help mitigate previously identified burden associated with implementing and reporting on a performance-based "Query of PDMP" measure; and how it would impact the numerator and denominator of a potential performance-based PDMP measure; and
- Other measure concepts that could focus on outcomes related to overdose prevention, especially those likely to involve the lowest effort and provide the highest value to the health care community.

Feedback is also sought on whether CMS should explore measures related to monitoring data from PDMPs that could assess multiple opioid prescriptions, opioid prescriptions from multiple prescribers, combined opioid and benzodiazepine prescriptions, or very high standardized dosage of opioids prescribed.

c. Expanding to Include All Schedule II Drugs

The Query of PDMP measure was expanded to not only include Schedule II opioids, but also include Schedule III and IV drugs, beginning with the EHR reporting period in 2023.[143] The measure description is "for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history." CMS clarified that the measure does not include or apply to Schedule II drugs that are not opioids.

CMS is considering expanding the Query of PDMP measure to include all Schedule II drugs rather than only including Schedule II opioids. This would, for example, include central nervous system stimulant drugs prescribed for Attention-Deficit Hyperactivity Disorder (ADHD). Table X.F.-09 shows examples of Schedule II opioid drugs and other Schedule II drugs. CMS seeks feedback on this potential expansion, including responses to the following specific questions:

- What challenges exist, if any, around expanding the Query of PDMP measure to include all Schedule II drugs?
- What are the potential benefits versus risks of expanding the Query of PDMP measure to include all Schedule II drugs?
- Would expanding the Query of PDMP measure to Schedule II non-opioid drugs create barriers for patients appropriately prescribed Schedule II non-opioid drugs (for example, central nervous stimulants appropriately prescribed for ADHD)?
- How should CMS account for varying levels of readiness and capacity for hospitals to meet an expanded scope of the measure, particularly for small and rural providers?
- What exclusions should be considered, if any?

10. RFI Regarding Performance-based Measures

Measures under the Public Health and Clinical Data Exchange objective require hospitals to indicate their level of active engagement with a PHA, but they do not measure the degree to which hospitals are exchanging the data specified under each measure. Further, these measures only require attestation. These requirements do not allow assessment of the comprehensiveness, quality, or timeliness of the data provided to the PHAs. CMS is interested in new measure concepts for public health that would better focus on aspects of the data quality of public health reporting; it seeks feedback on the following questions:

- What aspects of data quality and usability are most appropriate and valuable to measure in the context of the Public Health and Clinical Data Exchange objective of the Medicare PIP (e.g., timeliness and completeness of reporting)?
- How could data completeness be defined? For instance, how should "complete data" be defined? Should a threshold approach be considered, under which hospitals attest that they are successfully sending complete data for a minimum set of data elements to a PHA?
- Are there other metrics available that more directly relate to actions and outcomes that public health reporting is intended to enable (e.g., overdose prevention)?

[143] See the FY 2023 IPPS/LTCH PPS final rule (87 FR 49323 through 49325).

- Of the current types of public health data exchange reflected in the Public Health and Clinical Data Exchange objective measures, what use cases should be prioritized for a focus on data quality that would provide the highest value to the health care community while resulting in the least burden?

Currently, hospitals may earn 25 points for reporting on all six required measures. CMS is considering changes to the scoring methodology under this objective, and it seeks feedback on the following questions:

- Should eligible hospitals and CAHs be able to earn up to 5 points for each measure, for a total of 30 points for the objective, but be required to earn at least 1 point for each measure to earn a score, in addition to meeting the overall threshold for the program?
- Should all public health measures for which a numerator and denominator is finalized based on performance be scored, or should only a subset of measures based on performance be scored?

Recently, ONC finalized updates to certification criteria included in CEHRT to provide technical capabilities based on FHIR to facilitate efficient, scalable and standardized health information exchange. Approaches to public health reporting using FHIR have focused on greater automation of the interactions between health care providers and PHAs in order to reduce burden on providers, and to increase the ability of PHAs to obtain the information they need. CMS, ASTP and CDC plan to leverage FHIR-based capabilities within certified health IT to support public health reporting; feedback is requested on the following questions:

- What are the most promising uses of FHIR approaches to the public health reporting requirements under the Medicare PIP and which approaches have the most potential to reduce the burden of reporting on eligible hospitals and CAHs and increase the quality and timeliness of data submitted to PHAs?
- How might FHIR approaches to the exchange of public health data impact measurement of eligible hospital and CAH performance?
- If these approaches are implemented in certified health IT in the future, should the number of measures required in the Medicare PIP be streamlined or reduced?

11. RFI Regarding Data Quality

CMS believes hospitals should be able to seamlessly exchange high-quality health information with patients, providers, and payers across systems without gaps or discrepancies in data accuracy, completeness, reliability, and consistency. CMS defines “data quality” for purposes of this RFI as the degree to which health information is accurate, complete, timely, consistent, and reliable. CMS believes poor data quality poses direct threats to patient safety, especially when providers treat patients based on inaccurate or incomplete information, as well as to public health reporting and clinical research using real world evidence.

CMS seeks comment on the following questions:

- What data quality challenges does your health care organization experience (e.g., discrepancies in data accuracy, completeness, reliability, and consistency)? How are you working to address data quality challenges? What data quality challenges persist longitudinally across your patient populations?
- What are the primary barriers to collecting high-quality data?
- What resources would help your organization address these challenges?
- What solutions have hospitals found most effective to address data quality?
- What steps should CMS consider to drive further improvement in the quality and usability of health information being exchanged? What methods should CMS and other partners explore to further address data quality issues in the health care community?

