

An Analysis and Commentary on Federal Health Care Issues

by Larry Goldberg

May 28, 2024

## The Centers for Medicare & Medicaid Services (CMS) Issues the FY 2025 Proposed Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) PPS Rule



The Centers for Medicare and Medicaid Services (CMS) have issued a proposed rule to update the Hospital Inpatient Prospective Payment System (IPPS) and the Long-Term Care Hospital (LTCH) Prospective Payment System for fiscal year (FY) 2025.

The document is currently on public display at the **Federal Register** office and is scheduled for publication on May 2. A display version of the 1,902-page rule is currently available at: <u>https://public-inspection.federalregister.gov/2024-07567.pdf</u>. A 60-day comment period ending June 10 is provided.

The IPPS tables for this fiscal year (FY) 2025 proposed rule are available on the CMS website at: <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html</u>. Click on the link on the left side of the screen titled "FY 2025 IPPS Proposed rule Home Page" or "Acute Inpatient—Files for Download."

The LTCH PPS tables are available on the CMS website at: <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html</u> under the list item for Regulation Number CMS-1808-P.

Distributed by TPR Solutions, LLC with the permission of Larry Goldberg Consulting



#### Comments

This is a complex and extremely long rule. CMS has not provided any table of contents. In addition, it appears as inadvertent errors were made in this proposed ruling (examples will be identified below).

The proposal's order has been revised and is different from past rules.

The proposal's first 43 pages provides a basic executive summary of the changes being proposed; a summary of major provisions; and a summary of proposed provisions. Rather than attempting to distill the information, please refer to the summary of costs and benefits table below. The table is not all inclusive but does provide helpful information.

As is customary for us, we are adding page numbers based on the display version. In many cases we are showing more than a single location specific material is addressed.

Many payment issues can be found in the rule's Addendum (beginning on page 1,605).

This analysis does not follow the rule's organization.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Continuation of the Low Wage Index Hospital Policy	CMS is proposing to continue the low wage index hospital policy and the related budget neutrality adjustment for at least 3 years beginning in FY 2025.
Proposed Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines	CMS is proposing to make an IPPS payment adjustment for the additional resource costs that small, independent hospitals incur in establishing and maintaining access to a 6-month buffer stock of one or more essential medicine(s) beginning in FY 2025. This proposed payment adjustment would not be budget neutral. CMS estimates that 493 hospitals would qualify under this proposal. CMS estimates that the cost to those hospitals to establish buffer stocks of essential medicines would, in aggregate summed across all 493 hospitals, be approximately \$2.8 million. Under the proposal, Medicare would pay its share of those costs (approximately 11 percent of that amount, or \$0.3 million).
Uncompensated Care Payments	For FY 2025, CMS is proposing to update its estimates of the three factors used to determine uncompensated care payments. CMS is proposing to continue using uninsured estimates produced by OACT as part of the development in the calculation of Factor 2. As provided in the regulation at § 412.106(g)(1)(iii)(C)( <i>11</i> ), for FY 2025, CMS is proposing to use the 3 most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2019, FY 2020, and FY 2021 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals.
Proposed Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A, acute care hospitals are estimated to experience an increase of approximately \$3.2 billion in FY 2025, primarily driven by the changes in FY 2025 operating payments and capital payments and the expiration of the temporary changes in the low-volume hospital program and the expiration of the MDH program on January 1, 2025.
Comment	Note, a significant reason for CMS citing the \$3.2 billion increase is due to an increase of DSH payment amounts totaling \$560 million.

#### Summary of Costs and Benefits (Page 25)

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A, based on the best available data for the 330 LTCHs in CMS' database, the agency estimates that the proposed changes to the payment rates and factors that presented in the preamble of and Addendum of this proposed rule, which reflect the proposed update to the LTCH PPS standard Federal payment rate for FY 2025, would result in an estimated increase in payments in FY 2025 of approximately \$41 million.
Proposed Distribution of Additional Residency Positions Under the Provisions of Section 4122 of Subtitle C of the Consolidated Appropriations Act, 2023 (CAA, 2023)	Section 4122(a) of the CAA, 2023 amended section 1886(h) of the Act by adding a new paragraph 1886(h)(10) requiring the distribution of additional residency positions (also referred to as slots) to hospitals. CMS refers readers to section V.J.2. of this proposed rule for a summary of the provisions of section 4122 that it is proposing to implement. CMS estimates that the proposal would result in an estimated cost of approximately \$10 million for FY 2026.
Changes to the Value-Based Incentive Payments under the Hospital VBP Program	CMS estimates that there would be no net financial impact to the Hospital VBP Program for the FY 2025 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for that year, as estimated by the FY 2025 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2025 discharges is approximately \$1.7 billion.
Changes to the Hospital IQR Program	Across 3,050 IPPS hospitals, CMS estimates that its proposed changes for the Hospital IQR Program would result in a total information collection burden increase of 40,019 hours at a cost increase of \$1,274,980 associated with the proposed policies across a 3-year period from the CY 2025 reporting period/FY 2027 payment determination through the CY 2027 reporting period/FY 2029 payment determination.
Changes to the PCHQR Program	Across 11 PCHs, CMS estimates that its proposed changes for the PCHQR Program would result in a total information collection burden increase of 166 hours at a cost increase of \$4,047 beginning with the CY 2025 reporting period/FY 2027 program year.
Changes to the LTCH QRP	Across 329 LTCHs, CMS estimates that its proposed changes for the LTCH QRP would result in a total information collection burden increase of 116.55 hours associated with its policies and updated burden estimates and a total cost increase of approximately \$138,231.88 for the FY 2028 LTCH QRP.
Changes to the Medicare Promoting Interoperability Program	Across 4,550 eligible hospitals and CAHs, CMS estimates that its proposed changes for the Medicare Promoting Interoperability Program would result in an increase of 5,038 hours at a cost increase of \$262,581 to the information collection burden for the EHR reporting period in CY 2027 and subsequent years.
Transforming Episode Accountability Model (TEAM)	CMS estimates that testing TEAM would result in saving the Medicare program \$705 million across the 5 performance years.
CoP Requirements for Hospitals and CAHs to Report Acute Respiratory Illnesses	Across 6,384 hospitals and CAHs, CMS estimates that its proposed changes would result in 248,976 hours and a total cost of \$19,420,128 for the weekly reporting, which is \$3,042 per facility yearly. CMS estimates for PHE reporting, if declared by the secretary, Low to high hours range 1,005,480 to 3,495,240 and total cost ranging from \$78,427,440 to \$272,628,720 depending on the frequency of reporting required.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Proposed Changes for the Add-On Payments for New Services and Technologies	As discussed in Appendix A, CMS is proposing to change the April 1 cutoff to October 1 for determining whether a technology would be within its 2- to 3-year newness period. If CMS determines that all 10 of the FY 2025 new technology add-on payment applications that have been FDA-approved or cleared since the start of FY 2024 meet the specified criteria for new technology add-on payments and if CMS determines that none of these for technologies would be substantially similar to those technologies that were first approved for new technology add-on payments prior to FY 2025, based on preliminary information from the applicants at the time of this proposed rule, this proposal would increase IPPS spending by approximately \$380 million in FY 2027. CMS is also proposing to no longer consider a hold status to be an inactive status for the purposes of eligibility for the new technology add-on payment. CMS notes that the cost impact of this proposal is not estimable. CMS expects that some applicants who were ineligible to apply in FY 2025 may apply for new technology add-on payments for FY 2026. Finally, CMS is proposing, for certain gene therapies for the treatment of sickle cell disease (SCD), it will temporarily increase the new technology add-on payment percentage to 75 percent. CMS says that it is premature to estimate the potential payment impact for FY 2025 because CMS has not yet determined whether any gene therapy indicated and used specifically for the treatment of SCD will meet the specified criteria for new technology add-on payments for FY 2025

#### I. Proposed Changes to the Prospective Payment Rates (Pages 603 and Addendum Page 1,607)

The following items are located in the rule's proposed Section V – Other Decisions and Changes to the IPPS for Operating System. Please use the page numbers to locate the information.

#### (a) Proposed Rate Update (Page 611)

The applicable percentage increase under the IPPS for FY 2025 would be equal to the rate-of-increase in the hospital market basket, subject to the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide multifactor productivity (MFP) (the productivity adjustment).

CMS is proposing to base the FY 2025 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2023 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2023, which is estimated to be 3.0 percent. (Page 612)

For FY 2025, CMS is proposing a productivity adjustment of 0.4 percent. (Page 613)

Both the market basket and productivity adjustment may change in the final rule if more recent data becomes available. Normally, this has occurred.

CMS displays four possible applicable percentage increases as shown in the following table. (Page 614)

#### Proposed FY 2025 Applicable Percentage Increases for the IPPS

FY 2025	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data (Reduction of ¼ of market basket increase)	0.0	0.0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR (Reduction of ¾ of market basket)	0.0	-2.25	0.0	-2.25
MFP Adjustment	-0.4	-0.4	-0.4	-0.4
Applicable Percentage Increase Applied to Standardized Amount	2.6	0.35	1.85	-0.4

Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive an update of 0.35 percent, which includes a reduction of three-quarters of the market basket update and the reduction due to the productivity adjustment (3.0 - 2.25 = 0.75 - 0.4 productivity = 0.35).

Hospitals that fail to comply with the quality data submission requirements but are meaningful EHR users will receive an update of 1.85 percent. This update includes a reduction of one-quarter of the

market basket update for failure to submit this data (3.0 -0.725 = 2.275- 0.4 productivity = **1.85**).

Further, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive an update of -0.4 percent. Market basket minus market basket minus 0.4 percent productivity adjustment (3.0-3.0 = 0-0.4 = -0.4).



The current (FY 2024) large urban labor rate is \$4,392.49 and the non-labor rate is \$2,105.28 for a total of \$6,497.77. The other area labor rate is \$4,028.62 and the non-labor component is \$2,469.15 also for a total of \$6,497.77.

The following table (Page 1,667) illustrates the changes from the current FY 2024 national standardized amounts to the proposed FY 2025 national standardized amounts. The \$6,497.77 amounts are adjusted by the outlier, geographic and the rural demonstration reclassification factors, etc. as shown below resulting in a gross payment rate of \$7,073.98. This amount is then further adjusted by multiplying the proposed FY 2025 adjustments.