XI. Transforming Episode Accountability Model (TEAM)

A. Background

Under its 1115A waiver authority, in the IPPS final rule for 2025 (89 FR 68986), CMS finalized a mandatory 5-year episode-based payment model (January 1, 2026 – December 31, 2030) to evaluate participating hospitals' performance on cost and quality metrics for five surgical episode categories: coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion. CMS proposed this model within the CMMI strategic refresh framework[144] and developed it in light of the agency's experience with the Bundled Payments for Care Improvement (BPCI) Initiative, the BPCI Advanced Model, and the Comprehensive Care for Joint Replacement (CJR) Model, as well as comments received in response to the Episode-based Payment Model request for information (RFI) published in July 2023.[145] 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. In last year's final rule, CMS noted that several of the elements of TEAM that it had proposed in the corresponding proposed rule (89 FR 35934) had not been finalized, and several other policies were flagged for future rulemaking. In this proposed rule, CMS addresses these policies and proposes the following modifications for TEAM:

- A limited deferment period for certain hospitals.
- Linking Track 2 participation eligibility for hospitals with a Medicare Dependent Hospital (MDH) designation to the expiration of the MDH program.
- Adding the Information Transfer Patient Reported Outcome-based Performance Measure (Information Transfer PRO-PM).
- Applying a neutral quality measure score for TEAM participants with insufficient quality data.
- A methodology to construct target prices when there are coding changes.
- Reconstructing the normalization factor and prospective trend factor.

[144] Innovation Center Strategy Refresh: https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper
[145] https://www.federalregister.gov/documents/2023/07/18/2023-15169/request-for-information-episode-based-payment-model

- Replacing the Area Deprivation Index (ADI) with the Community Deprivation Index (CDI).
- Using a 180-day lookback period and Hierarchical Condition Categories (HCC) version 28 for beneficiary risk adjustment.
- Aligning the date range used for episode attribution.
- Removing health equity plans.
- Expanding the Skilled Nursing Facility (SNF) 3-Day Rule Waiver.
- Removing the Decarbonization and Resilience Initiative.

Model participants are acute care hospitals paid under the IPPS, as defined in section 1886(d)(1)(B) of the Act. Participation is mandatory for hospitals selected to participate in order to avoid selection issues that arise in voluntary models.[146]

TEAM participants exclusively (and not other providers and suppliers involved in the care provided during an episode) bear sole financial accountability for performance under the model. In the case of episodes involving multiple hospitalizations, financial accountability falls to the TEAM participant that initiated the episode.

There are three tracks in TEAM, defined by varying levels of potential risk and reward. Track 1 is available only in Performance Year (PY) 1 for all TEAM participants and would have only upside financial risk with quality adjustment applied to positive reconciliation amounts. Track 2 is available in PYs 2 through 5 to a limited set of TEAM participants, including safety net hospitals, and has two-sided financial risk with quality adjustment to reconciliation amounts. Lastly, Track 3 is available in PYs 1 through 5 for all TEAM participants and has two-sided financial risk with quality adjustment to reconciliation amounts. CMS permits 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 are allowed to select between one of two tracks for the first performance year of TEAM.

TEAM episodes include non-excluded Medicare Parts A and B items and services and will begin with an anchor hospitalization or anchor procedure and would end 30 days after hospital discharge. TEAM participants will continue to bill Medicare FFS as usual for items and services delivered to beneficiaries in an episode but will receive preliminary target prices for episodes prior to each performance year. Target prices will be based on three years of baseline data, prospectively trended forward to the relevant performance year, and calculated at the level of Medicare Severity Diagnosis Related Group/Healthcare Common Procedure Coding System (MS-DRG/HCPCS) episode type and region. Target prices will also include a discount factor and risk adjustment. Participants will receive reconciliation (final) target prices that will incorporate a capped retrospective trend factor adjustment and a capped normalization factor. Performance in the model will be assessed by comparing TEAM participants' actual Medicare FFS spending during a performance year to their reconciliation target price as well as by assessing performance on selected quality measures. TEAM participants may earn a payment from CMS, subject to a quality performance adjustment, if their spending is below the

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

reconciliation target price. TEAM participants may owe CMS a repayment amount, subject to a quality performance adjustment, if their spending was above the reconciliation target price.

B. TEAM Provisions

1. Participation

As finalized in the FY 2025 IPPS final rule (89 FR 69642), participation in TEAM is mandatory for IPPS hospitals in selected geographic areas.[147] In finalizing TEAM, CMS did not account for new hospitals that open, or existing hospitals that convert to IPPS hospitals before or during the TEAM performance period. CMS contends that such hospitals may experience "multiple disadvantages" relative to other TEAM participants. Therefore, in this proposed rule, **CMS proposes to establish a cutoff date after which new hospitals and hospitals that begin to meet the definition of a TEAM participant and that are located in a mandatory core-based statistical area would not be required to participate immediately in the model and would have a limited deferment period before beginning their participation in TEAM**. Specifically, any new hospital[148]—as identified by Medicare ID (CMS Certification Number–CCN) with an initial effective date after December 31, 2024, within the Medicare Provider Enrollment, Chain, and Ownership System (PECOS)—would not be required to participate in TEAM immediately and would have at least one full performance year of participation deferment before being required to participate in the model. CMS also proposes that any hospital that begins to satisfy the definition of TEAM participant after December 31, 2024, would not be required to participate in TEAM immediately and would have at least one full performance year of participation deferment before being required to participate in the model. (CMS considered, but did not propose, allowing new hospitals or hospitals converting to IPPS status during the performance period to be exempt from TEAM participation altogether, or allowing such hospitals to participate in TEAM with no downside risk. Alternatively, CMS considered, but did not propose, requiring such hospitals to participate in TEAM on their effective dates, and also considered, but did not propose, alternative cutoff dates.)

To avoid TEAM-participating hospitals shifting patients to TEAM-excluded hospitals (*e.g.*, to avoid downside risk), **CMS proposes to monitor specifically for the potential shifting of patients with high anticipated episode spending from TEAM participants to non-participant hospitals**.

CMS seeks comment on its proposals for deferred participation in TEAM, and monitoring hospital admissions for signs of shifting patients between TEAM participants and deferred hospitals.

CMS also proposes that a hospital that no longer meets the definition of a TEAM participant would end their participation in the model effective the date they no longer meet the definition.

[147] Certain hospitals participating in BPCI Advanced and CJR can voluntarily opt into TEAM participation.
[148] Excepting any new hospital that is created as part of a reorganization event as defined at §512.505.