### Proposed Changes from the Current FY 2024 Standardized Amounts to the Proposed FY 2025 Standardized Amounts

FY 2025 Base Rate after removing: 1. FY 2024 Geographic	Hospital Submitted Quality Data and is a Meaningful EHR User If Wage Index is Greater Than 1.0000: Labor (67.6%) \$4,782.01	Hospital Submitted Quality Data and is NOT a Meaningful EHR User If Wage Index is Greater Than 1.0000: Labor (67.6%) \$4,782.01	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User If Wage Index is Greater Than 1.0000: Labor (67.6%) \$4,782.01	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User If Wage Index is Greater Than 1.0000: Labor (67.6%) \$4,782.01
Reclassification Budget Neutrality (0.971295)	Nonlabor (32.4%) \$2,291.97	Nonlabor (32.4%) \$2,291.97	Nonlabor (32.4%) \$2,291.97	Nonlabor (32.4%) \$2,291.97
2. FY 2024 Operating Outlier Offset (0.949)	(Combined labor and nonlabor = \$7,073.98)	(Combined labor and nonlabor = \$7,073.98)	(Combined labor and nonlabor = \$7,073.98)	(Combined labor and nonlabor = \$7,073.98)
<ul> <li>3. FY 2024 Rural Demonstration</li> <li>Budget Neutrality Factor</li> <li>(0.999463)</li> </ul>	If Wage Index is less Than or Equal to 1.0000: Labor (62%) \$4,385.87 Nonlabor (38%)	If Wage Index is less Than or Equal to 1.0000: Labor (62%) \$4,385.87 Nonlabor (38%)	If Wage Index is less Than or Equal to 1.0000: Labor (62%) \$4,385.87 Nonlabor (38%)	If Wage Index is less Than or Equal to 1.0000: Labor (62%) \$4,385.87 Nonlabor (38%)
<ul> <li>4. FY 2024 Lowest Quartile Budget Neutrality Factor (0.997402)</li> <li>5. FY 2024 Cap Policy Wage</li> </ul>	\$2,688.11 (Combined labor and nonlabor = \$7,073.98)	\$2,688.11 (Combined labor and nonlabor = \$7,073.98	\$2,688.11 (Combined labor and nonlabor = \$7,073.98	\$2,688.11 (Combined labor and nonlabor = \$7,073.98
Index Budget Neutrality Factor (0.999645)	<i>\$1,010.00</i>	<i>\$7,073.30</i>	<i>\$7,67,37,50</i>	<i></i>
Proposed FY 2025 Update Factor	1.026	1.0035	1.0185	0.996
Proposed FY 2025 MS-DRG Weight Budget Neutrality Factor	0.997055	0.997055	0.997055	0.997055
Proposed FY 2025 Cap Policy MS- DRG Weight Budget Neutrality Factor	0.999617	0.999617	0.999617	0.999617
Proposed FY 2025 Wage Index Budget NeutralityFactor	0.999957	0.999957	0.999957	0.999957

	Subi Quali and Meai	spital mitted ty Data d is a ningful t User	Sub Quali and i Mea	spital mitted ty Data s NOT a ningful & User	NOT Qual an Mea	oital Did Submit ity Data d is a ningful R User	NOT Quali and i Mea	ital Did Submit ty Data s NOT a ningful & User
Proposed FY 2025 Reclassification Budget Neutrality Factor		0.976773		0.976773		0.976773		0.976773
Proposed FY 2025 Low Wage Index Budget Neutrality Factor		0.997498		0.997498		0.997498		0.997498
Proposed FY 2025 Cap Policy Wage Index Budget Neutrality Factor		0.997162		0.997162		0.997162		0.997162
Proposed FY 2025 Rural Demonstration Budget Neutrality Factor		0.999513		0.999513		0.999513		0.999513
Proposed FY 2025 Operating Outlier Factor		0.949		0.949		0.949		0.949
Proposed National Standardized Amount for FY2025 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	Labor: Nonlabor:	\$4,506.29 \$2,159.81	Labor: Nonlabor:	\$4,407.47 \$2,112.45	Labor: Nonlabor:	\$4,473.35 \$2,144.02	Labor: Nonlabor:	\$4,374.53 \$2,096.66
Proposed National Standardized Amount for FY2025 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	Labor: Nonlabor:	\$4,132.98 \$2,533.12	Labor: Nonlabor:	\$4,042.35 \$2,477.57	Labor: Nonlabor:	\$4,102.77 \$2,514.60	Labor: Nonlabor:	\$4.012.14 \$2,459.05

The change between the final FY 2024 full market-basket rate of increase amount of \$6,497.77 and the proposed FY 2025 amount of \$6,666.10 is \$168.33, which represents a 2.6 percent increase.

These amounts are before other adjustments such as the hospital value-based purchasing program, the hospital readmission program, and the hospital acquired conditions program.

#### Comment

CMS says 91 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2025 because they failed the quality data submission process or did not choose to participate but are meaningful EHR users. (Page 1,764)

CMS says 87 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2025 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act.

CMS says 26 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2025 because they are identified as not meaningful EHR users that do not submit quality data.

#### **Outlier Payments** (Page 1,634)

CMS' current estimate is using available FY 2023 claims data. The actual outlier payments for FY 2023 were approximately 5.23 percent of actual total MS-DRG payments.

CMS is proposing an outlier fixed-loss cost threshold for FY 2025 equal to the prospective payment rate for the MS-DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated

care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico

hospitals, and any add-on payments for new technology, plus **\$49,237.** The current threshold is \$42,750.

#### Comment

Once again, CMS argues that to make retroactive adjustments for errors in forecasting outlier payments "would remove an important aspect of the prospective nature of the IPPS. Because such an across-theboard adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized."

The skilled nursing PPS has an error correction process that changes the SNF market basket factors prospectively. CMS should be doing the same for all its PPS programs, including errors in not only the market basket payments but the outlier rate of increase as well.

#### (b) Changes to MS-DRGs Subject to Post-acute Care Transfer Policy and MS-DRG Special

#### Payments Policies (§ 412.4) (Page 603)

CMS is proposing the following DRG changes with respect to whether or not the proposed changes would be impacted by CMS' post-acute transfer policies.

List of Proposed New or Revised MS-DRGs Subject to Review of Post-acute Care Transfer Policy Status for FY 2025									
Proposed New or Revised MS- DRG	MS-DRG Title	Total Cases	Post-acute Care Transfer Cases (55 <sup>th</sup> percentile: 1,056)	Short-Stay Post-acute Care Transfer Cases	Percent of Short- Stay Post-acute Care Transfers to all Cases (55 <sup>th</sup> percentile: 10.178%)	FY 2024 Post-acute Transfer Policy Status	Proposed Post-acute Care Transfer Policy Status		
317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation	1,842	311*	14	0.8%*	New	No		
402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical	17,032	6,778	718	4.2%*	New	No		
426	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC	2,833	2,285	764	27%	New	Yes		
427	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC	13,259	8,047	2,313	17.4%	New	Yes		
428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC	8,329	3,482	329	4.0%*	New	Yes **		
429	Combined Anterior and Posterior Cervical Spinal Fusion with MCC	622	484*	172	27.7%	New	No		
430	Combined Anterior and Posterior Cervical Spinal Fusion without MCC	1,872	968*	128	6.8%*	New	No		
447	Multiple Level Spinal Fusion Except Cervical with MCC	2,200	1,814	778	35.4%	New	Yes		
448	Multiple Level Spinal Fusion Except Cervical without MCC	15,496	8,376	1,673	10.8%	New	Yes		
459	Single Level Spinal Fusion Except Cervical with MCC	1,170	897*	286	24.4%	Yes	No		
460	Single Level Spinal Fusion Except Cervical without MCC	14,830	6,355	750	5.1%*	Yes	No		
850	Acute Leukemia with Other Procedures	384	139*	46	12%	New	No		

\*Indicates a current post-acute care transfer policy criterion that the MS-DRG did not meet.

\*\* As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS-DRGs that share the same base MS-DRG will all qualify under the post-acute care transfer policy if any one of the MS-DRGs that share that same base MS-DRG qualifies.

Proposed	MS-DRG Title	Geometric	Average	50 Percent of	FY 2024	Proposed
New or		Mean	Charges of	Average	Special	Special
Revised		Length of	1-Day	Charges for	Payment	Payment
MS-DRG		Stay	Discharges	all Cases	Policy	Policy Status
				within MS-	Status	
				DRG		
426	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC	7.7	\$244,471	\$236,394	New	Yes
427	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC	4	\$211,714	\$156,062	New	Yes
428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC	2.6	\$214,986	\$107,493	New	Yes*
447	Multiple Level Spinal Fusion Except Cervical with MCC	8.1	\$163,042	\$145,144	New	Yes
448	Multiple Level Spinal Fusion Except Cervical without MCC	3.2	\$149,862	\$89,091	New	Yes*

\* As described in the policy at 42 CFR 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the special payment transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

# (c) Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96) (Page 618)

A rural hospital with less than 275 beds may be classified as an RRC if—

- The hospital's case-mix index (CMI) is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- The hospital's number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. (The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges.)

Case-mix

If rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2024, they must have a CMI value for FY 2023 that is:

- **1.7764** (national--all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The CMI values by region are set forth in the following table:

Region	Proposed Case-MixIndex Values
1. New England (CT, ME, MA, NH, RI, VT)	1.49655
2. Middle Atlantic (PA, NJ, NY)	1.5563
3. East North Central (IL, IN, MI, OH, WI)	1.6427
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7216
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6306
6. East South Central (AL, KY, MS, TN)	1.59315
7. West South Central (AR, LA, OK, TX)	1.7814
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.7804
9. Pacific (AK, CA, HI, OR, WA)	1.7821

A hospital must also have the number of discharges for its cost reporting period that began during FY 2022 a figure that is at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located.

CMS says that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this proposed rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

#### (d) Proposed Payment Adjustment for Low-Volume Hospitals (§ 412.101) (Page 625)

Section 306 of the CAA, 2024 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment through December 31, 2024. Beginning January 1, 2025, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011, and the preexisting low-volume hospital payment adjustment methodology and qualifying criteria, as implemented in FY 2005 will resume.

#### Comment

Any extension of this adjustment would require Congressional action.

#### (e) Proposed Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program

#### (§ 412.108) (Page 637)

Because section 307 of the CAA, 2024 extended the MDH program through December 31, 2024 only, beginning January 1, 2025, the MDH program will no longer be in effect. Since the MDH program is not authorized by statute beyond December 31, 2024, beginning January 1, 2025, all hospitals that previously qualified for MDH status under section 1886(d)(5)(G) of the Act will no longer have MDH status and will be paid based on the IPPS Federal rate.

CMS says that currently 173 MDHs, of which it estimates 114 would have been paid under the blended payment of the Federal rate and hospital-specific rate while the remaining 59 would have been paid based on the IPPS Federal rate.

In order for an MDH to receive SCH status effective January 1, 2025, the MDH must apply for SCH status at least 30 days before the expiration of the MDH program; that is, the MDH must apply for SCH status by December 2, 2024.

#### Comment

Any extension of this adjustment would require Congressional action.

# (f) Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 through 413.83) (Page 641)

Section 4122(a) of the **Consolidated Appropriations Act** (CAA), 2023 amended section 1886(h) of the Act by adding a new section 1886(h)(10) of the Act requiring the distribution of additional residency positions (also referred to as slots) to hospitals. Section 1886(h)(10)(A) of the Act requires that for FY

2026, the Secretary shall initiate an application round to distribute 200 residency positions. At least 100 of the positions made available under section 1886(h)(10)(A) shall be distributed for psychiatry or psychiatry subspecialty residency training programs.

WASHINGTON

perspectives

In determining the qualifying hospitals for which an increase is provided, section 1886(h)(10)(B)(i) of the Act requires the Secretary to take into account the "demonstrated likelihood" of the hospital filling the positions made available within the first 5 training years beginning after the date the increase would be effective, as determined by the Secretary.

The IME formula multiplier remains unchanged at 1.35.

#### Comment

The topic of GME has consistently been complex and detailed. Those involved with this subject need to carefully review the material being presented and proposed. CMS spends more than 30 pages discussing this.

# (g) 3. Proposed Modifications to the Criteria for New Residency Programs and Requests for Information (Page 670)

CMS notes that the question of what constitutes a "new" program for purposes of receiving additional Medicare-funded GME slots has taken on increasing significance in light of the ability of urban hospitals to reclassify as rural under 42 CFR 412.103 for IME purposes, and thus receive additional IME cap slots for any new program started. To ensure that newly funded cap slots are created appropriately, CMS is seeking to establish in rulemaking additional criteria for determining program newness.

CMS has outlined proposals and requests for information across four areas:

- Newness of Residents (Page 671)
- Newness of Faculty and Program Director (Page 674)
- Commingling of Residents in a New and an Existing Program (Page 678)
- One Hospital Sponsoring Two Programs in the Same Specialty (Page 679)

#### Comment

Providers should read carefully the proposals and requires for information that CMS has put forth in this section and provide comment.

#### (h) Separate IPPS Payment for Establishing and Maintaining Access to Essential Medicines

#### (Page 702)

CMS is proposing a separate payment for small, independent hospitals to establish and maintain a buffer stock of essential medicines for use during future shortages. These hospitals are particularly vulnerable to supply disruptions during shortages because they lack the resources of hospitals that are larger and/or are part of a chain organization.

The essential medicines list is contained in the Advanced Regenerative Manufacturing Institute's (ARMI's) Next Foundry for American Biotechnology, which has prioritized 86 essential medicines (hereinafter referred to as the "ARMI List" or "ARMI's List"). CMS proposes to define a small hospital as one with not more than 100 beds. CMS proposes to define an independent hospital as one that is not part of a chain organization, as defined for purposes of hospital cost reporting.

#### (i) Hospital Readmissions Reduction Program (Pages 725 & 1,813)

The Hospital Readmissions Reduction Program reduces payments to hospitals with excess readmissions. CMS is not proposing any changes to the Hospital Readmissions Reduction Program.

CMS says that 2,356 hospitals will subject to penalty under this provision.

#### (j) Hospital Value-Based Purchasing (VBP) Program (Pages 726 & 1,817)

The Hospital VBP Program is a budget-neutral program funded by reducing participating hospitals' base operating DRG payments each fiscal year by 2.0 percent and redistributing the entire amount back to the hospitals as value-based incentive payments. CMS is proposing to:

- Adopt the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year.
- Modify the HCAHPS Survey measure beginning with the CY 2025 reporting period/FY 2027 program year.
- Move up the start date for publicly displaying hospital performance on the Hospital Commitment to Health Equity measure to January 2026 or as soon as feasible thereafter.

The applicable percent reduction from each hospital for the FY 2025 program year is 2.00 percent. CMS estimates that the total amount available for value-based incentive payments for FY 2025 is approximately \$1.7 billion.

#### Comment

The material in this section details much scoring objectives and contains numerous benchmarks and achievement thresholds.

#### (k) Hospital-Acquired Condition (HAC) Reduction Program (Pages 740 & 1,820)

The HAC Reduction Program creates an incentive for hospitals to reduce the incidence of hospitalacquired conditions by reducing payment by 1.0 percent for applicable hospitals that rank in the worstperforming quartile on select measures of hospital-acquired conditions. CMS is not proposing any changes to the HAC Reduction Program for FY 2025.

CMS estimates 736 hospitals will be impacted negatively. (Page 1,821)

#### **II.** Proposed Changes to the Hospital Area Wage Index For Acute Care Hospitals (Page 457)

#### **Proposed Implementation of Revised Labor Market Area Delineations (Page 460)**

CMS is proposing to implement revised OMB delineations as described in the July 21, 2023 OMB Bulletin No. 23–01, beginning with the FY 2025 IPPS wage index.

#### Change to County-Equivalents in the State of Connecticut (Page 462)

The Census Bureau announced that it was implementing the State of Connecticut's request to replace the 8 counties in the State with 9 new "Planning Regions." Planning regions now serve as county-equivalents within the CBSA system. OMB Bulletin No. 23-01 is the first set of revised delineations that referenced the new county-equivalents for Connecticut.

CMS is providing the following crosswalk for each hospital in Connecticut with the current and proposed FIPS county and county-equivalent codes and CBSA assignments.

CCN	FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Area (County Equivalent)	Proposed CBSA
070002	09003	Hartford	25540	09110	Capitol	25540
070003	09015	Windham	49340	09150	Northeastern Connecticut	07
070004	09005	Litchfield	07	09160	Northwest Hills	07
070005	09009	New Haven	35300	09140	Naugatuck Valley	47930
070006	09001	Fairfield	14860	09190	Western Connecticut	14860
070007	09011	New London	35980	09180	Southeastern Connecticut	35980

CCN	FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Area (County Equivalent)	Proposed CBSA
070008	09013	Tolland	25540	09110	Capitol	25540
070010	09001	Fairfield	14860	09120	Greater Bridgeport	14860
070011	09005	Litchfield	07	09160	Northwest Hills	07
070012	09013	Tolland	25540	09110	Capitol	25540
070015	09005	Litchfield	07	09190	Western Connecticut	14860
070016	09009	New Haven	35300	09140	Naugatuck Valley	47930
070017	09009	New Haven	5300	09170	South Central Connecticut	35300
070018	09001	Fairfield	14860	09190	Western Connecticut	14860
070019	09009	New Haven	35300	09170	South Central Connecticut	35300
070020	09007	Middlesex	25540	09130	Lower Connecticut River Valley	25540
070021	09015	Windham	49340	09180	Southeastern Connecticut	35980
070022	09009	New Haven	35300	09170	South Central Connecticut	35300
070024	09011	New London	35980	09180	Southeastern Connecticut	35980
070025	09003	Hartford	25540	09110	Capitol	25540
070027	09003	Hartford	25540	09110	Capitol	25540
070028	09001	Fairfield	14860	09120	Greater Bridgeport	14860
070029	09003	Hartford	25540	09140	Naugatuck Valley	47930
070031	09009	New Haven	35300	09140	Naugatuck Valley	47930
070033	09001	Fairfield	14860	09190	Western Connecticut	14860
070034	09001	Fairfield	14860	09190	Western Connecticut	14860
070035	09003	Hartford	25540	09110	Capitol	25540
070036	09003	Hartford	25540	09110	Capitol	25540
070038	09009	New Haven	35300	09170	South Central Connecticut	35300
070039	09009	New Haven	35300	09170	South Central Connecticut	35300
07B010	09009	New Haven	35300	09170	South Central Connecticut	35300
07B022	09001	Fairfield	14860	09190	Western Connecticut	14860

CCN	FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Area (County Equivalent)	Proposed CBSA
07B033	09005	Litchfield	07	09190	Western Connecticut	14860

#### Comment

CMS has proposed adoption of OMB's No. 23-01 across all FY 2025 PPS programs. Each of the PPS programs appear to have minor changes. Make sure you use the program table for your facility.

#### Urban Counties That Would Become Rural Under the Revised OMB Delineations (Page 465)

The following chart lists 53 urban counties that would be rural if CMS finalizes its proposal to implement the revised OMB delineations. CMS notes that there are four cases (CBSA 14100 [Bloomsburg-Berwick, PA], CBSA 19180 [Danville, IL], CBSA 20700 [East Stroudsburg, PA], and CBSA 35100 [New Bern, NC]) where all constituent counties in an urban CBSA would become rural under the revised OMB delineations.

Counties that would Become Rural					
FIPS County Code	County Name	Current CBSA	Current CBSA Name		
01129	Washington	33660	Mobile, AL		
05025	Cleveland	38220	Pine Bluff, AR		
05047	Franklin	22900	Fort Smith, AR-OK		
05069	Jefferson	38220	Pine Bluff, AR		
05079	Lincoln	38220	Pine Bluff, AR		
10005	Sussex	41540	Salisbury, MD-DE		
13171	Lamar	12060	Atlanta-Sandy Springs-Alpharetta, GA		
16077	Power	38540	Pocatello, ID		
17057	Fulton	37900	Peoria, IL		
17077	Jackson	16060	Carbondale-Marion, IL		
17087	Johnson	16060	Carbondale-Marion, IL		
17183	Vermilion	19180	Danville, IL		
17199	Williamson	16060	Carbondale-Marion, IL		

	Counties that would Become Rural					
FIPS County Code	County Name Current Current Current		Current CBSA Name			
18121	Parke	45460	Terre Haute, IN			
18133	Putnam	26900	Indianapolis-Carmel-Anderson, IN			
18161	Union	17140	Cincinnati, OH-KY-IN			
21091	Hancock	36980	Owensboro, KY			
21101	Henderson	21780	Evansville, IN-KY			
22045	Iberia	29180	Lafayette, LA			
24001	Allegany	19060	Cumberland, MD-WV			
24047	Worcester	41540	Salisbury, MD-DE			
25011	Franklin	44140	Springfield, MA			
26155	Shiawassee	29620	Lansing-East Lansing, MI			
27075	Lake	20260	Duluth, MN-WI			
28031	Covington	25620	Hattiesburg, MS			
31051	Dixon	43580	Sioux City, IA-NE-SD			
36123	Yates	40380	Rochester, NY			
37049	Craven	35100	New Bern, NC			
37077	Granville	20500	Durham-Chapel Hill, NC			
37085	Harnett	22180	Fayetteville, NC			
37087	Haywood	11700	Asheville, NC			
37103	Jones	35100	New Bern, NC			
37137	Pamlico	35100	New Bern, NC			
42037	Columbia	14100	Bloomsburg-Berwick, PA			
42085	Mercer	49660	Youngstown-Warren-Boardman, OH-PA			
42089	Monroe	20700	East Stroudsburg, PA			
42093	Montour	14100	Bloomsburg-Berwick, PA			
42103	Pike	35084	Newark, NJ-PA			
45027	Clarendon	44940	Sumter, SC			
48431	Sterling	41660	San Angelo, TX			
49003	Box Elder	36260	Ogden-Clearfield, UT			
51113	Madison	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV			
51175	Southampton	47260	Virginia Beach-Norfolk-Newport News, VA-NC			

Counties that would Become Rural					
FIPS County Code	County Name	Current CBSA	Current CBSA Name		
51620	Franklin City	47260	Virginia Beach-Norfolk-Newport News, VA-NC		
54035	Jackson	16620	Charleston, WV		
54043	Lincoln	16620	Charleston, WV		
54057	Mineral	19060	Cumberland, MD-WV		
55069	Lincoln	48140	Wausau-Weston, WI		
72001	Adjuntas	38660	Ponce, PR		
72055	Guanica	49500	Yauco, PR		
72081	Lares	10380	Aguadilla-Isabela, PR		
72083	Las Marias	32420	Mayagüez, PR		
72141	Utuado	10380	Aguadilia-Isabela, PR		

#### Rural Counties That Would Become Urban Under the Revised OMB Delineations (Page 467)

Analysis of these OMB statistical area delineations shows that a total of 54 counties (and county equivalents) and 24 hospitals that were located in rural areas would be located in urban areas under the revised OMB delineations. The following chart lists the 54 rural counties that would be urban if CMS finalizes its proposal to implement the revised OMB delineations.

FIPS			
County Code	County Name	Proposed FY 2025 CBSA	Proposed FY 2025 CBSA Name
01087	Macon	12220	Auburn-Opelika, AL
01127	Walker	13820	Birmingham, AL
12133	Washington	37460	Panama City-Panama City Beach, FL
13187	Lumpkin	12054	Atlanta-Sandy Springs-Roswell, GA
15005	Kalawao	27980	Kahului-Wailuku, HI
17053	Ford	16580	Champaign-Urbana, IL
17127	Massac	37140	Paducah, KY-IL
18159	Tipton	26900	Indianapolis-Carmel-Greenwood, IN
18179	Wells	23060	Fort Wayne, IN

Counties that would Gain Urban Status				
FIPS County Code	County Name	Proposed FY 2025 CBSA	Proposed FY 2025 CBSA Name	
20021	Cherokee	27900	Joplin, MO-KS	
21007	Ballard	37140	Paducah, KY-IL	
21039	Carlisle	37140	Paducah, KY-IL	
21127	Lawrence	26580	Huntington-Ashland, WV-KY-OH	
21139	Livingston	37140	Paducah, KY-IL	
21145	McCracken	37140	Paducah, KY-IL	
21179	Nelson	31140	Louisville/Jefferson County, KY-IN	
22053	Jefferson Davis	29340	Lake Charles, LA	
22083	Richland	33740	Monroe, LA	
26015	Barry	24340	Grand Rapids-Wyoming-Kentwood, MI	
26019	Benzie	45900	Traverse City, MI	
26055	Grand Traverse	45900	Traverse City, MI	
26079	Kalkaska	45900	Traverse City, MI	
26089	Leelanau	45900	Traverse City, MI	
27133	Rock	43620	Sioux Falls, SD-MN	
28009	Benton	32820	Memphis, TN-MS-AR	
28123	Scott	27140	Jackson, MS	
30007	Broadwater	25740	Helena, MT	
30031	Gallatin	14580	Bozeman, MT	
30043	Jefferson	25740	Helena, MT	
30049	Lewis And Clark	25740	Helena, MT	
30061	Mineral	33540	Missoula, MT	
32019	Lyon	39900	Reno, NV	
37125	Moore	38240	Pinehurst-Southern Pines, NC	
38049	McHenry	33500	Minot, ND	
38075	Renville	33500	Minot, ND	
38101	Ward	33500	Minot, ND	
39007	Ashtabula	17410	Cleveland, OH	
39043	Erie	41780	Sandusky, OH	
41013	Crook	13460	Bend, OR	

		Counties that would Gair	ı Urban Status
FIPS			
County Code	County Name	Proposed FY 2025 CBSA	Proposed FY 2025 CBSA Name
41031	Jefferson	13460	Bend, OR
42073	Lawrence	38300	Pittsburgh, PA
45087	Union	43900	Spartanburg, SC
46033	Custer	39660	Rapid City, SD
47081	Hickman	34980	Nashville-DavidsonMurfreesboroFranklin, TN
48007	Aransas	18580	Corpus Christi, TX
48035	Bosque	47380	Waco, TX
48079	Cochran	31180	Lubbock, TX
48169	Garza	31180	Lubbock, TX
48219	Hockley	31180	Lubbock, TX
48323	Maverick	20580	Eagle Pass, TX
48407	San Jacinto	26420	Houston-Pasadena-The Woodlands, TX
51063	Floyd	13980	Blacksburg-Christiansburg-Radford, VA
51181	Surry	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC
55123	Vernon	29100	La Crosse-Onalaska, WI-MN

#### Urban Counties That Would Move to a Different Urban CBSA Under the Revised OMB

#### **Delineations** (Page 469)

In addition to rural counties becoming urban and urban counties becoming rural, some urban counties would shift from one urban CBSA to a new or existing urban CBSA. The following table lists the CBSAs where, under the proposed delineations, the CBSA name and number would change but the constituent counties would not change (not including instances where an urban county became rural, or a rural county became urban).

FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name
45540	The Villages, FL	48680	Wildwood-The Villages, FL
23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
15680	California-Lexington Park, MD	30500	Lexington Park, MD

FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name
35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
17460	Cleveland-Elyria, OH	17410	Cleveland, OH

The following table lists the CBSAs that, under the proposed delineations, would be subsumed by an another CBSA.

FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name
31460	Madera, CA	23420	Fresno, CA
36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
41900	San Germán, PR	32420	Mayagüez, PR

In other cases, some counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. For example, Calvert County, MD would move from the current CBSA 12580 (Washington-Arlington-Alexandria, DC-VA-MD-WV) into proposed CBSA 30500 (Lexington Park, MD).

The other constituent counties of CBSA 12580 would be split into urban CBSAs 47664 (Washington, DC-MD) and 11694 (Arlington-Alexandria-Reston, VA-WV). The following chart lists the urban counties that would split off from one urban CBSA and move to a newly proposed or modified urban CBSA if CMS adopts the revised OMB delineations.

Counties That Would Change To Another CBSA						
FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name	
11001	The District	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD	
12053	Hernando	45300	Tampa-St. Petersburg- Clearwater, FL	45294	Tampa, FL	
12057	Hillsborough	45300	Tampa-St. Petersburg- Clearwater, FL	45294	Tampa, FL	
12101	Pasco	45300	Tampa-St. Petersburg- Clearwater, FL	45294	Tampa, FL	
12103	Pinellas	45300	Tampa-St. Petersburg- Clearwater, FL		St. Petersburg-	

Counties That Would Change To Another CBSA						
FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name	
				41304	Clearwater- Largo, FL	
13013	Barrow	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13015	Bartow	12060	Atlanta-Sandy Springs- Alpharetta, GA	31924	Marietta, GA	
13035	Butts	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs- Roswell, GA	
13045	Carroll	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs- Roswell, GA	
13057	Cherokee	12060	Atlanta-Sandy Springs- Alpharetta, GA	31924	Marietta, GA	
13063	Clayton	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs- Roswell, GA	
13067	Cobb	12060	Atlanta-Sandy Springs- Alpharetta, GA	31924	Marietta, GA	
13077	Coweta	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13085	Dawson	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13089	De Kalb	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13097	Douglas	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13113	Fayette	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13117	Forsyth	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs- Roswell, GA	
13121	Fulton	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13135	Gwinnett	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13143	Haralson	12060	Atlanta-Sandy Springs- Alpharetta, GA	31924	Marietta, GA	
13149	Heard	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs- Roswell, GA	
13151	Henry	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13159	Jasper	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs- Roswell, GA	

Counties That Would Change To Another CBSA						
FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name	
13199	Meriwether	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13211	Morgan	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13217	Newton	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13223	Paulding	12060	Atlanta-Sandy Springs- Alpharetta, GA	31924	Marietta, GA	
13227	Pickens	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13231	Pike	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13247	Rockdale	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13255	Spalding	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
13297	Walton	12060	Atlanta-Sandy Springs- Alpharetta, GA	12054	Atlanta-Sandy Springs Roswell, GA	
17097	Lake	29404	Lake County-Kenosha County, IL-WI	29404	Lake County, IL	
21163	Meade	21060	Elizabethtown-Fort Knox, KY	31140	Louisville/Jefferson County, KY-IN	
22103	St. Tammany	35380	New Orleans-Metairie, LA	43640	Slidell-Mandeville- Covington, LA	
24009	Calvert	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD	
24017	Charles	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD	
24033	Prince Georges	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD	
24037	St. Mary's	15680	California-Lexington Park, MD	30500	Lexington Park, MD	
25015	Hampshire	44140	Springfield, MA	11200	Amherst Town- Northampton, MA	
34009	Cape May	36140	Ocean City, NJ	12100	Atlantic City- Hammonton, NJ	
37019	Brunswick	34820	Myrtle Beach-Conway-North Myrtle Beach, SC-NC	48900	Wilmington, NC	
39123	Ottawa	45780	Toledo, OH	41780	Sandusky, OH	
47057	Grainger	34100	Morristown, TN	28940	Knoxville, TN	
51013	Arlington	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston,	

Page 25

FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name
					VA-WV
51043	Clarke	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51047	Culpeper	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51059	Fairfax	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51061	Fauquier	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51107	Loudoun	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51153	Prince William	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51157	Rappahannock	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51177	Spotsylvania	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51179	Stafford	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51187	Warren	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51510	Alexandria City	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51600	Fairfax City	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51610	Falls Church City	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV
51630	Fredericksburg City	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV

FIPS County Code	County Name	FY 2024 CBSA Code	FY 2024 CBSA Name	Proposed FY 2025 CBSA Code	Proposed FY 2025 CBSA Name		
51683	Manassas City	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV		
51685	Manassas Park City	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV		
53061	Snohomish	42644	Seattle-Bellevue-Kent, WA	21794	Everett, WA		
54037	Jefferson	47894	Washington-Arlington- Alexandria, DC-VA-MD-WV	11694	Arlington- Alexandria- Reston, VA-WV		
55059	Kenosha	29404	Lake County-Kenosha County, IL-WI	28450	Kenosha, WI		
72023	Cabo Rojo	41900	San Germán, PR	32420	Mayagüez, PR		
72059	Guayanilla	49500	Yauco, PR	38660	Ponce, PR		
72079	Lajas	41900	San Germán, PR	32420	Mayagüez, PR		
72111	Penuelas	49500	Yauco, PR	38660	Ponce, PR		
72121	Sabana Grande	41900	San Germán, PR	32420	Mayagüez, PR		
72125	San German	41900	San Germán, PR	32420	Mayagüez, PR		
72153	Yauco	49500	Yauco, PR	38660	Ponce, PR		

#### **Proposed Occupational Mix Adjustment to the FY 2025 Wage Index (Page 499)**

The FY 2025 occupational mix adjustment is based on the calendar year (CY) 2022 survey. Hospitals were required to submit their completed 2022 surveys (Form CMS-10079, OMB Number 0938-0907, expiration date January 31, 2026) to their MACs by July 1, 2023.

The preliminary, unaudited CY 2022 survey data were posted on the CMS website on July 12, 2023. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2025 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

On page 499, CMS says the proposed FY 2025 *Unadjusted* National Average Hourly Wage is **\$54.80**. Later on, on page 504, CMS says the proposed FY 2025 Occupational Mix *Adjusted* National Average Hourly Wage is **\$54.73**. It is currently \$50.34.



The proposed FY 2025 national average hourly wages for each occupational mix nursing subcategory are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	\$60.40
National LPN and Surgical Technician	\$35.01
National Nurse Aide, Orderly, and Attendant	\$23.53
National Medical Assistant	\$23.11
National Nurse Category	\$50.17

#### Proposed Update to Rural Criteria at § 412.103(a)(1) (Page 508)

Section 1886(d)(8)(E) of the Act describes criteria for hospitals located in urban areas to be treated as being located in a rural area of their state. The criterion at section 1886(d)(8)(E)(ii)(I) of the Act requires that the hospital be located in a rural census tract of a metropolitan statistical area.

CMS is proposing to amend the regulation text at 412.103(a)(1) to read: the hospital is located in a rural census tract of a Metropolitan Statistical Area (MSA) as determined under the most recent version of the Goldsmith Modification, using the Rural-Urban Commuting Area codes and additional criteria, as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA).

#### Proposed Policy for Canceling § 412.103 Reclassifications of Terminated Providers

#### (Page 510)

CMS is proposing that § 412.103 reclassifications will be considered cancelled for the purposes of calculating area wage index for any hospital with a CMS Certification Number (CCN) listed as terminated or "tied-out" as of the date that the hospital ceased to operate with an active CCN.

# *Medicare Geographic Classification Review Board (MGCRB) Reclassification Issues for FY* **2025** (Page 516)



There are 610 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2025. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2025, hospitals reclassified beginning in FY 2023 or FY 2024 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 237 hospitals approved for wage index reclassifications in FY 2023 that will continue for FY 2025, and 316 hospitals approved for wage index reclassifications in FY 2024 that will continue for FY 2026 and FY 2026.

Applications for FY 2026 reclassifications are due to the MGCRB by September 1, 2024.

#### Effects of Implementation of Proposal to Adopt Revised OMB Labor Market Area

#### **Delineations on Reclassified Hospitals (Page 518)**

If CMS adopts the revised OMB delineations based on the OMB Bulletin No. 23–01 beginning in FY 2025 the CBSAs to which hospitals have been reclassified, or the CBSAs where they are located, may change.

Hospitals with current reclassifications are encouraged to verify area wage indexes in Table 2 in the appendix of this proposed rule, and to confirm that the CBSAs to which they have been reclassified for FY 2025 would continue to provide a higher wage index than their geographic area wage index.

Hospitals may withdraw or terminate their FY 2025 reclassifications by contacting the MGCRB within 45 days from the date this proposed rule is issued in the *Federal Register*.

Wage Index Adjustments: Rural Floor, Imputed Floor, State Frontier Floor, Out-Migration Adjustment, Low Wage Index, and Cap on Wage Index Decrease Policies (Page 542)

#### Rural Floor (Page 543)

By statute, no urban hospital can have a wage index lower than the statewide rural amount. CMS estimates that 494 hospitals would receive the rural floor in FY 2025.

#### State Frontier Floor (Page 546)

For FY 2025, 41 hospitals will receive the frontier floor value of 1.0000 for their wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.



#### <u>Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees</u> (Page 547)

Table 4A (which is available on the CMS website) lists the proposed out-migration adjustments for the FY 2025 wage index.

#### <u>Proposed Continuation of the Low Wage Index Hospital Policy and Budget Neutrality</u> <u>Adjustment (Page 549)</u>

The wage index for hospitals with a wage index value below the 25<sup>th</sup> percentile wage index value is increased by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals (the low wage index hospital policy). The FY 2025 25th Percentile Wage Index Value is 0.8879.

#### Permanent Cap on Wage Index Decreases and Budget Neutrality Adjustment (Page 555)

A hospital's wage index will not be less than 95 percent of its final wage index for the prior FY.

#### FY 2025 Wage Index Tables (Page 556)

CMS has included the following wage index tables: Table 2 titled "Case-Mix Index and Wage Index Table by CCN"; Table 3 titled "Wage Index Table by CBSA"; Table 4A titled "List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act"; and Table 4B titled "Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties)."

#### **Proposed Labor-Related Share for the FY 2025 Wage Index (Page 556)**

For FY 2025, CMS is not proposing to make any further changes to the labor-related share.

#### **III.** Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs)



#### for FY 2025 (§ 412.106) (Page 560)

Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments.

Section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the remaining estimate of 75 percent of uncompensated care payment is the product of three factors.