In the 2025 IPPS final rule, CMS specified that certain types of safety net hospitals, such as Medicare dependent hospitals (MDH) would be eligible for TEAM Track 2, with lower levels of two-sided financial risk. The statute authorizing the MDH program is currently set to expire September 30, 2025, which could potentially change MDHs' status with respect to TEAM participation if Congress does not extend the program. Therefore, **CMS proposes that TEAM participants that are classified as MDHs would still be eligible for Track 2 participation as long as the MDH program is active at the time that participation track selections are due to CMS**. (CMS believes that a large proportion of MDHs would be eligible to participate in TEAM Track 2 even if they lose their MDH status by virtue of being located in rural areas; rural hospitals are also eligible for Track 2.) **CMS seeks comment on its proposal to determine MDHs' eligibility for Track 2 participation in TEAM based on the hospitals' status in the MDH program on the date CMS requires the TEAM participants to submit their track selections for the upcoming PY. The agency also seeks comment on the potential to provide support to TEAM participants whose MDH designation ended as a result of the expiration of the MDH program in determining their eligibility for other hospital designations, such as rural and SCH, that are eligible for participation in Track 2 in PYs 2 through 5 of TEAM**.

CMS notes that it did not exempt Indian Health Service (IHS)/Tribal hospitals from TEAM participation because IHS/Tribal hospitals are paid under the IPPS. However, IHS/Tribal hospitals are not paid under the OPPS, as described in §419.20. While the TEAM participant definition does not explicitly state a hospital needs to be paid under the OPPS to participate in the model, CMS recognizes that allowing hospitals to participate in TEAM that are not paid under the OPPS may create challenges when constructing target prices for episodes that initiate in the hospital outpatient department, specifically for the LEJR and spinal fusion anchor procedures. Specifically, CMS is concerned that TEAM target prices for LEJR and spinal fusion procedures may not accurately reflect IHS/Tribal hospitals' episode spending. Oddly, CMS does not make specific proposals to address this problem, but rather inventories policies it considered, but did not propose.[149] CMS asks for comment on the policies it considered, or for alternative policies it did not consider.

2. Quality Measures

TEAM incorporates quality measures that focus on care coordination, patient safety, and patient reported outcomes (PROs), which CMS believes represent areas of quality that are particularly important to patients undergoing acute procedures. Where possible, CMS has attempted to align TEAM quality measures with those used in ongoing models and programs to minimize participant burden.

In the FY 2025 IPPS final rule, CMS finalized a set of quality measures for TEAM, summarized in Table XI.A.-02 of the proposed rule, reproduced below.

[149] For example, excluding IHS/Tribal hospitals from initiating anchor procedures, excluding IHS/Tribal hospitals from initiating episode categories that include both anchor hospitalizations and anchor procedures, excluding IHS/Tribal hospitals from the TEAM model entirely, or constructing IHS/Tribal hospital-specific target prices.

TABLE XI.A.-02: TEAM QUALITY MEASURES BY PERFORMANCE YEAR

FY 2025 IPPS/ LTCH PPS Finalized TEAM Quality Measures		
Performance Year 1	All Episode Categories	Hybrid Hospital-Wide All-Cause Readmission measure (CMIT ID #356)
Performance Year 1	All Episode Categories	CMS Patient Safety and Adverse Events Composite (CMIT ID #135)
Performance Year 1	Lower Extremity Joint Replacement Episodes	Hospital-Level Total Hip and/or Knee Arthroplasty (THA/THK) Patient Reported Outcome Based Measure (CMIT ID #1618)
Performance Year 2-5	All Episode Categories	Hospital Harm – Fall with Injury (CMIT ID #1518)
Performance Year 2-5	All Episode Categories	Hospital Harm – Postoperative Respiratory Failure (CMIT ID #1788)
Performance Year 2-5	All Episode Categories	Thirty-Day Risk – Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Compilations Mortality Rate)) (CMIT ID #134)

In the FY 2025 IPPS final rule, CMS stated that the agency may adjust the TEAM measure set in future performance years, via rulemaking, by adding new measures or removing measures if it determined those adjustments to be appropriate at the time. In this proposed rule, CMS is proposing several changes to and clarifications around the TEAM quality measure set finalized in the FY 2025 IPPS final rule.

The Hybrid Hospital-Wide All-Cause Readmission measure used under the Hospital Inpatient Quality Reporting (IQR) program has been made voluntary through June 30, 2026, given hospitals' early experience with that measure. However, CMS believes that hospitals will have sufficient experience with the measure such that the hybrid readmissions measure's first mandatory reporting period under the IQR should still serve as the baseline performance period for TEAM. Thus, **CMS proposes to align with the requirements set forth at 89 FR 93912, including utilizing the mandatory reporting period of July 1, 2025 – June 30, 2026, as TEAM's PY1 baseline period. CMS seeks comment on this proposal, as well as alternatives to it.**

In considering additional quality measures for TEAM, CMS evaluated certain measures currently used in the Hospital Outpatient Quality Reporting Program (OQR), and in this proposed rule **CMS proposes to use the OQR's Information Transfer PRO-PM for all episode categories in TEAM**.[150] This measure would be added to TEAM for performance years 3-5. **CMS seeks comment on the addition of this quality measure to TEAM**.

In the 2025 IPPS final rule, CMS recognized that some TEAM-participating hospitals (*e.g.*, a hospital newly participating in Medicare in 2025) may not have data on some quality measures during the TEAM performance period. This lack of data may make calculating the TEAM composite quality score (CQS)—a key mechanism for allocating rewards and penalties in

[150] Measure specifications for Information Transfer PRO-PRM are here: https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf

TEAM—challenging, but CMS believes it is important that TEAM participants not be penalized for incomplete data. Therefore, **CMS proposes to assign a neutral quality measure score to TEAM participants with no or an incomplete raw quality measure score for a given quality measure. Specifically, a TEAM participant that does not have a raw quality measure score for a given quality measure would be assigned a scaled quality measure score of 50, which is the midpoint on the CQS scale of 0-100**. CMS asserts that this approach would not disadvantage a TEAM participant who may be providing high quality care, because this neutral quality measure score ensures providers are not unfairly penalized due to insufficient quality measure data. Such an approach is consistent with the CJR model.

CMS seeks comment on its proposal at §512.547(b)(1)(i)(D) to assign a scaled quality measure score of 50 when the TEAM participant has no or an incomplete raw quality measure score for a given quality measure.