The 3 factors are:

#### Proposed Calculation of Factor 1 for FY 2025 (Page 571)

This factor represents CMS' estimate of 75 percent of the estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

CMS used the Office of the Actuary (OACT's) January 2024 Medicare DSH estimates, which were based on data from the December 2023 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2024 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2024 IPPS/LTCH PPS final rule.

The January 2024 OACT's estimate for Medicare DSH payments for FY 2025, without regard to the application of section 1886(r)(1) of the Act, is approximately \$13.943 billion.

Therefore, in this proposed rule, CMS is determining that Factor 1 for FY 2025 would be **\$10,457,250,000**, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2025 (\$13.943 X 0.75). CMS says that consistent with its approach in previous rulemakings, OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2025 IPPS/LTCH PPS final rule.

#### Calculation of Proposed Factor 2 for FY 2025 (Page 577)

The second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified).



The calculation of the proposed Factor 2 for FY 2025 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2024: 8.5 percent.
- Percent of individuals without insurance for CY 2025: 8.8 percent.
- Percent of individuals without insurance for FY 2025 (0.25 times 0.085) + (0.75 times 0.088) = 8.7 percent. 1 |((0.14 0.087)/0.14)| = 1 0.3786 = 0.6214 (62.14 percent).

CMS is proposing that Factor 2 for FY 2025 would be 62.14 percent. The proposed FY 2025 uncompensated care amount is equivalent to proposed Factor 1 multiplied by proposed Factor 2, which is **\$6,498,135,150.00**.

The following shows the 75 percent yearly amounts for DSH payments.

٠	The FY 2024 "pool" was	\$5.938 billion
٠	The FY 2025 "pool" will be	\$6.498 billion

The pool amount for FY 2025 will be \$560 million more than the current FY 2024 amount.

#### Calculation of Factor 3 for FY 2023 (Page 580)

Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made.

For purposes of this FY 2025 IPPS/LTCH PPS proposed rule, CMS is using reports from the December 2023 HCRIS extract to calculate Factor 3. CMS says it intends to use the March 2024 update of HCRIS to calculate the final Factor 3 for the FY 2025 IPPS/LTCH PPS final rule.

For FY 2025, CMS will use 3 years of audited Worksheet S–10 data to calculate Factor 3 for all eligible hospitals (2019, 2020 & 2021 data).

IV. Changes to the Medicare Severity Diagnosis-Related Group (MS-DRG) Classifications and Relative Weights (Page 43)

**Proposed Changes to Specific MS-DRG Classifications (Page 44)** 

For this FY 2025 IPPS/LTCH PPS proposed rule, CMS' MS-DRG analysis was based on ICD-10 claims data from the September 2023 update of the FY 2023 MedPAR file, which contains hospital bills received from October 1, 2022 through September 30, 2023.

Listed below are specific MS-DRG items CMS is addressing in this rule.

(1) Logic for MS-DRGs 023 through 027 (Page 58)

CMS is continuing its analysis of the claims data with respect to MS-DRGs 023 through 027. CMS says it continues to seek public comments and feedback on other factors that should be considered in the potential restructuring of these MS-DRGs. CMS is maintaining the current assignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator), without modification.

(2) Intraoperative Radiation Therapy (IORT) (Page 63)

CMS says it is unable to evaluate whether the use of IORT directly impacts resource utilization. For this reason, CMS is proposing to maintain the current structure of MS-DRGs 023, 024, 025, 026, and 027 for FY 2025.

(3) Ultras Concomitant Left Atrial Appendage Closure and Cardiac Ablation (Page 67)

For FY 2025, taking into consideration that it clinically requires greater resources to perform concomitant left atrial appendage closure and cardiac ablation procedures, CMS is proposing to create a new base MS-DRG for cases reporting a LAAC procedure and a cardiac ablation procedure in MDC 05. The proposed new MS-DRG is proposed new MS-DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation).

(4) Neuromodulation Device Implant for Heart Failure (Barostim<sup>™</sup> Baroreflex Activation Therapy)

#### (Page 72)

The BAROSTIM<sup>™</sup> system is the first neuromodulation device system designed to trigger the body's main cardiovascular reflex to target symptoms of heart failure. CMS received a request to again review the MS-DRG assignment of the ICD-10-PCS procedure codes that describe the implantation of the BAROSTIM<sup>™</sup> system.

For FY 2025, CMS is proposing to reassign all cases with one of the following ICD-10-PCS code combinations capturing cases reporting procedure codes describing the implantation of a BAROSTIM<sup>™</sup> system, to MS-DRG 276, even if there is no MCC reported:

WASHINGTON

perspectives

- 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HK3MZ (Insertion of stimulator lead into right internal carotid artery, percutaneous approach); and
- 0JH60MZ (Insertion of stimulator generator into chest subcutaneous tissue and fascia, open approach) in combination with 03HL3MZ (Insertion of stimulator lead into left internal carotid artery, percutaneous approach).

CMS is also proposing to change the title of MS-DRG 276 from "Cardiac Defibrillator Implant with MCC" to "Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator."

(5) Endovascular Cardiac Valve Procedures (Page 81)

CMS has received a request to delete MS-DRGs 266 and 267 and to move the cases reporting transcatheter aortic valve replacement or repair (supplement) procedures currently assigned to those MS-DRGs into MS-DRGs 216, 217, 218, 219, 220, and 221.

CMS says it continues to believe that endovascular cardiac valve replacement and supplement procedures are clinically coherent in their currently assigned MS-DRGs. Therefore, CMS is proposing to maintain the structure of MS-DRGs 266 and 267 for FY 2025.

(6) MS-DRG Logic for MS-DRG 215 (Page 91)

CMS received a request to review the GROUPER logic for MS-DRG 215 (Other Heart Assist System Implant) in MDC 05 (Diseases and Disorders of the Circulatory System). The requestor stated that when the procedure code describing the revision of malfunctioning devices within the heart via an open approach is assigned, the encounter groups to MS-DRG 215.

CMS is proposing to maintain the GROUPER logic for MS-DRG 215 for FY 2025.

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

(Page 95)

CMS is proposing the reassignment of procedure codes 0DB83ZZ, 0DBA3ZZ, 0DBA4ZZ, 0DBB3ZZ, 0DBB4ZZ, 0DBC0ZZ, 0DBC3ZZ, and 0DBC4ZZ from MS-DRGs 347, 348, and 349 (Anal and Stomal Procedures with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 06, effective FY 2025.

(8) MS-DRG Logic for MS-DRGs 456, 457, and 458 (page 99)

CMS is proposing to add diagnosis codes M43.8X4, M43.8X5, M43.8X6, M43.8X7, and M43.8X8 to the "OR Secondary Diagnosis" logic list for MS-DRGs 456, 457, and 458, effective October 1, 2024 for FY 2025

(9) Interbody Spinal Fusion Procedures (Page 101)

Based on CMS' review and analysis of the spinal fusion cases in MS-DRGs 453, 454, and 455, CMS believes new MS-DRGs are warranted. (Page 121)

CMS is proposing to create new MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC), 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). (Page 123)

CMS is proposing to create new base MS-DRG 402 (Single Level Combined Anterior and Posterior

Spinal Fusion Except Cervical). (Page 124)

CMS is proposing to create new MS-DRG 429 (Combined Anterior and Posterior Cervical Spinal

Fusion with MCC) and new MS-DRG 430 (Combined Anterior and Posterior Cervical Spinal Fusion without MCC). (Page 126)

For FY 2025, CMS is proposing to maintain the current structure of MS-DRGs 456, 457, and 458, without modification. (Page 128)

CMS is proposing to create new MS-DRGs 447 (Multiple Level Spinal Fusion Except Cervical with MCC) and new MS-DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC). CMS is also proposing to revise the title for existing MS-DRGs 459 and 460 to "Single Level Spinal Fusion Except Cervical with MCC and without MCC", respectively. (Page 131)



In conclusion, for FY 2025, CMS is proposing to delete MS-DRGs 453, 454, and 455 and proposing to create 8 new MS-DRGs – new MS-DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC), MS-DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), MS-DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC), MS-DRG 402 (Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical), MS-DRG 429 (Combined Anterior and Posterior Cervical Spinal Fusion with MCC), MS-DRG 430 (Combined Anterior and Posterior Cervical Spinal Fusion With MCC), MS-DRG 440 (Multiple Level Spinal Fusion Except Cervical Spinal Fusion Except Cer

(10) Resection of Right Large Intestine (Page 132)

CMS is proposing to add procedure codes 0DTF0ZZ and 0DTF4ZZ to MDC 10 in MS-DRGs 628, 629, and 630 effective October 1, 2024 for FY 2025.

(11) MS-DRG 795 Normal Newborn (Page 132)

CMS is proposing to reassign diagnosis code P05.19 from the "principal or secondary diagnosis" list under MS-DRG 794 to the "principal diagnosis" list under MS-DRG 795 (Normal Newborn). CMS is also proposing to add diagnosis codes Q38.1 and Q82.5 to the "only secondary diagnosis" list under MS-DRG 795 (Normal Newborn). Under this proposal, cases with a principal diagnosis described by an ICD-10-CM code from category Z38 (Liveborn infants according to place of birth and type of delivery), followed by codes P05.19, Q38.1, or Q82.5 will be assigned to MS-DRG 795.

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

(12) Acute Leukemia (Page 137)

CMS is proposing the reassignment of diagnosis codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 from MS-DRGs 823, 824 and 825 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC, with CC, and without CC/MCC, respectively), and MS-DRGs 840, 841, and 842 (Lymphoma and Non-Acute Leukemia with MCC, with CC, and without CC/MCC, respectively) to MS-DRGs 834, 835, and 836 (Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC,

respectively) and MS-DRGs 837, 838, and 839 (Chemotherapy with Acute Leukemia as Secondary Diagnosis, or with High Dose Chemotherapy Agent with MCC, with CC or High Dose Chemotherapy Agent, and without CC/MCC, respectively) in MDC 17, effective FY 2025.



Under this proposal, diagnosis codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 will continue to be assigned to surgical MS-DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

CMS is proposing to add 12 procedure codes that describe bypass procedures from the cerebral ventricle to the subgaleal space or cerebral cisterns listed previously to MS-DRGs 820, 821, 822, 826, 827, and 828 in MDC 17 for FY 2025.

In summary, for FY 2025, CMS is proposing to create a new base surgical MS-DRG for cases reporting a principal diagnosis describing a type of acute leukemia with an ICD-10-PCS procedure code designated as O.R. procedure that is not listed in the logic list of MS-DRGs 820, 821, and 822 in MDC 17. The proposed new MS-DRG is proposed new MS-DRG 850 (Acute Leukemia with Other Procedures).

CMS is proposing to add 27 ICD-10-CM diagnosis codes describing various types of acute leukemias currently listed in the logic list entitled "Principal Diagnosis" in MS-DRGs 834, 835, and 836 as well as ICD-10-CM codes C94.20, C94.21, C94.22, C94.40, C94.41, and C94.42 to the proposed new MS-DRG

850. CMS is also proposing to add the procedure codes from current MS-DRGs 823, 824, and 825 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC, with CC, and

without CC/MCC, respectively) to the proposed new MS-DRG 850.

CMS notes that in the current logic list of MS-DRGs 823, 824, and 825 there are 189 procedure codes describing stereotactic radiosurgery of various body parts that are designated as non-O.R. procedures affecting the MS-DRG, therefore, as part of the logic for new MS-DRG 850, CMS is also proposing to designate these 189 codes as non-O.R. procedures affecting the MS-DRG.

In addition, CMS is proposing to revise the titles for MS-DRGs 834, 835, and 836 by deleting the reference to "Major O.R. Procedures" in the title. Specifically, to revise the titles of medical MS-DRGs 834, 835, and 836 from "Acute Leukemia without Major O.R. Procedures with MCC, with CC, and without CC/MCC", respectively to "Acute Leukemia with MCC, with CC, and without CC/MCC", respectively to better reflect the GROUPER logic that will no longer include ICD-10-PCS procedure codes designated as O.R. procedures.

(13) Review of Procedure Codes in MS-DRGs 981 through 983 and 987 through 989 (Page 148)

For FY 2025 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.



(14) Laparoscopic Biopsy of Intestinal Body Parts (Page 155)

CMS is proposing to add procedure codes 0DBF4ZX, 0DBG4ZX, 0DBL4ZX, 0DBM4ZX and 0DBN4ZX to the FY 2025 ICD-10 MS-DRG Version 42 Definitions Manual in Appendix E--Operating Room Procedures and Procedure Code/MS-DRG Index as O.R. procedures assigned to MS-DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS-DRGs 329, 330, and 331 (Major Small and Large Bowel Procedures, with MCC, with CC, and without CC/MCC, respectively) in MDC 06 (Diseases and Disorders of the Digestive System); MS-DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, CC, without CC/MCC, respectively) and MS-DRGS 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 17 (Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); MS-DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS-DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

(15) Laparoscopic Biopsy of Gallbladder and Pancreas (Page 157)

CMS is proposing to add procedure code 0FB44ZX to the FY 2025 ICD-10 MS-DRG Version 42 Definitions Manual in Appendix E--Operating Room Procedures and Procedure Code/MS-DRG Index as an O.R. procedure assigned to MS-DRGs 411, 412, and 413 (Cholecystectomy with C.D.E., with MCC, with CC, and without CC/MCC, respectively) and MS-DRGs 417, 418, and 419 (Laparoscopic Cholecystectomy without C.D.E., with MCC, with CC, and without CC/MCC, respectively) in MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas); MS-DRGs 820, 821, and 822 (Lymphoma and Leukemia with Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and MS-DRGS 826, 827, and 828 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with

Major O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 17

(Myeloproliferative Diseases and Disorders, Poorly Differentiated Neoplasms); MS-DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively) in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs); and MS-DRGs 957, 958, and 959 (Other O.R. Procedures for Multiple Significant Trauma with MCC, with CC, and without CC/MCC, respectively) in MDC 24 (Multiple Significant Trauma).

(16) Proposed Changes to Severity Levels (Page 166)

• SDOH - Inadequate Housing/Housing Instability (Page 166)



CMS is proposing to change the severity level designation for diagnosis codes Z59.10 (Inadequate housing, unspecified), Z59.11 (Inadequate housing environmental temperature), Z59.12 (Inadequate housing utilities), Z59.19 (Other inadequate housing), Z59.811 (Housing instability, housed, with risk of homelessness), Z59.812 (Housing instability, housed, homelessness in past 12 months) and Z59.819 (Housing instability, housed unspecified) from

Non-CC to CC for FY 2025.

# Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2025

(Page 176)

The following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2025 and are available on the CMS website at: <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html</u>.

- Table 6I.1—Proposed Additions to the MCC List—FY 2025;
- Table 6J.1—Proposed Additions to the CC List—FY 2025; and
- Table 6J.2—Proposed Deletions to the CC List—FY 2025

In addition, CMS is proposing changes to the ICD-10 MS-DRGs Version 42 CC Exclusion List based on diagnosis code updates. (Page 184)

- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List--FY 2025;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List--FY 2025;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List--FY 2025;
- Table 6H.2.--Proposed Principal Diagnosis Order Deletions to the CC Exclusions List--FY 2025.

Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this proposed rule are available on the CMS website at: <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-</u> <u>Payment/AcuteInpatientPPS/index.html</u>.

# Changes to the ICD-10-CM and ICD-10-PCS Coding Systems (Page 185)

CMS is also making available on the CMS website at: <u>https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html</u> the following tables associated with this proposed rule:

- WASHINGTON perspectives
- Table 6A.—New Diagnosis Codes-FY 2025;
- Table 6B.—New Procedure Codes-FY 2025;
- Table 6C.—Invalid Diagnosis Codes-FY 2025;
- Table 6D.—Invalid Procedure Codes-FY 2025;
- Table 6E.—Revised Diagnosis Code Titles-FY 2025;
- Table 6F.—Revised Procedure Code Titles-FY 2025;

# **Replaced Devices Offered without Cost or with a Credit (Page 200)**

The existing MS-DRGs currently subject to the replaced device policy is displayed in the rule's table on page 201.

# Comment

The MS-DRG material above consumes some 175 pages. CMS has provided much information regarding its proposed actions. Our analysis just tries to provide the changes being proposed and but not on the intensive analysis CMS says it has made and provides to reach it proposal conclusions.

Note, that not all items are addressed in our summaries. Since DRG assignments and weighting factors are a critical component of overall payments, providers need to review in-depth the changes being proposed.

This analysis has not addressed changes to Surgical Hierarchies and Maintenance of the ICD-10-CM and ICD-10-PCS Coding Systems.

# V. Add-On Payments for New Services and Technologies for FY 2025 (Page 219)

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as "new technologies") under the IPPS.

# Proposed FY 2025 Status of Technologies Receiving New Technology Add-On Payments for

FY 2024 (Page 235)



In this section of the proposed rule, CMS discusses the proposed FY 2025 status of 31 technologies approved for FY 2024 new technology add-on payments, as set forth in the tables that follow.

# Proposed Continuation of Technologies Approved for FY 2024 New Technology

# Add-On Payments Still Considered New for FY 2025 Because 3-Year Anniversary Date Will Occur on or After April 1, 2025 (Page 237)

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Dateof Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2025	Coding Used to Identify Cases Eligible for NTAP
1	Thoraflex™ Hybrid Device	04/19/2022	10/1/2022	04/19/2025	87 FR 48974 through 48975 88 FR 58800	\$22,750.00	X2RX0N7 in combination with X2VW0N7
2	ViviStim® Paired VNS System	04/29/2022	10/1/2022	04/29/2025	87 FR 48975 through 48977 88 FR 58800	\$23,400.00	X0HQ3R8
3	GORE® TAG® Thoracic Branch Endoprosthesis	05/13/2022	10/1/2022	05/13/2025	87 FR 48966 through 48969 88 FR 58800		02VW3DZ in combination with 02VX3EZ
4	Cerament® G	05/17/2022	10/1/2022	05/17/2025	87 FR 48961 through 48966	\$4,918.55	XW0V0P7

# April 29, 2024

# WASHINGTON perspectives

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Dateof Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2025	Coding Used to Identify Cases Eligible for NTAP
					88 FR 58800		
5	iFuse Bedrock Granite Implant System	05/26/2022	10/1/2022	05/26/2025	87 FR 48969 through 48974 88 FR 58800	\$9,828.00	XNH6058         or           XNH6358         or           XNH7058         or           XNH7358         or           XRGE058         or           XRGE358         or           XRGF058         or           XRGF358         or
6	CYTALUX® (pafolacianine) (ovarian indication)	04/15/2022	10/1/2023	04/15/2025	88 FR 58804 through 58810	\$2,762.50	8E0U0EN, 8E0U3EN, 8E0U4EN, 8E0U7EN, or 8E0U8EN
7	CYTALUX® (pafolacianine) (lung indication)	06/05/2023	10/1/2023	06/05/2026	88 FR 58810 through 58818	\$2,762.50	8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN, or 8E0W8EN
8	EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab- gxbm)	05/19/2023	10/1/2023	05/19/2026	88 FR 58818 through 58835	\$6,504.07	XW013S9, XW033P9, or XW043P9
9	Lunsumio™ (mosunetuzumab)	12/22/2022	10/1/2023	12/22/2025	88 FR 58835 through 58845	\$17,492.10	XW03358 or XW04358
10	REBYOTA™ (fecal microbiota, live- jslm) and VOWST™ (fecal microbiota spores, live- brpk)	01/23/2023	10/1/2023	01/23/2026	88 FR 58848 through 58868	\$6,789.25	XW0H7X8 or XW0DXN9
11	SPEVIGO® (spesolimab)	09/01/2022	10/1/2023	09/01/2025	88 FR 58879 through 58885	\$33,236.45	XW03308
12	TECVAYLI™ (teclistamab- cqyv)	11/09/2022	10/1/2023	11/09/2025	88 FR 58885 through 58891	\$8,940.54	XW01348
13	TERLIVAZ® (terlipressin)	10/14/2022	10/1/2023	10/14/2025	88 FR 58891 through 58906	\$16,672.50	XW03367 or XW04367
14	Aveir™ AR Leadless Pacemaker	06/29/2023	10/1/2023	06/29/2026	88 FR 58919 through 58923	\$10,725.00	X2H63V9
15	Aveir™ Dual-Chamber Leadless Pacemaker	06/29/2023	10/1/2023	06/29/2026	88 FR 58923 through 58925	\$15,600.00	X2H63V9 in combination with X2HK3V9

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Dateof Entry onto U.S. Market	Previous Final Rule Citations	Proposed Maximum NTAP Amount for FY 2025	Coding Used to Identify Cases Eligible for NTAP
16	Ceribell Status Epilepticus Monitor	05/23/2023	10/1/2023	05/23/2026	88 FR 58927 through 58930	\$913.90	XX20X89
17	DETOUR System	06/07/2023	10/1/2023	06/07/2026	88 FR 58930 through 58932	\$16,250.00	X2KH3D9, X2KH3E9, X2KJ3D9, or X2KJ3E9
18	DefenCath™ (taurolidine/heparin)	11/15/2023	1/1/2024	11/15/2026	88 FR 58942 through 58944	\$17,111.25	XY0YX28
19	EchoGo Heart Failure 1.0	11/23/2022	10/1/2023	11/23/2025	88 FR 58932 through 58935	\$1,023.75	XXE2X19
20	Phagenyx® System	04/12/2023	10/1/2023	04/12/2026	88 FR 58935 through 58937	\$3,250.00	XWHD7Q7
21	REZZAYO™ (rezafungin for injection)	03/22/2023	10/1/2023	03/22/2026	88 FR 58944 through 58946	\$4,387.50	XW033R9 or XW043R9
22	SAINT Neuromodulation System	09/01/2022	10/1/2023	09/01/2025	88 FR 58937 through 58939	\$12,675.00	X0Z0X18
23	TOPS™ System	06/15/2023	10/1/2023	06/15/2026	88 FR 58940 through 58942	\$11,375.00	XRHB018 in combination with M48.062
24	XACDURO® (sulbactam/durlobactam)	05/23/2023	10/1/2023	05/23/2026	88 FR 58946 through 58948	\$13,680.00	XW033K9 or XW043K9 in combination with one of the following: Y95 and J15.61; <u>OR</u> J95.851 and B96.83

The table below lists the technologies for which CMS will discontinue making new technology add-on payments for FY 2025 because they are no longer "new" for purposes of new technology add-on payments.

# Proposed Discontinuation of Technologies Approved for FY 2024 New Technology Add-On Payments No Longer Considered New for FY 2025 Because 3-Year Anniversary Date Will Occur Prior To April 1, 2025 (Page 240)

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations
1	Intercept® Fibrinogen Complex (PRCFC)	05/05/2021	10/1/2021	5/05/2024	86 FR 45149 through 45150 86 FR 67875
					87 FR 48913
					88 FR 58800
2	Rybrevant® (amivantamab)	05/21/2021	10/1/2021	05/21/2024	86 FR 44988 through 44996
					87 FR 48913
					88 FR 58800
3	StrataGraft®	06/15/2021	10/1/2021	06/15/2024	86 FR 45079 through 45090
					87 FR 48913
					88 FR 58800
4	aprevo® Intervertebral Body Fusion Device (TLIF indication)	6/30/2021 (TLIF)	10/1/2021	6/30/2024 (TLIF)	86 FR 45127 through 45133
					86 FR 67874 through 67876
					87 FR 48913
					88 FR 58800
5	Hemolung Respiratory Assist System (RAS) (non- COVID-	11/15/2021	10/1/2022	11/15/2024 (other)	87 FR 48937 through 48948
	19 related use)	(other)			88 FR 58800
6	Livtencity™ (maribavir)	12/2/2021	10/1/2022	12/2/2024	87 FR 48948 through 48954
					88 FR 58800
7	Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System	10/04/2021	10/1/2023	10/04/2024	88 FR 58925 through 58927

# Proposed FY 2025 Applications for New Technology Add-On Payments (Traditional

# Pathway) (Page 241)

CMS received 16 applications for new technology add-on payments for FY 2025 under the new technology add-on payment traditional pathway.