3. Pricing Methodology

CMS summarizes the pricing methodology finalized in the FY 2025 IPPS final rule (the agency recaps the calculation of episode target prices, risk adjustment, normalization, *et cetera*. For details, see HPA's summary of the FY 2025 IPPS final rule). In this proposed rule, CMS makes multiple proposals under the general topic of "pricing methodology." We have summarized each separately here for ease of reading.

Accounting for Future Changes to MS-DRGs and HCPCS

During the development of the FY 2025 IPPS final rule, CMS reconciled an inconsistency between its proposal to create spinal fusion TEAM episodes and changes that the agency had simultaneously proposed to spinal fusion MS-DRGs under the IPPS. CMS is addressing the potential for future inconsistencies in this proposed rule, given that failing to incorporate MS-DRG or HCPCS changes that arise between the baseline period and the performance year may lead to a significant drop in episode volume during the performance year and limit the number of beneficiaries exposed to the potential benefits of the model.

In this rule, **CMS is proposing a standard, three-step approach to account for MS-DRG and HCPCS/APC changes by remapping and adjusting relevant MS-DRG/HCPCS episode types during the baseline period to estimate performance year costs**. Step 1 would identify diagnosis or procedure codes that are being moved from one MS-DRG or HCPCS/APC to another based on the FY IPPS/LTCH or CY OPPS/ASC final rules of the relevant performance year, and then map these codes to the new or revised MS-DRGs or HCPCS/APCs. For Step 2, CMS proposes to construct episodes using the remapped MS-DRG or HCPCS/APC triggers. Under this proposal, an anchor hospitalization or anchor procedure based on the remapped MS-DRG or HCPCS would initiate the TEAM episode, rather than the original MS-DRG or HCPCS. CMS proposes that preliminary prices would then be constructed in the same manner described in §512.540 of the FY 2025 IPPS/LTCH PPS final rule, with target prices for each MS-DRG/HCPCS episode type, inclusive of episodes initiated by anchor hospitalizations and anchor procedures that would be related to these newly incorporated diagnosis or procedure codes. Lastly, CMS proposes that Step 3 would adjust the standardized allowed amounts used in target

price calculations to account for changes in fee-for-service rates between the baseline period and performance year due to changes to MS-DRG or HCPCS/APC weights. As part of this step, CMS would apply a scaling factor to calculate the final total adjusted episode cost.[151]

As an alternative to this proposal, CMS considered updating TEAM target prices to reflect Medicare payment rule updates, similar to the approach used in BPCI Advanced and the early years of the CJR model, but the agency did not proceed with this approach for TEAM given the potential confusion that would result from participants having to manage two different episode target prices.

CMS seeks comment on its proposed approach at §512.505 to define scaling and at §512.540(a)(2)(i) through (iii) to account for MS-DRG and HCPCS/APC changes between the baseline period and the performance year that arise from Medicare payment rule changes.

US Territories and Census Division 9

In the FY 2025 IPPS final rule, CMS indicated that hospitals in the U.S. territories[152] would be grouped in Census Division 9 (the Pacific region) for purposes of calculating regional target prices in TEAM. Here, **CMS formally proposes to revise the definition for region at §512.505 to mean one of the nine U.S. census divisions, as defined by the U.S. Census Bureau, with the U.S. territories included in Census Division 9. CMS seeks comment on this proposal**.

Calculation and Application of Normalization Factors

The normalization factor finalized in the FY 2025 IPPS final rule is the ratio of the average benchmark divided by the average risk-adjusted benchmark price. CMS multiplies the risk-adjusted benchmark prices by the normalization factor to ensure the average benchmark price after risk adjustment does not exceed the average benchmark price prior to risk adjustment.

In this proposed rule, **CMS proposes to update the language at §512.505 to clarify that the prospective normalization factor will be calculated using the benchmark prices (that is, the average non-risk adjusted preliminary benchmark price divided by the average risk adjusted preliminary benchmark price) rather than using preliminary target prices**. Specifically, the agency is proposing to revise the definition for prospective normalization factor to mean the multiplier incorporated into the preliminary target price. **CMS similarly proposes to revise the definition for final normalization factor at §512.505 to mean the benchmark price for each MS-DRG/HCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS-DRG/HCPCS episode type and region. CMS asks for comment on these proposals.**

[151] CMS defines the scaling factor at proposed §512.505 as the ratio of the re-mapped MS-DRG or HCPCS/APC relative weight in the performance year, as applicable to the original MS-DRG or HCPCS/APC relative weight in the baseline period.

[152] American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.

To further ensure consistency in calculating target prices, **CMS proposes to calculate normalization factors at the MS-DRG/HCPCS region level as the average regional non-risk adjusted benchmark price divided by the average regional risk-adjusted preliminary benchmark price for each MS-DRG/HCPCS episode type**. This will produce a unique normalization factor for each region and MS-DRG/HCPCS episode type for a total of 261 normalization factors (as opposed to just 29 normalization factors, as previously proposed). CMS contends that this approach is preferable because it will ensure that the regional average MS-DRG/HCPCS target price is equal to the regional average MS-DRG/HCPCS benchmark price. **CMS seeks comment on its proposal at §§512.540(b)(6) and 512.545(e)(1)(i) to construct the normalization factors for each MS-DRG/HCPCS at the region level**.

Lastly in this section, **CMS proposes that two separate preliminary target prices will be made available to all participants**: (1) the regional average target price for each MS-DRG/HCPCS episode type, before application of the risk adjustment factors or normalization factors; and (2) a TEAM participant-specific preliminary target price, including the TEAM participant's average risk adjustment factors (calculated based on the TEAM participant's case mix in the baseline period) and the regional MS-DRG/HCPCS normalization factors. **CMS seeks comment on this proposal**.

Calculation of the Prospective Trend Factor

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, CMS finalized a pricing methodology using a 3 percent capped retrospective trend factor. CMS contended that providing TEAM participants with preliminary target prices before each performance year—and ensuring the accuracy and reliability of preliminary target prices—is essential to participants' success. The methodology finalized in the FY 2025 IPPS/LTCH PPS final rule calculates preliminary target prices by applying a trend factor to average regional MS-DRG spending in the final year of the baseline period, in other words, the 2-year percentage change from baseline year 1 (BY1) to baseline year 3 (BY3)—specifically average regional MS-DRG spending in BY3 divided by average regional MS-DRG spending in BY1.

Subsequent to finalizing this method, CMS determined that using a simple BY1 to BY3 approach created undue volatility in the calculation of preliminary target prices and is now proposing several refinements to the trend factor calculation. First, **CMS proposes to change the calculation of the prospective trend factor from a percentage change based between BY1 and BY3 to an annual percentage change calculated using a linear regression model which would fit the model to logarithmically transformed values of average regional MS-DRG spending for each of the baseline years**. (CMS provides a detailed example of this calculation in the preamble text.) **Second, CMS proposes to use two additional years of data (the two years immediately prior to the 3-year baseline period) in the calculation of the prospective trend factor**. **Third, CMS proposes to use a blend of regional and national trend factors in the calculation of target prices**. Lastly, CMS proposes a change in how the agency applies the high-cost outlier cap finalized in the FY 2025 IPPS final rule. Specifically, **CMS proposes to revise the definition for high-cost outlier cap at §512.505 to mean the 99th percentile of regional spending for a given MS-DRG/HCPCS episode type, region, and baseline year**, which is the amount at which episode spending would be capped for purposes of determining baseline and performance year episode spending.

CMS seeks comment on its proposals at §512.540(b)(7) to reconstruct the prospective trend factor and at §512.540(b)(4) to calculate the high-cost outlier cap for each baseline year in the baseline period.

Standardizing Area Deprivation Index (ADI)

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), CMS finalized a social need risk adjustment factor for beneficiary-level risk adjustment in the construction of the preliminary and reconciliation TEAM target prices. This variable is a single binary variable with a value of yes=1 if the beneficiary (1) was eligible for full Medicaid benefits; (2) was eligible for the Medicare Part D Low Income Subsidy (LIS); or (3) resided in a census block group with an Area Deprivation Index (ADI) above the 80th percentile of either national ranking or 8th decile of the state-level ranking. At that time, CMS stated that the agency would continue to explore whether standardization of the ADI variables would be appropriate for the purposes of TEAM's risk adjustment approach and would propose any such changes in future rulemaking.

Subsequent to that final rule, based on additional analyses, CMS is now in this proposed rule proposing several changes to the social need risk adjustment factor in TEAM.

First, CMS **proposes to rename the social needs risk adjustment factor to the "beneficiary economic risk adjustment factor," and replace the use of the ADI in the construction of this factor with a similar index, the Community Deprivation Index (CDI).[153] Second, CMS proposes to use only national-level CDI rankings in the calculation of the beneficiary economic risk adjustment factor (in contrast to the previously finalized policy of using national- and state-level ADIs).** Lastly, CMS considered, but is not proposing, to omit the dual-eligibility variable from the construction of the beneficiary economic risk factor.

CMS seeks comment on these proposals, as well on whether or not to remove the dual-eligibility variable from the calculation of the economic risk adjustment factor.

Hierarchical Condition Categories in Risk Adjustment

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), CMS finalized the use of beneficiary-level variables that are episode-category specific. These beneficiary-level variables are drawn from the HCCs used in the CMS-HCC risk adjustment model that informs the Medicare Advantage (MA) capitation rates and Part C and Part D Payment Policies. While the specific HCCs were finalized for each episode category in TEAM, CMS did not specify how far back from the episode start date CMS would look to capture HCC data to determine the total count of HCCs and the episode-specific HCC variables.

In this proposed rule, **CMS proposes a 180-day lookback for each beneficiary, starting with the day prior to the anchor hospitalization or anchor procedure. The agency proposes to use the beneficiary's Medicare FFS claims from that 180-day lookback period to determine**

[153] The CDI is a composite of variables collected from the U.S. Census Bureau. https://pmc.ncbi.nlm.nih.gov/articles/PMC11629994/

which HCC variables the beneficiary is assigned and determine the HCC episode-specific flags as well as the TEAM HCC count flag. CMS also proposes that the TEAM beneficiary would need to meet beneficiary inclusion criteria, as described in §512.535, during the entire 180-day lookback period. CMS seeks comment on its proposal at proposed §512.545(a) to use a 180-day lookback period to determine the HCC flags to which the beneficiary is assigned.

In the development of TEAM episode target prices, CMS used version 22 (v22) of the CMS-HCC model to risk-adjust target prices for beneficiaries' clinical characteristics. Subsequently, CMS promulgated version 28 (v28) of the model in the 2023 Risk Adjustment Data Validation (RADV) final rule (88 FR 6643). **CMS now proposes to use CMS-HCC model v28 to risk-adjust target episode prices in TEAM**. CMS includes a detailed crosswalk between the v22 and v28 risk adjusters in Table XI.A.-011 of this proposed rule (not reproduced here for brevity).[154] **CMS seeks comment on its proposal at §512.545(a)(6)(i) through (v) to use HCC v28 to construct TEAM episode-category-specific HCC risk adjusters**.

Low-Volume Hospitals

CMS notes that in prior CMMI models (*e.g.*, CJR and BPCI Advanced), low-volume hospitals faced challenges under two-sided financial risk arrangements due to year-over-year volatility in pricing resulting from low volumes of cases. As a result, CMS developed low-volume policies specific to each of those models. CMS also proposed a low-volume policy for TEAM in the FY 2025 IPPS proposed rule (89 FR 35934), under which TEAM hospitals with less than 31 total episodes (across all episode categories) would be subject to Track 1 stop-loss and stop-gain limits in PY1, and Track 2 stop-loss and stop gain limits in PYs 2-5. In light of public comments received, however, CMS did not finalize this policy. In this proposed rule, **CMS proposes to maintain its current policy of no low-volume episode policy for TEAM**. However, CMS is considering potential future low-volume policies for TEAM and solicits public input on these ideas.

CMS is considering, but not proposing, that a low-volume threshold would apply to specific episode categories in the baseline period for a given PY, similar to BPCI Advanced. CMS is also considering, but not proposing, different low-volume thresholds for the above considered policy in the baseline period for a given episode category, including 91, 61, 51, 41, 21, and 11 episodes. The agency is also considering limiting the scope of any potential low-volume policy in TEAM only to safety net and rural hospitals. Alternatively, CMS is considering excluding from TEAM reconciliation any episodes that do not meet a low-volume threshold, or limiting the stop-gain and stop-loss amounts for low-volume hospitals participating in TEAM to 5 percent (or lower).