Of the 16 applications received, one applicant was not eligible for consideration for new technology addon payment and three applicants withdrew their application prior to the issuance of this proposed rule.

CMS is addressing the remaining 12 applications. CMS notes that the manufacturer for CasgevyTM (exagamglogene autotemcel) submitted a single application, but for two separate indications,

each of which is discussed separately in this section. Therefore, there are 13 items listed below.

- (1) CASGEVY<sup>™</sup> (exagamglogene autotemcel) First Indication: Sickle Cell Disease (SCD) (Page 242)
- (2) CasgevyTM (exagamglogene autotemcel) Second Indication: Transfusion-Dependent β-Thalassemia (TDT) (Page 252)
- (3) DuraGraft® (Vascular Conduit Solution) (Page 260)
- (4) ELREXFIO<sup>™</sup> (elranatamab-bcmm) (Page 269)
- (5) FloPatch FP120 (Page 283)
- (6) HEPZATO<sup>™</sup> KIT (melphalan for injection/hepatic delivery system) (Page 295)
- (7) Lantidra<sup>™</sup> (donislecel-jujn (Allogeneic Pancreatic Islet Cellular Suspension for hepatic portal vein infusion)) (Page 308)
- (8) AMTAGVI<sup>™</sup> (lifileucel) (Page 314)
- (9) LYFGENIA<sup>™</sup> (lovotibeglogene autotemcel) (Page 326)
- (10) Quicktome Software Suite (Quicktome Neurological Visualization and Planning Tool) (Page 336)
- (11) TALVEY<sup>™</sup> (talquetamab-tgvs) (Page 349)
- (12) Odronextamab, First Indication: Relapsed or Refractory Diffuse Large B-Cell Lymphoma (Page 359)
- (13) Odronextamab, Second Indication: Relapsed or Refractory Follicular Lymphoma (R/R FL) (Page 370)

#### Comment

Since CMS decided to include most of an applicant's request, the length of this material continues to grow. The above section is 140 pages. All discussions seek additional comments.

# **Proposed FY 2025 Applications for New Technology Add-On Payments (Alternative Pathways)** (Page 381)

CMS says it received 23 applications for new technology add-on payments for FY 2025 under the new technology add-on payment alternative pathway. (Page 382)

Of the 23 applications, seven applications were not eligible for consideration for new technology add-on payment and two applicants withdrew their applications prior to the issuance of this proposed rule.

The 14 remaining are as follows:

(1) Annalise Enterprise Computed Tomography Brain (CTB) Triage – Obstructive Hydrocephalus (OH) (Page 384)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the Annalise Enterprise CTB Triage - OH would be \$241.39 for FY 2025 (that is, 65 percent of the average cost of the technology).

(2) ASTar® System (Page 390)

CMS invites public comments on whether the ASTar® System meets the cost criterion and its proposal to approve new technology add-on payments for the ASTar® System for FY 2025, subject to the technology receiving FDA marketing authorization as a Breakthrough Device by May 1, 2024.

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the ASTar® System would be \$97.50 for FY 2025 (that is, 65 percent of the average cost of the technology).

(3) cefepime-taniborbactam (Page 394)

CMS is proposing to approve cefepime-taniborbactam for new technology add-on payments for FY 2025, subject to the technology receiving FDA marketing authorization as a Qualified Infectious Disease Product (QIDP) for the indication corresponding to the QIDP designation by July 1, 2024.

(4) Edwards EVOQUETM Tricuspid Valve Replacement System (Transcatheter Tricuspid Valve

Replacement System) (Page 398)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the EVOQUETM System would be \$31,850 for FY 2025 (that is, 65 percent of the average cost of the technology).

(5) GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device) (Page 401)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the TAMBE Device would be \$47,238.75 for FY 2025 (that is, 65 percent of the average cost of the technology).

(6) LimFlow<sup>™</sup> System (Page 405)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the LimFlow<sup>™</sup> System would be \$16,250 for FY 2025 (that is, 65 percent of the average cost of the technology).

(7) Paradise<sup>™</sup> Ultrasound Renal Denervation System (Page 409)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the Paradise<sup>™</sup> Ultrasound Renal Denervation System would be \$14,950 for FY 2025 (that is, 65 percent of the average cost of the technology).

(8) PulseSelect<sup>™</sup> Pulsed Field Ablation (PFA) Loop Catheter (Page 415)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the PulseSelect<sup>™</sup> PFA Loop Catheter would be \$6,337.50 for FY 2025 (that is, 65 percent of the average cost of the technology).

(9) restor3d TIDAL<sup>™</sup> Fusion Cage (Page 419)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the restor3d TIDAL<sup>™</sup> Fusion Cage would be \$18,196.75 for FY 2025 (that is, 65 percent of the average cost of the technology).

(10) Symplicity Spyral<sup>™</sup> Multi-Electrode Renal Denervation Catheter (Page 424)

Based on the information from the applicant, it appears that the Symplicity G3<sup>™</sup> Generator is a capital cost. Therefore, it appears that this component is not eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, CMS only makes new technology add-on payments for operating costs.

(11) Transdermal Glomerular Filtration Rate (GFR) Measurement System utilizing Lumitrace (Page 429)

As noted, the applicant stated that the cost of the Transdermal GFR Measurement System Monitor is a capital cost. Therefore, it appears that this component is not eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, CMS only makes new technology add-on on payments for operating costs.

(12) TriClip<sup>™</sup> G4 (Page 433)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of TriClipTM G4 would be \$26,000 for FY 2025 (that is, 65 percent of the average cost of the technology).

(13) VADER® Pedicle System (Page 436)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of the VADER® Pedicle System would be \$28,242.50 for FY 2025 (that is, 65 percent of the average cost of the technology).

(14) ZEVTERA<sup>™</sup> (ceftobiprole medocaril) (Page 440)

CMS is proposing that the maximum new technology add-on payment for a case involving the use of ZEVTERATM for FY 2025 would be \$8,625.00 for the indication of SAB and \$2,812.50 for the indications of ABSSSI and CABP (that is, 75 percent of the average cost of the technology).

# Proposed Change to the Method for Determining whether a Technology would be Within its 2to 3-Year Newness Period when Considering Eligibility for New Technology Add-on Payments (Page 446)

CMS is proposing to change the April 1 cutoff for determining whether a technology would be within its 2- to 3-year newness period when considering eligibility for new technology add-on payments. CMS says it believes this proposed change would continue the flexibility applicants had with respect to when they apply to FDA and when they apply for new technology add-on payment, while preserving a predictable and consistent payment methodology for new technologies throughout the fiscal year.

Specifically, CMS is proposing that beginning with new technology add-on payments for FY 2026, in assessing whether to continue the new technology add-on payments for those technologies that are first

approved for new technology add-on payments in FY 2025 or a subsequent year, CMS would extend new technology add-on payments for an additional fiscal year when the three-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. CMS is proposing that this policy change would become effective beginning with those technologies that are initially approved for new technology add-on payments in FY 2025 or a subsequent year to allow additional flexibility for those applications for new technologies which were first subject to the change in the deadline for FDA marketing authorization from July 1 to May 1

# VI. Changes to the Hospital Inpatient Quality Reporting (IQR) Program (Pages 848 & 1,867)

CMS is proposing to adopt seven new quality measures, remove five existing quality measures, and modify one current electronic clinical quality measures (eCQMs). CMS is also proposing two changes to current policies related to data validation: an increase over two years in the total number of mandatory eCQMs reported by hospitals and cross-program modifications to the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure.

# CMS is proposing to adopt the following seven new measures: (Page 903)

- (1) Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 payment determination; (Page 849)
- (2) Age Friendly Hospital measure beginning with the CY 2025 reporting period/FY 2027 payment; (Page 903)
- (3) Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the CY 2026 reporting period/FY 2028 payment determination; (Page 913)
- (4) Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations measure beginning with the CY 2026 reporting period/FY 2028 payment determination; (Page 924)
- (5) Hospital Harm Falls with Injury eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; (Page 933)
- (6) Hospital Harm Postoperative Respiratory Failure eCQM beginning with the CY 2026 reporting period/FY 2028 payment determination; and (Page 940)
- (7) Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failureto-Rescue) measure beginning with the July 1, 2023 – June 30, 2025 reporting period/FY 2027 payment determination. (Page 947)

# CMS is proposing to modify the following measures: (Page 963)

Global Malnutrition Composite Score eCQM beginning with the CY 2026 reporting period/FY 2028
payment determination. This modification adds patients ages 18 to 64 to the current cohort of
patients 65 years or older.



HCAHPS Survey in the Hospital IQR beginning with the CY 2025 reporting period/FY 2027 payment determination. The proposed updates would refine the current HCAHPS Survey measure by adding three new sub-measures, removing one existing sub-measure, and revising one existing sub-measure. The new survey sub-measures would include: "Care Coordination," "Restfulness of Hospital Environment," and "Information about Symptoms." These three new sub-measures would be publicly reported beginning in October 2026. One current sub-sub-measure, "Care Transition," would be removed from reporting on Hospital Compare in January 2026. Additionally, the current "Responsiveness of Hospital Staff" sub-measure would be altered starting in January 2025, with the "Call Button" questions being removed from the survey and a new "Get Help" question being added.

#### CMS is proposing to remove five measures: (Page 960)

- (1) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Acute Myocardial Infarction (AMI Payment).
- (2) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure (HF Payment).
- (3) Hospital-level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia (PN Payment).
- (4) Hospital-level, Risk-Standardized Payment Associated with a 30-day Episode of Care for Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA Payment).
- (5) Removing the Death Among Surgical Inpatients with Serious Treatable Complications (CMS PSI-04) measure beginning with the July 1, 2023 - June 30, 2025 reporting period/FY 2027 payment determination. (Page 1,867)

CMS is proposing to remove the four payment items beginning with the FY 2026 payment determination, which is associated with a performance period of: July 1, 2021 – June 30, 2024, for the AMI Payment, HF Payment, and PN Payment measures and April 1, 2021 – March 31, 2024 for the THA/TKA Payment measure. These four measures are condition-specific assessments of hospital risk-standardized payment associated with a 30-day episode of care for AMI, HF, PN, and THA/TKA. CMS is proposing to remove these measures due to the availability of a more broadly applicable measure, specifically the Medicare Spending Per Beneficiary-Hospital measure (MSPB Hospital) in the Hospital VBP Program.

CMS is proposing to increase the total number of eCQMs reported from six to eleven over two years. Currently, the Hospital IQR Program requires reporting of six total eCQMs, three selected by CMS and three self-selected by hospitals. For the CY 2026 reporting period/FY 2028 payment determination, CMS is proposing that hospitals report on nine total eCQMs, with six selected by CMS and three self-selected by hospitals. For the CY 2027 reporting period/FY 2029 payment determination, CMS is proposing that hospitals report on 11 total eCQMs, with eight selected by CMS and three self-selected by hospitals.

# Reporting and Submission Requirements for eCQMs for the CY 2026 Reporting Period/FY 2028 Payment Determination (Page 980)

Beginning with the CY 2026 reporting period/FY 2028 payment determination, CMS is proposing to modify the eCQM reporting and submission requirements to require hospitals to report on the following three eCQMs in addition to the existing eCQMs: (1) Hospital Harm - Severe Hypoglycemia eCQM; (2) Hospital Harm - Severe Hyperglycemia eCQM; and (3) Hospital Harm - Opioid-Related Adverse Events eCQM. If this proposal is finalized, beginning with the CY 2026 reporting period/FY 2028 payment determination, hospitals would be required to report four calendar quarters of data for a total of nine eCQMs (six specified eCQMs and three self-selected eCQMs).