CMS seeks comment on its proposal to continue no low-volume episode policy in TEAM, the alternatives it is considering, and the agency asks commenters for other approaches beyond those articulated in this proposed rule.

[154] https://public-inspection.federalregister.gov/2025-06271.pdf#page=1018

Aligning Date Range in the Baseline and Performance Years and Timing of Reconciliation

In the FY 2025 IPPS PPS final rule (89 FR 68986), CMS finalized a policy under which the agency would calculate preliminary TEAM episode target prices using a 3-year rolling baseline period as described in §512.540(b)(2).[155] In this proposed rule, to better align TEAM episode attribution and pricing methodologies across the baseline and performance periods, **CMS is proposing to modify its approach to attribution of episodes to baseline years for the purposes of calculating preliminary target prices, adopting the same approach that the agency finalized for attribution of performance year episodes. CMS proposes that an episode with an anchor hospitalization beginning in a given baseline year and an anchor hospitalization discharge date in the subsequent baseline year would be attributed to the baseline year when the anchor hospitalization discharge date occurred**. For example, an episode with an anchor hospitalization beginning in December 2022 with an anchor hospitalization discharge date in January 2023 would be included in the baseline for both PY 1 (as baseline year 2 of a baseline period from January 1, 2022, to December 31, 2024) and PY 2 (as baseline year 1 of a baseline period from January 1, 2023, to December 31, 2025). This modification does not make any change to the methodology for attribution of episodes to the performance year. **CMS also proposes to reconcile an episode based on the episode's anchor hospitalization or anchor procedure discharge date**.

CMS seeks comment on both of these proposals.

Converting Target Prices and Reconciliation Amounts to Real Dollars

In the FY 2025 IPPS PPS final rule (89 FR 68986), CMS finalized the methodology for constructing TEAM regional target prices and, ultimately, determining performance year spending and reconciliation amounts, using standardized dollar amounts (referred to as "standardized dollars") as opposed to actual, nominal dollar amounts reflected on claims (referred to as "real dollars"). CMS acknowledges, however, that when target prices and reconciliation amounts are denominated in standardized dollars, they may not reflect relative differences in costs faced by TEAM participants. Therefore, CMS considered approaches to converting standardized target prices and reconciliation amounts back to real dollars as other CMMI models have done. However, CMS believes that such approaches may unduly negatively impact TEAM participants. Thus, in this proposed rule **the agency is not proposing any methodology for converting standardized target prices and reconciliation amounts to real dollars and is keeping target prices and reconciliation amounts in standardized dollars**. However, **CMS seeks comment on whether it should convert these amounts to real dollars and the preferred methodology for doing so**. Additionally, **CMS seeks comment on whether, if a TEAM participant's average post-episode spending in the MS-DRG/HCPCS episode type exceeds the region's threshold in that MS-DRG/HCPCS episode type, the amount above the threshold should be converted from standardized to real dollars using a hospital-level real-to-standardized spending ratio**. Lastly, **CMS seeks comment on its consideration to determine post-episode spending amounts at the MS-DRG-hospital level rather than an episode level**.

[155] *E.g.*, for PY 1, covering the period from January 1, 2026, to December 31, 2026, CMS would use a baseline period from January 1, 2022, to December 31, 2024.

4. Health Data Reporting

CMS asserts that due to the new Administration's priorities and concern over placing additional burdens on TEAM participants in a mandatory model, the agency "need[s] to remove the voluntary health equity plan and the health-related social needs data to reduce burden on TEAM participants." **Therefore, CMS proposes to**:

- Completely remove the health equity plan and health related social needs data policies from TEAM, including all references to health equity plans,
- Remove the "Health equity reporting" title at §512.563 and replace it with "Health data reporting,"
- Remove the definition for "Health equity goal," "Health equity plan," "Health equity plan strategy," "Health equity plan performance measure," and "Underserved community" from the definitions at §512.505,
- Remove the voluntary collection of health-related social needs screening and reporting,
- Explicitly not collect variables such as sexual orientation, race, ethnicity, or gender identity, and
- To align with the Administration's executive order to identify an individual's immutable biological classification as either male or female, to update the name of a beneficiary-identifiable data variable, which is not used for pricing or payment purposes, from "gender" (identified at §512.562(c)(3)) to "sex."

CMS seeks comment on these proposals.

5. Referral to Primary Care Services

In last year's 2025 IPPS final rule, CMS finalized a requirement for TEAM participants to refer participating beneficiaries to primary care services on discharge from an anchor hospitalization or after an anchor procedure. CMS is not changing this policy in this proposed rule, but recognizes the potential for disruption of continuity of care should a TEAM hospital refer a beneficiary to a primary care provider other than a primary care provider they may currently have. **CMS seeks comment on whether not specifically requiring that beneficiaries be referred back to suppliers with whom they have an existing relationship could disrupt fair competition as well as limit access to high-value care**, as well as alternative approaches to the standing primary care referral requirement.

6. Waivers of Medicare Program Requirements – 3-Day SNF Rule

In the FY 2025 IPPS final rule (89 FR 69833), CMS finalized a TEAM policy that waives the requirement for a 3-day inpatient hospital stay as a prerequisite for a covered post-acute care (PAC) stay in a skilled nursing facility (SNF). The finalized policy did not include SNF stays provided in hospital (or critical access hospital) swing beds, despite public comments supporting such a policy. However, in this proposed rule, to address stakeholder concerns surrounding PAC access in rural and underserved areas, **CMS now proposes to allow TEAM participants to use the TEAM SNF 3-day rule waiver for TEAM beneficiaries discharged to hospitals and CAHs providing PAC under swing bed arrangements**. CMS proposes to revise the

regulations governing the SNF 3-day rule waiver at §512.580(b)(1) to indicate that, for purposes of determining SNF qualification for the SNF 3- day rule waiver, SNFs include providers furnishing SNF services under swing bed arrangements.

CMS seeks comments on this proposal.

7. Decarbonization and Resilience Initiative

In the FY 2025 IPPS final rule (89 FR 69859), CMS finalized a voluntary Decarbonization and Resilience Initiative (DRI) under TEAM, under which TEAM hospitals could voluntarily report information on certain defined greenhouse gas emissions (organizational, building energy, anesthetic gas, and transportation) and thus receive technical assistance on reducing emissions.

CMS indicates that while the DRI is a voluntary initiative for TEAM participants and their hospital corporate affiliates, the agency recognizes that it does not align with the Administration's priorities. Therefore, **the agency proposes to remove the DRI from TEAM, and seeks comments on removing DRI from the corresponding regulations at §512.598**.

C. Information Collection Requirements for TEAM

Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. As stated in section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule for TEAM need not be reviewed by the Office of Management and Budget.

XII. Medicare Payment Advisory (MedPAC) Recommendations

In its March 2025 Report to Congress, MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law plus 1.0 percent. CMS responded that consistent with the statute, it is proposing an applicable percentage increase for FY 2026 of 2.4 percent provided the hospital submits quality data and is a meaningful EHR user.

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 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 FOR FY 2026

	Number of Hospitals[1]	Proposed FY 2026 Outlier Payments (1)[2]	Proposed FY 2026 Hospital Rate Update (2)[3]	MDH Expiration (3)[4]	Proposed FY 2026 Uncompensated Care Payments (4)[5]	Proposed FY 2026 Weights and DRG Changes with Application of Recalibration Budget Neutrality (5)[6]	Proposed FY 2026 Wage Index (6)[7,8,9]	All Proposed FY 2026 Changes (7)[10]
All Hospitals	3,038	0.2	2.3	-0.1	1.3	0.0	-0.2	3.4
By Geographic Location:								
Urban hospitals	2,369	0.2	2.3	-0.1	1.3	0.0	-0.2	3.5
Rural hospitals	669	0.1	2.3	-0.6	1.0	-0.5	0.3	2.5
Bed Size (Urban):								
0-99 beds	643	0.1	2.3	-1.5	1.3	0.2	0.1	2.6
100-199 beds	675	0.1	2.3	-0.3	1.1	-0.3	-0.2	2.8
200-299 beds	405	0.2	2.3	0.0	1.3	-0.1	-0.3	3.3
300-499 beds	393	0.2	2.3	0.0	1.2	0.0	-0.3	3.4
500 or more beds	251	0.3	2.2	0.0	1.4	0.2	-0.2	4.0
Bed Size (Rural):								
0-49 beds	320	0.0	2.3	-1.3	1.6	-0.6	0.5	2.3
50-99 beds	182	0.0	2.3	-1.6	1.0	-0.7	-0.2	0.9
100-149 beds	94	0.0	2.3	-0.1	1.0	-0.7	0.3	2.9
150-199 beds	42	0.1	2.3	0.0	0.8	-0.4	0.5	3.3
200 or more beds	31	0.1	2.3	0.0	0.6	-0.1	0.7	3.7
Urban by Region:								
New England	104	0.2	2.3	-0.2	0.6	-0.1	-2.0	0.8
Middle Atlantic	274	0.3	2.3	-0.1	1.0	-0.1	-0.5	2.8
East North Central	366	0.2	2.3	-0.3	0.7	0.0	-0.5	2.4
West North Central	156	0.2	2.3	0.0	0.7	0.2	1.7	5.1
South Atlantic	393	0.2	2.2	-0.1	1.7	0.0	-0.5	3.7
East South Central	142	0.2	2.3	0.0	1.8	0.1	1.0	5.3
West South Central	352	0.2	2.1	-0.1	3.4	0.1	0.5	6.3
Mountain	180	0.2	2.3	0.0	1.1	0.2	0.0	3.8
Pacific	351	0.3	2.3	0.0	0.6	0.1	-0.4	2.9
Rural by Region:								
New England	19	0.2	2.4	-1.5	0.3	-0.2	0.7	1.8
Middle Atlantic	50	0.1	2.4	-0.2	0.5	-0.5	0.0	2.2
East North Central	107	0.0	2.3	-1.5	0.7	-0.5	-0.4	0.6
West North Central	74	0.1	2.4	-0.4	0.3	-0.5	0.9	2.8
South Atlantic	108	0.0	2.2	-0.8	1.8	-0.6	0.3	3.0
East South Central	128	0.0	2.3	-0.4	1.5	-0.6	0.9	3.7
West South Central	118	0.1	2.2	-0.2	2.0	-0.5	0.4	4.0
Mountain	41	0.0	2.4	0.0	0.4	-0.2	0.5	3.1
Pacific	24	0.0	2.4	0.0	0.2	-0.8	-0.3	1.6
Puerto Rico								
Puerto Rico Hospitals	51	0.1	1.6	0.0	8.5	0.0	-0.9	9.4
By Payment Classification:								
Urban hospitals	1,609	0.2	2.3	0.0	1.5	-0.1	-0.1	3.8
Rural areas	1,429	0.2	2.3	-0.2	1.1	0.0	-0.3	3.2
Teaching Status:								
Nonteaching	1,765	0.1	2.3	-0.4	1.2	-0.2	-0.1	3.0
Fewer than 100 residents	980	0.2	2.3	-0.1	1.1	0.0	-0.1	3.3
100 or more residents	293	0.4	2.2	0.0	1.5	0.1	-0.4	3.8
Urban DSH:								
Non-DSH	334	0.1	2.4	-0.1	0.0	0.3	-0.2	2.6