# Reporting and Submission Requirements for eCQMs for the CY 2027 Reporting Period/FY 2029 Payment Determination and for Subsequent Years (Page 980)

Beginning with the CY 2027 reporting period/FY 2029 payment determination, CMS is proposing to modify the eCQM reporting and submission requirements to require hospitals to report on the following two eCQMs in addition to the eCQMs proposed for the CY 2026 reporting period/FY 2028 payment determination: (1) Hospital Harm - Pressure Injury eCQM; and (2) Hospital Harm - Acute Kidney Injury eCQM. If this proposal is finalized, beginning with the CY 2027 reporting period/FY 2029 payment determination, hospitals would be required to report four calendar quarters of data for a total of eleven eCQMs (eight specified eCQMs and three self-selected eCQMs).

# VII. Proposed Changes to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program (Page 990)

The PCHQR Program is a quality reporting program for the eleven cancer hospitals that are statutorily exempt from the IPPS.

CMS is proposing the following:

- Adopting the Patient Safety Structural measure beginning with the CY 2025 reporting period/FY 2027 program year.
- Modifying the HCAHPS Survey measure beginning with the CY 2025 reporting period/FY 2027 program year. These changes are the same as mentioned in the Hospital IQR Program,
- Moving up the start date for publicly displaying hospital performance on the Hospital Commitment to Health Equity measure to January 2026 or as soon as feasible thereafter.

# VIII. Long-Term Care Hospital Quality Reporting Program (LTCH QRP) (Page 994)

LTCHs that do not meet LTCH QRP reporting requirements are subject to a 2.0 percentage point reduction in their annual percentage update.

CMS is proposing to add four items, modify one item, and modify one administrative requirement for the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS), as well as two RFIs), for the LTCH QRP

Beginning with the FY 2028 LTCH QRP (beginning with patients admitted on October 1, 2026), CMS is proposing to adopt four new Social Determinants of Health (SDOH) items and modify one – categories: (1) one item for Living Situation; (2) two items for Food; and (3) one item for Utility.

Beginning with the FY 2028 LTCH QRP (beginning with patients admitted on October 1, 2026), CMS is proposing to modify the Transportation assessment item under the SDOH Category.

In addition, CMS is seeking feedback on two RFIs:

- Future Measure Concepts for the LTCH QRP: The purpose of this RFI is to receive feedback on potential measurement concepts that could be developed into LTCH QRP measures.
- LTCH QRP Star Rating-System.

#### IX. Medicare Promoting Interoperability Program (Page 1020)

CMS is proposing the following measure-related proposals in the Medicare Promoting Interoperability Program for eligible hospitals and CAHs:

- Separate the Antimicrobial Use and Resistance (AUR) Surveillance measure into two measures, Antimicrobial Use (AU) Surveillance and Antimicrobial Resistance (AR) Surveillance, beginning with the EHR reporting period in CY 2025; add a new exclusion for eligible hospitals or CAHs that lack discrete electronic access to data elements that are required for AU or AR Surveillance reporting; modify the applicability of the existing exclusions for the AUR Surveillance measure to apply to the proposed AU Surveillance and AR Surveillance measures, respectively; and treat the AU Surveillance and AR Surveillance measures as two new measures with respect to active engagement beginning with the EHR reporting period in CY 2025.
- Adopt two new eCQMs for eligible hospitals and CAHs to select as one of their three self-selected eCQMs, in alignment with the Hospital IQR Program, beginning with the CY 2026 reporting period:
  - Hospital Harm Falls with Injury eCQM.
  - Hospital Harm Postoperative Respiratory Failure eCQM.
- Modify the Global Malnutrition Composite Score eCQM by adding patients ages 18 to 64 to the current cohort of patients 65 years or older.

• Modify eCQM data reporting and submission requirements in alignment with the Hospital IQR Program by proposing a progressive increase in the number of mandatory eCQMs eligible hospitals and CAHs would be required to report on beginning with the EHR reporting period in CY 2026.

WASHINGTON

perspectives

CMS is notifying eligible hospitals and CAHs of the following:

- Notifying eligible hospitals and CAHs of the changes to the definition of CEHRT in the Medicare Promoting Interoperability Program at 42 CFR 495.4 beginning with the CY 2024 EHR reporting period based on revisions made in the CY 2024 Medicare Physician Fee Schedule final rule.
- Notifying eligible hospitals and CAHs of the proposed changes to the definition of Meaningful EHR User at 42 CFR 495.4 in the Department of Health and Human Services (HHS) proposed rule, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (hereafter referred to as the HHS proposed rule).

CMS is also issuing an RFI describing goals and principles for the Medicare Promoting Interoperability Program's Public Health and Clinical Data Reporting objective and soliciting feedback in response to a series of questions related to that objective and related topic.

CMS is also proposing to increase the performance-based scoring threshold for eligible hospitals and CAHs reporting to the Medicare Promoting Interoperability Program from 60 points to 80 points beginning with the EHR reporting period in CY 2025.

The rule's table IX.F-01 beginning on page 1,028 provides a summary of Objectives and Measures for the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2025.

# X. Proposed Changes to the Long-Term Care Hospital Prospective Payment System

(LTCH PPS) for FY 2025 (Page 766)

# Medicare Severity Long-Term Care Diagnosis-Related Group (MS-LTC-DRG) Classifications and Relative Weights for FY 2025 (Page 774)

The proposed MS-LTC-DRGs for FY 2025 are the same as the MS-DRGs being proposed for use under the IPPS for FY 2025.

Table 11, which is listed in section VI of the Addendum to this proposed rule lists the proposed MS-LTC-DRGs and their respective proposed relative weights, proposed geometric mean length of stay, and proposed five-sixths of the geometric mean length of stay (used to identify Short Stay Outliers (SSO) cases under § 412.529(a)) for FY 2025.

CMS is also making available on its website the proposed MS-LTC-DRG relative weights prior to the application of the 10 percent cap on MS-LTC-DRG relative weight reductions and corresponding proposed cap budget neutrality factor. (Page 802)

# Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the

LTCH PPS for FY 2025 (Page 808)

CMS is proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2025 of **2.8 percent** (that is, the LTCH PPS market basket increase of 3.2 percent less the productivity adjustment of 0.4 percentage point). For LTCHs that fail to submit quality reporting

data CMS is proposing to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for an overall increase of 0.8 percent.

# **Proposed Rebasing of the LTCH Market Basket (Page 810)**



CMS proposes to rebase and revise the 2017-based LTCH market basket to reflect a 2022 base year, which would maintain a historical frequency of rebasing the market basket every 4 years.

#### Comment

CMS spends nearly 40 pages explaining changes from 2017 to 2022. Perhaps the most important aspect is the change in the labor-related share component as noted below.

	FY 2025	FY 2024 Final	
	Proposed Labor-Related Share based on Proposed 2022-based LTCH Market Basket <sup>1</sup>	Labor-Related Share based on 2017-based LTCH Market Basket <sup>2</sup>	
Wages and Salaries	54.6	47.6	
Employee Benefits	8.1	6.7	
Professional Fees: Labor-Related <sup>3</sup>	3.0	4.4	
Administrative and Facilities Support Services	0.5	1.0	
Installation, Maintenance, and Repair Services	1.0	2.1	
All Other: Labor-Related Services	1.7	2.5	
Subtotal	68.9	64.3	
Labor-Related portion of capital (46%)	3.9	4.2	
Total Labor-Related Share	72.8	68.5	

1 IHS Global Inc. 4th quarter 2023 forecast.

2 Based on IHS Global Inc. 2nd quarter 2023 forecast as published in the August 28, 2023 Federal Register (84 FR 59367).

3 Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management

consulting, and home office/related organization contract labor costs.

CMS is applying an update factor of 1.028 to the FY 2024 LTCH PPS standard Federal payment rate of \$48,116.62 to determine the proposed FY 2025 LTCH PPS standard Federal payment rate. (Page 1,696)

CMS has determined a proposed FY 2025 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 0.9959347.

Thus, the proposed LTCH PPS standard payment rate for FY 2025 is **\$49,262.80** (calculated as \$48,116.62 x 1.028 x 0.9959347). (Page 1,697)

perspectives

WASHINGTON

For LTCHs that fail to submit quality reporting data, the LTCH PPS standard Federal payment rate is **\$48,304.38** (calculated as \$48,116.62 x 1.008 x .9959347).

The FY 2024 wage index values are presented in Table 12A (for urban areas) and Table 12B (for rural areas), available on the CMS web site.

# **Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases (Page 1,715)**

As required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8.0 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

CMS is proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2025 of **\$90,921.** The current amount is \$59,873. (Page 1,728)

CMS says that actual high-cost outlier payments accounted for 11.6 percent of total LTCH PPS

standard Federal payment rate payments in FY 2023. CMS says that high-cost outlier payments in FY 2024 will account for 9.3 percent of total LTCH PPS. Hence the huge jump from \$59,973.

# High-Cost Outlier Payments for Site Neutral Payment Rate Cases (Page 1,731)

CMS is proposing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the proposed IPPS fixed-loss amount. That is, CMS is proposing a fixed-loss amount for site neutral payment rate cases of **\$49,237**, which is the same proposed FY 2025 IPPS fixed-loss amount.

# XI. Other Provisions Included in this Proposed Rule

# A. Proposed Transforming Episode Accountability Model (TEAM) (Page 1,070)

This item extends some 330 pages in the proposed rule. The material below is from CMS' press release regarding the proposed FY 2025 IPPS and LTCH Update.

"As part of this proposed rule, CMS is also proposing a mandatory model to test whether episode-based payments for five common, costly procedures would reduce Medicare expenditures while preserving or

enhancing the quality of care. Building on lessons learned from previous models, the mandatory Transforming Episode Accountability (TEAM) Model would incentivize coordination between care providers during a surgery, as well as the services provided during the 30 days that follow and require referral to primary care services to support continuity of care and drive positive long-term health outcomes."

The proposed model would launch on January 1, 2026, and run for five years, ending on December 31, 2030. Prior to the model launch, all model policies would be finalized through rulemaking.

The surgical procedures included in the model would be lower extremity joint replacement; surgical hip femur fracture treatment; spinal fusion; coronary artery bypass graft; and major bowel procedure. For purposes of TEAM, CMS would provide participating hospitals with a target price that would represent most Medicare spending during an episode of care, which would include the surgery (including the hospital inpatient stay or outpatient procedure) and items and services following hospital discharge, such as skilled nursing facility stays or provider follow-up visits.

Holding individuals accountable for all the costs of care for an episode may incentivize care coordination, improve patient care transitions, and decrease the risk of avoidable readmission."

# Comment

CMS expects to accrue savings – some \$700+ million over the program's 5-year performance run. The model will impact providers that exceed the model's target costs.

#### **FINAL COMMENTS**

This is probably the longest proposed IPPS and LTCH update rule since the IPPS began in FY 1984.

This analysis has not discussed a number of issues including (1) a request for information on the use of Medicare IPPS Payment rates for Maternity Care by other payers; (2) Request for information to advance patient safety across the hospital quality programs; and (3) Hospital and CAH data reporting.

We have found inadvertent errors, some of which are payment related and others which are simply formatting in nature.

We have argued for many years that these annual updates contain too much old, redundant and historical material. While some may find such information helpful, we believe most just find it laborious to read through.

WASHINGTON

perspectives

This proposal has rearranged many of its subjects to different areas. For example, the issue of outlier payments had been located within the rule's preamble and within the rule's Addendum. This year, the relevant discussions for setting and for the thresholds are located only in the rule's Addendum on page 1,666. As a result, the rule has become fragmented in numerous areas.

The Addendum is a very helpful tool. Perhaps all the payment rate material should be consolidated in the Addendum.

While the rule focuses on the hospital market basket rate update and its offsetting productivity, it does not address or clearly state a number of important and significant other payment factors. The rule addresses that the rate of increase will be 2.6 percent, it does clearly show the \$560 million in additional payments estimated to be made for DSH hospitals. Furthermore, the rule does reflect the extensive increase in the proposed outlier threshold.

The amount of quality provisions continues to grow. CMS says its goal is to produce payments reflecting quality.

Once again, this is another rule that does not contain a table of contents.

CMS spends considerable effort in describing changes of adopting OMB's latest area delineations. It is apparent CMS does not consider the extent of these changes to be significant.