	Number of Hospitals[1]	Proposed FY 2026 Outlier Payments (1) [2]	Proposed FY 2026 Hospital Rate Update (2) [3]	MDH Expiration (3)[4]	Proposed FY 2026 Uncompensated Care Payments (4) [5]	Proposed FY 2026 Weights and DRG Changes with Application of Recalibration Budget Neutrality (5) [6]	Proposed FY 2026 Wage Index (6) [7,8,9]	All Proposed FY 2026 Changes (7)) [10]
100 or more beds	916	0.2	2.3	0.0	1.6	-0.1	-0.1	3.9
Less than 100 beds	359	0.1	2.2	-0.3	2.2	-0.5	0.2	3.9
Rural DSH:								
Non-DSH	91	0.2	2.4	-1.7	0.0	0.2	-1.2	-0.3
SCH	231	0.0	2.3	0.0	0.6	-0.6	0.0	2.4
RRC	858	0.3	2.3	-0.1	1.1	0.1	-0.3	3.4
100 or more beds	45	0.2	2.2	-0.5	3.2	0.0	0.2	5.2
Less than 100 beds	204	0.1	2.2	-4.3	2.2	-0.6	0.7	-0.1
Urban teaching and DSH:								
Both teaching and DSH	531	0.2	2.3	0.0	1.7	-0.1	0.0	4.1
Teaching and no DSH	54	0.1	2.4	-0.3	0.0	0.0	-0.3	1.9
No teaching and DSH	744	0.2	2.3	0.0	1.5	-0.2	-0.2	3.5
No teaching and no DSH	280	0.1	2.4	0.0	0.0	0.6	-0.1	3.1
Special Hospital Types:								
RRC	132	0.1	2.3	-0.5	1.3	-0.3	0.2	3.1
RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	649	0.3	2.3	-0.1	1.2	0.1	-0.4	3.3
SCH	225	0.0	2.3	0.0	0.8	-0.6	0.0	2.5
SCH that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	38	0.0	2.4	0.0	0.1	-0.4	0.0	2.1
SCH and RRC	116	0.1	2.4	0.0	0.4	-0.4	0.3	2.7
SCH and RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	50	0.0	2.4	0.0	0.2	0.0	0.4	3.0
Type of Ownership:								
Voluntary	1,903	0.2	2.3	-0.2	0.9	0.0	-0.2	3.1
Proprietary	723	0.1	2.3	-0.1	1.4	0.0	-0.4	3.4
Government	412	0.3	2.1	-0.1	3.0	0.0	0.0	5.5
Medicare Utilization as a Percent of Inpatient Days:								
0-25	1,543	0.3	2.2	0.0	1.8	0.0	0.0	4.4
25-50	1,400	0.2	2.4	-0.3	0.6	-0.1	-0.5	2.3
50-65	65	0.1	2.4	-0.4	0.2	0.3	-0.8	1.9
Over 65	14	0.3	2.5	-0.6	0.0	3.1	0.7	6.0
Medicaid Utilization as a Percent of Inpatient Days:								
0-25	1,861	0.2	2.3	-0.2	0.9	0.0	-0.2	3.0
25-50	1,052	0.3	2.3	0.0	1.4	0.0	-0.2	3.7
50-65	93	0.3	2.0	0.0	5.6	-0.4	-0.5	6.9
Over 65	31	0.1	1.6	0.0	14.3	-0.4	-0.2	15.5
FY 2026 Reclassifications:								
All Reclassified Hospitals	1,172	0.2	2.3	-0.2	1.1	0.0	-0.3	3.3
Non-Reclassified Hospitals	1,866	0.2	2.3	-0.1	1.5	-0.1	-0.1	3.7
Urban Hospitals Reclassified	1,011	0.3	2.3	-0.1	1.2	0.1	-0.3	3.4
Urban Non-reclassified Hospitals	1,371	0.2	2.3	0.0	1.5	-0.1	-0.1	3.7
Rural Hospitals Reclassified Full Year	280	0.0	2.3	-0.4	0.9	-0.5	0.4	2.8
Rural Non-reclassified Hospitals Full Year	376	0.1	2.3	-0.8	1.1	-0.5	0.3	2.4
All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	812	0.3	2.3	-0.2	1.2	0.1	-0.3	3.3
Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lugar hospitals)	52	0.1	2.3	-2.3	1.1	-0.6	0.3	0.7

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2024, and hospital cost report data are from the latest available reporting periods.
[2] This column displays the effects of estimated outlier payments returning to their targeted levels in FY 2026 as compared to the estimated outlier payments for FY 2025.
[3] This column displays the payment impact of the hospital rate update, including the proposed 2.4 percent update to the national standardized amount and the hospital-specific rate (the proposed 3.2 percent IPPS market basket rate-of-increase reduced by the proposed 0.8 percentage point for the productivity adjustment).
[4] This column displays the impact of the expiration of the MDH status on October 1, 2025, a non-budget neutral payment provision.
[5] This column displays the effects of the proposed changes to estimated uncompensated care payments in FY 2026 as compared to FY 2025. See also the table in section I.G.2 of this Appendix.
[6] This column displays the payment impact of proposed Version 43 GROUPER, the proposed changes to the relative weights and the proposed recalibration of the MS-DRG weights based on FY 2024 MedPAR data, and the 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 factor and the proposed 10-percent cap budget neutrality factor (which can be found in section II.A.4 of the Addendum of this proposed rule).
[7]This column displays the effects of the changes to the proposed FY 2026 wage index. This includes (1) the proposed update to wage index data using FY 2022 cost report data, the application of the proposed wage budget neutrality factor and the proposed update to the labor and nonlabor shares. (2) The effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB), showing the payment impact of going from FY 2025 reclassifications to the reclassifications scheduled to be in effect for FY 2026. (3) The effects of the application of the proposed rural floor. (4) The effects of urban to rural reclassifications under section 1886(d)(8) of the Act on the proposed wage index. (5) The effects of the application of "LUGAR" status under section 1886(d)(10) of the Act on the proposed wage index. (6) The proposed adjustments to the wage index driven by non-budget neutral policies. These include (a) the imputed floor for all-urban states; (b) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (c) 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. The budget neutrality factors for the effects that are budget neutral can be found in section II.A.4 of the Addendum of this proposed rule.
[8] For the traditional wage index information showing the effect of including or excluding particular wage index polices from the computation of the FY 2026 wage index instead of the impact of the wage index changes from FY 2025 to FY 2026 shown in Table I, we refer readers to the data file available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html (click on the link on the left side of the screen titled "FY 2026 IPPS Proposed Rule Home Page".)
[9] We note that because the low wage index hospital policy was removed for FY 2025, the proposed discontinuation of the policy effective FY 2026 has no impact on the estimated change in proposed payments from FY 2025 to FY 2026. However, the proposed budget neutral transition for the discontinuation of the low wage index hospital policy will redistribute payments from hospitals that do not benefit from the proposed transition to hospitals that do benefit (primarily all the hospitals located in Puerto Rico) due to the associated budget neutrality factor. The budget neutrality factor for the proposed transition can be found in section II.A.4 of the Addendum of this proposed rule.
[10] This column shows the estimated change in proposed payments from FY 2025 to FY 2026.